

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

218490Orig1s000

REMS

Macitentan-Containing Products REMS

I. Administrative Information

Risk: Embryo-fetal toxicity

Initial Shared System REMS Approval: 04/2021

Most Recent REMS Update: 03/2024

II. REMS Goal

The goal of the Macitentan-Containing Products REMS is to mitigate the risk of embryo-fetal toxicity associated with macitentan-containing products by:

1. Ensuring prescribers are educated on the following:
 - the risks of embryo-fetal toxicity
2. Ensuring prescribers are educated on and adhere to the following:
 - counseling patients about these risks and the need for monthly monitoring
 - enrolling patients in the Macitentan-Containing Products REMS
 - monitoring patients at baseline and monthly
3. Ensuring that pharmacies are educated on the following:
 - the risks of embryo-fetal toxicity
4. Ensuring that pharmacies are educated on and adhere to the following:
 - confirming that the appropriate patient monitoring and counseling has occurred before dispensing macitentan-containing products
5. Ensuring that patients are informed about:
 - the risks of embryo-fetal toxicity
 - appropriate baseline and monthly patient monitoring
 - appropriate contraception

III. REMS Requirements

Macitentan-Containing Products Applicants must ensure that healthcare providers, patients, pharmacies, and wholesalers-distributors comply with the following requirements:

1. Healthcare Providers who prescribe macitentan-containing products must:

To become certified to prescribe	1. Review the drug's Prescribing Information. 2. Review the following: Prescriber and Pharmacy Guide. 3. Enroll in the REMS by completing the Prescriber Enrollment Form and submitting it to the Macitentan-Containing Products REMS.
Before treatment initiation (first dose)	4. For all females: Assess the patient's reproductive status using the definitions in the Prescriber and Pharmacy Guide. Document and submit the results to the Macitentan-Containing Products REMS using the Patient Enrollment Form. 5. For all females: Counsel the patient that the drug is only available through a restricted distribution program.

6. For females of reproductive potential: Assess the patient's pregnancy status by ordering and reviewing her pregnancy test result.
7. For females of reproductive potential: Counsel the patient on the risk of embryo-fetal toxicity, the need to use reliable contraception during treatment and for one month following treatment discontinuation, and emergency contraception using the [Guide for Female Patients](#).
8. For pre-pubertal females: Counsel the patient on the risk of embryo-fetal toxicity and to immediately contact her prescriber if she begins to menstruate using the [Guide for Female Patients](#).
9. Enroll all female patients by completing and submitting the [Patient Enrollment Form](#) and submitting it to the Macitentan-Containing Products REMS.

During treatment; before each prescription	10. For females of reproductive potential: Counsel the patient if she is not complying with required testing, if she is not using appropriate contraception, and to contact her prescriber if she misses a menstrual period or suspects that she is pregnant. 11. For females of reproductive potential: Assess the patient's pregnancy status by ordering and reviewing her pregnancy test result.

During Treatment; at least annually	12. For pre-pubertal females at least age 8 years or older: Document reproductive potential status and submit to the Macitentan-Containing Products REMS using the Change in Reproductive Potential Status and Pre-pubertal Annual Verification Form .

After treatment discontinuation, one month	13. For females of reproductive potential: Assess the patient's pregnancy status by ordering and reviewing her pregnancy test result.

At all times	14. For pre-pubertal females: Assess the patient's reproductive status. 15. Report pregnancies to the REMS Coordinating Center.

At all times, within 10 business days	16. Report a change or misclassification in reproductive status to the Macitentan-Containing Products REMS using the Change in Reproductive Potential Status and Pre-pubertal Annual Verification Form .

2. Females of reproductive potential who are prescribed macitentan-containing products:

Before treatment initiation	1. Review the Guide for Female Patients. 2. Get a pregnancy test. 3. Enroll in the REMS by completing the Patient Enrollment Form with the prescriber. Enrollment information will be provided to the Macitentan-Containing Products REMS. 4. Receive counseling from the prescriber on the risk of embryo-fetal toxicity, the need to use reliable contraception, and emergency contraception using the Guide for Female Patients. 5. Adhere to the safe use condition: Communicate with the pharmacy to confirm completion of pregnancy testing.

During treatment; before each dispensing	6. Receive counseling from the pharmacy on the risk of embryo-fetal toxicity, the need for reliable contraception during treatment and for one month after stopping treatment, to get monthly pregnancy tests, and to immediately contact her prescriber if she misses a menstrual period or suspects she is pregnant. 7. Get a pregnancy test.

8. Adhere to the safe use condition: Communicate with the pharmacy to confirm completion of pregnancy testing.

During treatment and after treatment discontinuation for one month

9. Adhere to the safe use condition: Use reliable contraception as described in the **Guide for Female Patients**.
10. Agree to be contacted by the REMS Coordinating Center if you become pregnant.

After treatment discontinuation; one month

11. Get a pregnancy test.

At all times

12. Inform the prescriber immediately if you miss a menstrual period or suspect a pregnancy.

3. Pre-pubertal females who are prescribed macitentan-containing products:

Before treatment initiation

1. Review the **Guide for Female Patients**.
2. Enroll in the Macitentan-Containing Products REMS by completing the **Patient Enrollment Form** with the prescriber. Enrollment information will be provided to the Macitentan-Containing Products REMS.
3. Receive counseling from the prescriber on the risk of embryo-fetal toxicity and to contact your prescriber if you begin to menstruate using the **Guide for Female Patients**.

At all times

4. If over the age of 8: Be monitored for a change in reproductive status.
5. Inform the prescriber if there is a change in reproductive status.

4. Post-menopausal females or females with other medical reason for permanent, irreversible infertility who are prescribed macitentan-containing products:

Before treatment initiation

1. Review the **Guide for Female Patients**.
2. Enroll in the Macitentan-Containing Products REMS by completing the **Patient Enrollment Form** with the prescriber. Enrollment information will be provided to the Macitentan-Containing Products REMS.

At all times

3. Inform the prescriber if there is a change in your reproductive status.

5. Outpatient Pharmacies that dispense macitentan-containing products must:

To become certified to dispense

1. Designate an authorized representative to carry out the certification process and oversee implementation and compliance with the Macitentan-Containing Products REMS on behalf of the outpatient pharmacy.
2. Have the authorized representative review the Prescribing Information and the **Prescriber and Pharmacy Guide**.
3. Have the authorized representative enroll in the Macitentan-Containing Products REMS by completing the **Outpatient Pharmacy Enrollment Form** and submitting it to the Macitentan-Containing Products REMS.

4. Train all relevant staff involved in dispensing on the Macitentan-Containing Products REMS requirements, procedures, and REMS materials.

Before dispensing	5. Obtain authorization to dispense each prescription by contacting the Macitentan-Containing Products REMS to verify female patients are enrolled, the reproductive status has not changed, the prescriber is certified, and pregnancy test is completed for females of reproductive potential or the prescriber authorizes the refill. 6. For females of reproductive potential: Counsel the patient on the risk of embryo-fetal toxicity, the need to use reliable contraception during treatment and for one month after stopping treatment, to get monthly pregnancy tests, and to inform the prescriber immediately if she misses a menstrual period or suspects she is pregnant. 7. For females of reproductive potential: Dispense no more than a 30-days' supply.
To maintain certification to dispense	8. Have a new authorized representative enroll in the Macitentan-Containing Products REMS by completing the Outpatient Pharmacy Enrollment Form if the authorized representative changes.
At all times	9. Report pregnancies to the REMS Coordinating Center. 10. Not distribute, transfer, loan, or sell macitentan-containing products, except to certified dispensers. 11. For all females: Maintain and submit records of daily product dispensing data. 12. Maintain records that all processes and procedures are in place and are being followed. 13. Comply with audits carried out by the manufacturers or a third party acting on behalf of the manufacturers to ensure that all processes and procedures are in place and are being followed.

6. Inpatient Pharmacies that dispense macitentan-containing products must:

To become certified to dispense	1. Designate an authorized representative to carry out the certification process and oversee implementation and compliance with the Macitentan-Containing Products REMS on behalf of the pharmacy. 2. Have the authorized representative review the Prescribing Information and the Prescriber and Pharmacy Guide. 3. Have the authorized representative enroll in the Macitentan-Containing Products REMS by completing the Inpatient Pharmacy Enrollment Form and submitting it to the Macitentan-Containing Products REMS. 4. Train all relevant staff involved in dispensing macitentan-containing products on the Macitentan-Containing Products REMS requirements, procedures, and REMS materials. 5. Establish processes and procedures to verify the female patient is enrolled in the Macitentan-Containing Products REMS or will be enrolled prior to discharge, her reproductive status, and the female patient is under the supervision and care of a certified prescriber.

6. For females of reproductive potential: establish processes and procedures to verify pregnancy testing is complete, and that the patient is counseled on the risk of embryo-fetal toxicity, the need to use reliable contraception, to get monthly pregnancy tests, and to inform the prescriber of a pregnancy immediately.

Before dispensing	7. Verify the female patient is under the supervision and care of a certified prescriber, and that she is enrolled or will be enrolled in the Macitentan-Containing Products REMS prior to discharge through the processes and procedures established as a requirement of the Macitentan-Containing Products REMS. 8. For females of reproductive potential: Verify the pregnancy testing is complete, and that the patient is counseled on the risk of embryo-fetal toxicity, the need to use reliable contraception, to get monthly pregnancy tests, and to inform the prescriber of a pregnancy immediately through the processes and procedures established as a requirement of the Macitentan-Containing Products REMS.
To maintain certification to dispense	9. Have a new authorized representative enroll in the Macitentan-Containing Products REMS by completing the Inpatient Pharmacy Enrollment Form if the authorized representative changes.
At discharge	10. Dispense no more than a 15-days' supply.
At all times	11. Report pregnancies to the REMS Coordinating Center. 12. Not distribute, transfer, loan, or sell macitentan-containing products, except to certified dispensers. 13. Maintain records that all processes and procedures are in place and are being followed. 14. Comply with audits carried out by the manufacturers or a third party acting on behalf of the manufacturers to ensure that all processes and procedures are in place and are being followed.

7. Wholesalers-distributors that distribute macitentan-containing products must:

To be able to distribute	1. Establish processes and procedures to ensure that the drug is distributed only to certified pharmacies and registered wholesalers-distributors. 2. Train all relevant staff involved in distribution on the Macitentan-Containing Products REMS requirements.
At all times	3. Distribute only to certified pharmacies and registered wholesalers-distributors. 4. Maintain and submit records of monthly drug distribution for all macitentan-containing products shipments. 5. Comply with audits carried out by the manufacturers or a third party acting on behalf of the manufacturers to ensure that all processes and procedures are in place and are being followed.

Macitentan-Containing Products Applicants must provide training to healthcare providers who prescribe macitentan-containing products.

The training includes the following educational materials: Prescribing Information and **Prescriber and Pharmacy Guide**. The training must be available online and by calling the Macitentan-Containing Products REMS.

Macitentan must provide training to pharmacies that dispense macitentan-containing products.

The training includes the following educational materials: Prescribing Information and **Prescriber and Pharmacy Guide**. The training must be available online and by calling the Macitentan-Containing Products REMS.

To support the REMS operations, Macitentan-Containing Products Applicants must:

1. Establish and maintain a REMS website, www.MacitentanREMS.com. The Macitentan-Containing Products REMS website must include the capability to complete prescriber and pharmacy enrollment online, the capability to enroll and manage patients online, including obtaining patient authorization status, and the option to print the Prescribing Information, Medication Guide, and REMS materials. All product websites for consumers and healthcare providers must include prominent REMS-specific links to the Macitentan-Containing Products REMS website. The Macitentan-Containing Products REMS website must not link back to the promotional product website.
2. Make the Macitentan-Containing Products REMS website operational and all REMS materials available through the Macitentan-Containing Products REMS website or REMS Coordinating Center within 90 calendar days of March 22, 2024.
3. Establish and maintain a REMS Coordinating Center for REMS participants at 1-888-572-2934.
4. Establish and maintain a validated, secure database of all REMS participants who are enrolled and/or certified in the Macitentan-Containing Products REMS.
5. Ensure prescribers and pharmacies are able to complete the certification process online and by fax.
6. Ensure prescribers are able to report change in reproductive status online and by fax.
7. Ensure prescribers are able to complete the patient enrollment process online and by fax.
8. Ensure outpatient pharmacies are able to obtain authorization before dispensing by phone and online. The authorization must include the patient's counseling status. The authorization number is valid for 5 calendar days after the expected refill date.
9. Ensure inpatient pharmacies are able to verify patient enrollment status and prescriber certification by phone and online.
10. Ensure prescribers are able to confirm pregnancy testing by phone and online.
11. Ensure the REMS Coordinating Center contacts the prescriber of a pre-pubertal female annually to have the prescriber verify the pre-pubertal female's reproductive status by completing the **Change in Reproductive Potential Status and Pre-pubertal Annual Verification Form**.
12. Ensure the REMS Coordinating Center updates the database and notifies certified pharmacies of patient's change in reproductive status within one business day of receipt of a completed **Change in Reproductive Potential Status and Pre-pubertal Annual Verification Form**.
13. Ensure pharmacies are able to enroll as inpatient (including, but not limited to, pharmacies in hospitals, long-term care facilities, prisons, and state psychiatric units) or as outpatient pharmacies.
14. Provide the **Prescriber Enrollment Form** and **Prescriber and Pharmacy Guide** to prescribers who (1) attempt to prescribe macitentan-containing products and are not yet certified or (2) inquire about how to become certified.
15. Provide certified prescribers access to the database of certified pharmacies and enrolled patients.
16. Provide certified pharmacies access to the database of certified prescribers and enrolled patients.
17. Provide registered wholesalers-distributors access to the database of certified pharmacies and registered wholesalers-distributors.

To ensure REMS participants' compliance with the REMS, Macitentan-Containing Products Applicants must:

18. Maintain adequate records to demonstrate that REMS requirements have been met, including, but not limited to records of: macitentan-containing products distribution and dispensing; certification of prescribers and pharmacies; enrolled patients; and audits of REMS pharmacies and wholesalers-distributors. These records must be readily available for FDA inspections.

19. Establish and maintain a plan for addressing noncompliance with Macitentan-Containing Products REMS requirements.
20. Monitor prescribers, pharmacies, and wholesalers-distributors on an ongoing basis to ensure the requirements of the REMS are being met. Take corrective action if non-compliance is identified, including de-certification.
21. Audit all certified outpatient pharmacies and registered wholesalers-distributors within 180 days after they become certified, to ensure that all REMS processes and procedures are in place, functioning, and support the Macitentan-Containing Products REMS requirements.
22. Audit all certified outpatient pharmacies, all registered wholesalers-distributors, the coordinating center for macitentan-containing products, and at least 10% or at least 20 whichever is greater of certified inpatient pharmacies that have ordered macitentan-containing products annually to ensure that all REMS processes and procedures are in place, functioning, and support the Macitentan-Containing Products REMS requirements.
23. Take reasonable steps to improve operations of and compliance with the requirements in the Macitentan-Containing Products REMS based on monitoring and evaluation of the Macitentan-Containing Products REMS.

IV. REMS Assessment Timetable

Macitentan-Containing Products NDA Applicants must submit REMS Assessments starting April 6, 2023, and annually thereafter. To facilitate inclusion of as much information as possible while allowing reasonable time to prepare the submission, the reporting interval covered by each assessment should conclude no earlier than 60 calendar days before the submission date for that assessment. Macitentan-Containing Products NDA Applicants must submit each assessment so that it will be received by the FDA on or before the due date.

V. REMS Materials

The following materials are part of the Macitentan-Containing Products REMS:

Enrollment Forms

Prescriber:

1. [Prescriber Enrollment and Agreement Form](#)

Patient:

2. [Patient Enrollment Form](#)

Pharmacy:

3. [Inpatient Pharmacy Enrollment Form](#)
4. [Outpatient Pharmacy Enrollment Form](#)

Training and Educational Materials

Prescriber:

5. [Prescriber and Pharmacy Guide](#)

Patient:

6. [Guide for Female Patients](#)

Pharmacy:

7. [Prescriber and Pharmacy Guide](#)

Patient Care Form

8. Change in Reproductive Potential Status and Pre-pubertal Annual Verification Form

Other Materials

9. REMS website (www.MacitentanREMS.com)

VI. Statutory Elements

This REMS is required under section 505-1 of the Federal Food, Drug and Cosmetic Act (FD&C Act) and (21 U.S.C. 355-1) consists of the following elements:

1. Elements to Assure Safe Use:

- Health care providers who prescribe macitentan-containing products are specially certified under 505-1(f)(3)(A).
- Pharmacies and health care settings that dispense macitentan-containing products are specially certified under 505-1(f)(3)(B).
- Macitentan-containing products are dispensed to patients with evidence or other documentation of safe-use conditions under 505-1(f)(3)(D).

2. Implementation System

3. Timetable for Submission of Assessments

Macitentan-Containing Products REMS Prescriber Enrollment and Agreement Form

To enroll and become certified in the REMS, complete this form [online](#) at www.MacitentanREMS.com

OR [fax](#) this form to 1-833-681-0003.

Contact the Macitentan-Containing Products REMS at 1-888-572-2934 with any questions.

Prescriber Information (please print; * required field)

First name * _____ MI _____ Last name * _____
Email address * _____ NPI # * _____ Professional designation * _____
 MD NP PA DO

Primary Office Practice/Clinical Information (please print)

A Prescriber may grant administrative rights to an Office Contact(s), which allows the Office Contact(s) to view, edit, and initiate paperwork related to the Macitentan-Containing Products REMS on the Prescriber's behalf. By completing the below, the Prescriber confirms they are granting administrative rights to the Office Contact(s). The Prescriber understands they must review and sign all paperwork prior to submitting it to the REMS.

Office practice/clinic name * _____ Specialty * _____ Affiliated hospital _____
Address * _____ City * _____
State * _____ ZIP * _____ Phone * _____ Fax * _____
Office contact first name _____ Office contact last name _____ Office contact phone _____
Office contact email address _____
 Phone Fax Email
Preferred method of contact

Secondary Office Practice/Clinical Information (please print)

Office practice/clinic name _____ Specialty _____ Affiliated hospital _____
Address _____ City _____
State _____ ZIP _____ Phone _____ Fax _____
Office contact first name _____ Office contact last name _____ Office contact phone _____
Office contact email address _____
 Phone Fax Email
Preferred method of contact

Macitentan-Containing Products REMS Prescriber Agreement

By signing below, you signify your understanding of the risks of macitentan-containing product treatment and your obligation as a prescriber of macitentan-containing products to educate your female patients about the Macitentan-Containing Products REMS (Risk Evaluation and Mitigation Strategy), monitor them appropriately, and report any pregnancies to the REMS Coordinating Center. Specifically, you attest to the following:

- I have reviewed the **Prescribing Information** and the **Prescriber and Pharmacy Guide** and agree to comply with the Macitentan-Containing Products REMS requirements.
- For all Females, I will:
 - Assess the patient's reproductive status using the definitions in the **Prescriber and Pharmacy Guide** and document and submit the results using the **Patient Enrollment Form**.
 - Counsel the female patient that macitentan-containing products are only available through a restricted distribution program called the Macitentan-Containing Products REMS.
 - Enroll all female patients by completing and submitting the **Patient Enrollment Form**.

- For Females of Reproductive Potential, I will:
 - Counsel the Females of Reproductive Potential about the risk of embryo-fetal toxicity, the need to use reliable contraception during treatment and for one month following treatment discontinuation, and emergency contraception using the **Guide for Female Patients**.
 - Assess the patient's pregnancy status by ordering and reviewing a pregnancy test before the start of treatment, monthly during treatment, and for one month after stopping treatment.
 - Counsel the patient if she is not complying with the required testing or if she is not using appropriate contraception, and to contact her prescriber if she misses a menstrual period or suspects that she is pregnant.

- For Pre-pubertal Females I will:
 - Counsel the Pre-Pubertal Female patient and her parent/guardian on the risk of embryo-fetal toxicity and to immediately contact her prescriber if she begins to menstruate using the **Guide for Female Patients**.
 - Regularly assess the reproductive status of each Pre-Pubertal Female during their treatment with macitentan-containing products.
 - Document the reproductive potential status of Pre-Pubertal Females who are at least 8 years or older and submit to the REMS at least annually using the **Change in Reproductive Potential Status and Pre-pubertal Annual Verification Form**.

- At all times, I will:
 - Report any change or misclassification in reproductive status to the REMS by submitting a **Change in Reproductive Potential Status and Pre-pubertal Annual Verification Form** within 10 business days of becoming aware of the change.
 - Report any pregnancies to the REMS at 1-888-572-2934.

Signature _____ Date _____

Please visit www.MacitentanREMS.com or call 1-888-572-2934 for more information about the Macitentan-Containing Products REMS.

Macitentan-Containing Products REMS Patient Enrollment Form

Complete this form for ALL female patients.

To enroll, complete this form [online](http://www.MacitentanREMS.com) at www.MacitentanREMS.com OR [fax](mailto:1-833-681-0003) this completed form to 1-833-681-0003. Contact the Macitentan-Containing Products REMS at 1-888-572-2934 with any questions.

1 Patient Information (please print; * required field [legal guardian information required for patients less than 18 years of age])

First name *		Middle initial	Last name *	
Birth date *	Primary Language		Email address	
Primary phone # *		Alternate phone #		Best time to call
Address *		City*	State *	ZIP *
Legal guardian *	Relationship *	Email		Phone # *
Emergency contact		Relationship		Phone #

2 Female Patient Agreement

- **For Females Who Can Get Pregnant:**

Before I begin macitentan-containing products treatment, I will:

- review the **Guide for Female Patients**.
- get a pregnancy test.
- enroll in the REMS by completing the **Patient Enrollment Form** with the prescriber. Enrollment information will be provided to the REMS.
- receive counseling from the prescriber on the risk of serious birth defects, the need to use reliable contraception during macitentan-containing products treatment and for one month after stopping macitentan-containing products treatment, and emergency contraception using the **Guide for Female Patients**.
- communicate with the pharmacy to confirm completion of pregnancy testing.

Before I receive each prescription of macitentan-containing products, I will:

- receive counseling from the pharmacy on the risk of serious birth defects and the need to use reliable contraception during macitentan-containing products treatment and for one month after stopping macitentan-containing products treatment, to get monthly pregnancy tests, and to immediately contact my prescriber if I miss a menstrual period or suspect I am pregnant.
- communicate with the pharmacy to confirm completion of pregnancy testing.

During my treatment with macitentan-containing products and for one month after stopping treatment, I will:

- use reliable contraception as described in the **Guide for Female Patients**.
- get a pregnancy test.
- inform my prescriber immediately if I miss a menstrual period or suspect that I am pregnant.
- agree to be contacted by the REMS Coordinating Center if I become pregnant.

- **For Pre-Pubertal Females (and her parent/guardian):**

Before I begin macitentan-containing products treatment, I will:

- review the **Guide for Female Patients**.
- enroll in the REMS by completing the **Patient Enrollment Form** with the prescriber. Enrollment information will be provided to the REMS.
- receive counseling from the prescriber on the risk of serious birth defects and to contact my healthcare provider immediately if I get my menstrual period, using the **Guide for Female Patients**.

If I am over the age of 8 and while I am being treated with macitentan-containing products, I will be monitored regularly for a change in reproductive status (ability to become pregnant). I will tell my prescriber if my reproductive status changes.

- **For Post-Menopausal Females and Females with other medical reasons for permanent, irreversible infertility:**

Before I begin macitentan-containing products treatment, I will:

- review the **Guide for Female Patients**.
- enroll in the REMS by completing the **Patient Enrollment Form**. Enrollment information will be provided to the REMS.

I will tell my prescriber if my reproductive status (ability to become pregnant) changes.

(REQUIRED FOR ALL FEMALES) Patient or Parent/Guardian Signature

Date

3 Prescriber Information (please print)

First name *	Middle initial	Last name *	
Address *		City *	
State *	ZIP *	Phone # *	NPI # *
Fax #	Office contact and email address		

4 Prescriber Authorization: Check the correct female patient category (please see definitions of these terms below):

REQUIRED (Check one category)

Female of Reproductive Potential

▶ If this patient is a Female of Reproductive Potential (which **includes** females who have undergone **tubal sterilization**), has a negative pregnancy test been completed prior to prescribing macitentan-containing products?

Yes No

Female of Non-Reproductive Potential

- Pre-pubertal Female
- Post-menopausal Female
- Female with other medical reasons for permanent, irreversible infertility

I certify that the above therapy ordered is medically necessary and agree to follow the "Prescriber Requirements" indicated on the second page of this form. Further, I hereby authorize the Macitentan REMS sponsors and/or their designated representative(s), to act on my behalf for the limited purposes of providing this prescription to the certified pharmacy for patient treatment purposes.



(REQUIRED FOR ALL PRESCRIBERS)

Date *

Prescriber Signature *

Definitions of Reproductive Potential Status

Females of Reproductive Potential

- Females of reproductive potential include girls who have entered puberty and all females who have a uterus and have not passed through menopause (as defined below).
- For the purposes of this REMS, puberty includes those girls who are at least Tanner Stage 3 and have not yet had a menses (premenarchal).
- For the purposes of this REMS, females who have undergone **tubal sterilization** are classified as females of **reproductive potential**.

Females of Non-Reproductive Potential

- Pre-pubertal Females: Females who are at Tanner Stages 1 and 2 are not considered to be of reproductive potential.
- Post-menopausal Females: Females who have passed through menopause. Menopause is defined as 12 months of spontaneous amenorrhea (not amenorrhea induced by a medical condition or medical therapy) or post-surgical from bilateral oophorectomy.
- Females with other medical reasons for permanent, irreversible infertility.

Prescriber Requirements

For All Females

- I acknowledge that I have counseled the patient (and parent/guardian when appropriate) that macitentan-containing products are only available through a restricted distribution program under an FDA-required REMS.
- I will evaluate the patient and agree to document any change or misclassification in reproductive potential status by submitting a **Change in Reproductive Potential Status and Pre-pubertal Annual Verification Form** within 10 business days of becoming aware of the change.

For Females of Reproductive Potential

- I acknowledge that I have counseled the patient (and parent/guardian when appropriate) on the risks of embryo-fetal toxicity, the need to use reliable contraception during treatment and for one month following treatment discontinuation, and emergency contraception using the **Guide for Female Patients**.
- I will order and review pregnancy tests prior to initiation of macitentan-containing products treatment, monthly during treatment, and for 1 month after stopping treatment in accordance with the Macitentan-Containing Products REMS.
- I will counsel the patient if she is not complying with required testing, if she is not using appropriate contraception, and to contact her prescriber if she misses a menstrual period or suspects that she is pregnant.

For Pre-pubertal Females

- I acknowledge that I have counseled the patient and parent/guardian on the risks of macitentan-containing products, including the risk of embryo-fetal toxicity, and to immediately contact her prescriber if she begins to menstruate using the **Guide for Female Patients**.
- I will evaluate the patient's reproductive potential status, verify reproductive potential status annually for pre-pubertal females who are at least 8 years of age and older, and agree to report any change or misclassification in reproductive potential status on a **Change in Reproductive Potential Status and Pre-pubertal Annual Verification Form** within 10 business days of becoming aware of the change.

5 Fax this form to 1-833-681-0003

Macitentan-Containing Products REMS Inpatient Pharmacy Enrollment Form

To enroll and become certified in the REMS, complete this form [online](http://www.MacitentanREMS.com) at www.MacitentanREMS.com OR [fax](tel:1-833-681-0003) this completed form to 1-833-681-0003.

Contact the Macitentan-Containing Products REMS at 1-888-572-2934 with any questions.

Due to the risk of embryo-fetal toxicity for female patients, macitentan-containing products are available only through a restricted program called the Macitentan-Containing Products REMS (Risk Evaluation and Mitigation Strategy). Inpatient pharmacies that wish to stock this product must be certified in the Macitentan-Containing Products REMS and agree to comply with the requirements of the program. An Authorized Representative must complete and submit this form on behalf of the inpatient pharmacy.

Inpatient Pharmacy Information (please print; all fields required)

Name

- Hospital Nursing home Hospice Asylum/Mental facility Assisted living Prison Rehabilitation
 Other (please specify): _____

National Provider Identifier (NPI) Number _____

Address _____

City _____ State _____ ZIP _____

Phone # _____ Fax # _____

Ship to Address (if different from above)

Address _____

City _____ State _____ ZIP _____

Phone # _____ Fax # _____

Authorized Representative Information (please print; all fields required)

Title:

- Hospital pharmacist Head of Pharmacy and Therapeutics (P&T) committee Other title: _____

Name _____

Authorized Representative phone # _____ Fax _____

Authorized Representative email _____

Authorized Representative Agreement

I am the authorized representative designated by my inpatient pharmacy to coordinate the activities of the Macitentan-Containing Products REMS. Therefore, I must:

- Carry out the certification process and oversee implementation of and compliance with the REMS on behalf of the pharmacy.
- Review the **Prescribing Information** and the **Prescriber and Pharmacy Guide**.
- Certify by enrolling in the REMS by completing the **Inpatient Pharmacy Enrollment Form** and submitting it to the REMS.
- Train all relevant staff involved in dispensing macitentan-containing products on the REMS requirements, procedures and REMS materials.
- Establish processes and procedures to verify the female patient is enrolled in the REMS or will be enrolled prior to discharge, her reproductive status, and the female patient is under the supervision and care of a certified prescriber.
- For females of reproductive potential: establish processes and procedures to verify pregnancy testing is complete and that the patient is counseled on the risk of embryo-fetal toxicity, the need to use reliable contraception during treatment and for one month after stopping treatment, to get monthly pregnancy tests, and to inform the prescriber immediately if she misses a menstrual period or suspects she is pregnant.

Before dispensing:

- Verify the female patient is under the supervision and care of a certified prescriber, and that she is enrolled or will be enrolled in the REMS prior to discharge, through the processes and procedures established as a requirement of the REMS.
- Verify pregnancy testing is complete, and that the patient is counseled on the risk of embryo-fetal toxicity, the need to use reliable contraception during treatment and for one month after stopping treatment, to get monthly pregnancy tests, and to inform the prescriber immediately if she misses a menstrual period or suspects she is pregnant, through the processes and procedures established as a requirement of the REMS for females of reproductive potential.

To maintain certification to dispense:

- Have a new authorized representative certify by enrolling in the REMS by completing the **Inpatient Pharmacy Enrollment Form** if the authorized representative changes.

At discharge:

- Dispense no more than a 15-day's supply of macitentan-containing products.

At all times:

- Not distribute, transfer, loan, or sell macitentan-containing products, except to certified dispensers.
- Report any pregnancies to the REMS Coordinating Center.
- Maintain records that all processes and procedures are in place and are being followed.
- Comply with audits by the manufacturer or a third party acting on behalf of the manufacturer to ensure all processes and procedures are in place and being followed.

Note: If your inpatient pharmacy needs macitentan-containing products and is not certified in the Macitentan-Containing Products REMS, please go to www.MacitentanREMS.com for immediate online certification, or contact the REMS Coordinating Center at 1-888-572-2934 for assistance in certifying.

Signature _____ Date _____

Please visit www.MacitentanREMS.com or call 1-888-572-2934 for more information about the Macitentan-Containing Products REMS.

Macitentan-Containing Products REMS Outpatient Pharmacy Enrollment Form

To enroll and become certified in the REMS, complete this form [online](http://www.MacitentanREMS.com) at www.MacitentanREMS.com **OR** fax this completed form to 1-833-681-0003.

Contact the Macitentan-Containing Products REMS at 1-888-572-2934 with any questions.

Due to the risk of embryo-fetal toxicity for female patients, macitentan-containing products are available only through a restricted program called the Macitentan-Containing Products REMS (Risk Evaluation and Mitigation Strategy). Outpatient pharmacies that wish to stock this product must certify by enrolling in the Macitentan-Containing Products REMS and agree to comply with the requirements of the program. An Authorized Representative must complete and submit this form on behalf of the outpatient pharmacy.

Only one outpatient pharmacy location per organization is required to certify; all outpatient pharmacy locations within the organization are not required to additionally certify, as these locations will be considered certified under the primary pharmacy organization's certification.

The REMS Coordinating Center will complete the pharmacy's certification process after ensuring the pharmacy is contracted with a manufacturer in the Macitentan REMS Group and is able to support submitting daily product dispensing data.

Outpatient Pharmacy Information (please print; all fields required)

Name

National Provider Identifier (NPI #)

Address

City

State

ZIP

Phone #

Fax #

Authorized Representative Information (please print; all fields required)

Name

Credentials

RPh PharmD BCPS Other: _____

Position/Title

Authorized Representative email

Authorized Representative phone #

Fax

Authorized Representative Agreement

I am the authorized representative designated by my outpatient pharmacy to coordinate the activities of the Macitentan-Containing Products REMS. **Therefore, I must:**

- Carry out the certification process and oversee implementation of and compliance with the REMS on behalf of the pharmacy.
- Review the Prescribing Information and **Prescriber and Pharmacy Guide**.
- Certify by enrolling in the REMS by completing the **Outpatient Pharmacy Enrollment Form** and submitting it to the REMS.
- Train all relevant staff involved in dispensing on the REMS requirements, procedures, and REMS materials.

Before dispensing, the outpatient pharmacy must:

- Obtain a REMS Dispense Authorization (RDA) from the Macitentan-Containing Products REMS Coordinating Center or the Macitentan-Containing Products REMS website that verifies female patients are enrolled, the reproductive status has not changed, the prescriber is certified, and pregnancy test is completed for females of reproductive potential - or the prescriber authorizes the dispensing.
- Counsel females of reproductive potential on the risk of embryo-fetal toxicity, the need to use reliable contraception during treatment and for one month after stopping treatment, to get monthly pregnancy tests, and to inform her prescriber immediately if she misses a menstrual period or suspects she is pregnant.
- Dispense no more than a 30-days' supply for females of reproductive potential.

To maintain certification to dispense:

- Have a new authorized representative certify by enrolling in the REMS by completing the **Outpatient Pharmacy Enrollment Form** if the authorized representative changes.

At all times, the outpatient pharmacy must:

- Report pregnancies to the REMS.
- Not distribute, transfer, loan, or sell macitentan-containing products, except to certified dispensers.
- Maintain and submit records of daily product dispensing data for all females.
- Maintain records that all processes and procedures are in place and being followed.
- Comply with audits carried out by the manufacturers or a third party acting on behalf of the manufacturers to ensure that all processes and procedures are in place and are being followed.

Signature _____ Date _____

Please visit www.MacitentanREMS.com or call 1-888-572-2034 for more information about the Macitentan-Containing Products REMS.

Prescriber and Pharmacy Guide for the Macitentan-Containing Products REMS

(Risk Evaluation and Mitigation Strategy)

Macitentan-Containing
Products

REMS

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Introduction to Macitentan-Containing Products

Indication

Macitentan is an endothelin receptor antagonist (ERA) indicated for the treatment of pulmonary arterial hypertension (PAH, WHO Group I) to reduce the risks of disease progression and hospitalization for PAH.

Effectiveness was established in a long-term study in PAH patients with predominantly WHO Functional Class II-III symptoms treated for an average of 2 years. Patients had idiopathic and heritable PAH (57%), PAH caused by connective tissue disorders (31%), and PAH caused by congenital heart disease with repaired shunts (8%).

OPSYNVI™ is the combination of macitentan and tadalafil indicated for the chronic treatment of adults with pulmonary arterial hypertension (WHO Group I and WHO Functional Class II-III). Individually, macitentan reduces the risk of clinical worsening events and hospitalization, and tadalafil improves exercise ability).

Tadalafil is a phosphodiesterase 5 (PDE5) inhibitor indicated for the treatment of pulmonary arterial hypertension (PAH, WHO Group 1) to improve exercise ability.

Efficacy of OPSYNVI was established in a study in PAH patients with WHO Functional Class II-III treated for 16-weeks. Patients treated with OPSYNVI had idiopathic and heritable PAH (54.2%), PAH caused by connective tissue disorders (33.6%), heritable PAH (3.7%), PAH associated with HIV

infection (3.7%), PAH associated with congenital heart disease (2.8%), Drug- and- toxin induced (0.9%) and PAH associated with congenital heart disease (0.9%).

Risk of Embryo-Fetal Toxicity

Macitentan-containing products are contraindicated in females who are pregnant. Macitentan-containing products may cause fetal harm when administered to a pregnant woman. Macitentan was consistently shown to have embryo-fetal toxicity effects when administered to animals. If macitentan-containing products are used during pregnancy, advise the patient of the potential risk to a fetus. To prevent pregnancy, females of reproductive potential must use reliable contraception during treatment and for one month after stopping macitentan-containing products. Patients must not become pregnant while taking macitentan-containing products.

Macitentan-Containing Products REMS (Risk Evaluation and Mitigation Strategy)

Due to the risk of embryo-fetal toxicity, macitentan-containing products are only available to females through a restricted distribution program required by the FDA called the Macitentan-Containing Products REMS (Risk Evaluation and Mitigation Strategy).

The goal of the Macitentan -Containing Products REMS is to mitigate the risk of embryo-fetal toxicity associated with macitentan-containing products by:

1. Ensuring prescribers are educated on the following:
 - the risks of embryo-fetal toxicity
2. Ensuring prescribers are educated on and adhere to the following:
 - counseling patients about these risks and the need for monthly monitoring
 - enrolling patients in the Macitentan-Containing Products REMS
 - monitoring patients at baseline and monthly
3. Ensuring that pharmacies are educated on the following:
 - the risks of embryo-fetal toxicity
4. Ensuring that pharmacies are educated on and adhere to the following:
 - confirming that the appropriate patient monitoring and counseling has occurred before dispensing macitentan-containing products
5. Ensuring that patients are informed about:
 - the risks of embryo-fetal toxicity
 - appropriate baseline and monthly patient monitoring
 - appropriate contraception

Macitentan-Containing Products REMS Overview

- All healthcare providers must certify in the Macitentan-Containing Products REMS and comply with the requirements to prescribe macitentan-containing products
- All female patients must enroll in the Macitentan-Containing Products REMS to receive macitentan-containing products
- Prescribers must counsel females of reproductive potential and pre-pubertal females of non-reproductive potential about the risks of macitentan-containing products, including the risk of serious birth defects
- Prescribers must order and review pregnancy testing for females of reproductive potential prior to initiation of treatment, monthly during treatment, and one month after stopping treatment
- Prescribers must report any change or misclassification in a female's reproductive potential status to the Macitentan-Containing Products REMS
- Definitions of reproductive potential status
 - Females of reproductive potential
 - Females of reproductive potential include girls who have entered puberty and all females who have a uterus and have not passed through menopause (as defined below)
 - For the purpose of this REMS, puberty includes those girls who are at least Tanner Stage 3 and have not yet had a menses (premenarchal)
 - For the purpose of this REMS, females who have undergone **tubal sterilization** are classified as females of **reproductive** potential
 - Females of non-reproductive potential
 - Pre-pubertal females: Females who are at Tanner Stages 1 and 2 are not considered to be of reproductive potential
 - Post-menopausal females: Females who have passed through menopause. Menopause is defined as 12 months of spontaneous amenorrhea (not amenorrhea induced by a medical condition or medical therapy) or post-surgical from bilateral oophorectomy
 - Females with other medical reasons for permanent, irreversible infertility
- For females of reproductive potential:
 - Pregnancy must be ruled out prior to drug initiation, monthly during treatment, and one month after stopping treatment
 - She must agree to be contacted by the REMS Coordinating Center if she becomes pregnant either while on macitentan-containing products or within one month of treatment discontinuation
- Only pharmacies certified in the Macitentan-Containing Products REMS can dispense macitentan-containing products to outpatients
- Only inpatient pharmacies that are certified in the Macitentan-Containing Products REMS may stock macitentan-containing products for inpatient use

Summary of Macitentan-Containing Products REMS Requirements for Female Patients

All **prescribers** must be certified in the Macitentan-Containing Products REMS. To become certified, a healthcare provider must complete a **Prescriber Enrollment and Agreement Form** agreeing to follow the Macitentan-Containing Products REMS requirements. This form must be submitted to the Macitentan-Containing Products REMS [online](http://www.MacitentanREMS.com) at www.MacitentanREMS.com **or** by [faxing](#) the completed form to 1-833-681-0003.

All **females** must be enrolled in the Macitentan-Containing Products REMS in order to receive macitentan-containing products. To become enrolled, a patient must complete a **Patient Enrollment Form** with her prescriber. This form must be submitted to the Macitentan-Containing Products REMS and can be completed [online](http://www.MacitentanREMS.com) at www.MacitentanREMS.com **or** [faxing](#) the completed form to the REMS Coordinating Center at 1-833-681-0003.

Prescribers must determine whether the patient is a female of reproductive potential or a female of non-reproductive potential (pre-pubertal female, post-menopausal female, or a female with other medical reasons for permanent, irreversible infertility). **This category must be documented on the Patient Enrollment Form.** (See definitions of reproductive potential status.)

Based on whether the patient is a female of reproductive potential or a female of non-reproductive potential (pre-pubertal female, post-menopausal female, or a female with other medical reasons for permanent, irreversible infertility), the prescriber must perform certain actions before initiating treatment, during treatment, and after the patient stops taking macitentan-containing products.

Summary of Macitentan-Containing Products REMS Requirements for Female Patients (continued)

Requirement	Females of Reproductive Potential	Females of Non-Reproductive Potential	
		Pre-pubertal	Post-menopausal or other medical reasons for permanent, irreversible infertility
Prescriber enrolls female patients into Macitentan-Containing Products REMS	●	●	●
Prescriber counsels with <i>Guide for Female Patients</i>	●	●*	●
Prescriber must order and review pregnancy tests prior to initiation of treatment, monthly during treatment, and for 1 month after stopping treatment	●		
Prescriber must verify reproductive status annually in pre-pubertal patients 8 years of age or older by completing the <i>Change in Reproductive Potential Status and Pre-pubertal Annual Verification Form</i>		●	
Prescriber must complete the <i>Change in Reproductive Potential Status and Pre-pubertal Annual Verification Form</i> upon becoming aware of any change or misclassification in reproductive potential status within 10 business days of awareness	●	●	●

*Counsel pre-pubertal female patient and/or parent/guardian.

Prescriber's Role in the Macitentan-Containing Products REMS

Healthcare providers must complete the following steps in the Macitentan-Containing Products REMS:

1. **Read** the macitentan-containing products Prescribing Information and this guide to understand the risks of macitentan-containing products and to learn about the Macitentan-Containing Products REMS
2. **Complete** a **Prescriber Enrollment and Agreement Form**
3. **Determine** the reproductive potential of female patients
4. **Educate and counsel** all female patients about the risks of macitentan-containing products
5. **Enroll** female patients into the Macitentan-Containing Products REMS by completing a **Patient Enrollment Form**
6. **Check** patient's pregnancy status (if patient is a female of reproductive potential)
7. **Monitor** pregnancy and reproductive potential status for female patients during treatment

The next section provides specific information on each step:

1. **Read the macitentan-containing products Prescribing Information and this guide to understand the risks of macitentan-containing products and to learn about the Macitentan-Containing Products REMS**
 - Prescribers must understand the risks of macitentan-containing products and become familiar with the Macitentan-Containing Products REMS
2. **Complete a Prescriber Enrollment and Agreement Form**
 - You can download the **Prescriber Enrollment and Agreement Form** from www.MacitentanREMS.com and **fax** it to the REMS Coordinating Center at 1-833-681-0003 **or** you may certify by enrolling **online** at www.MacitentanREMS.com. A completed enrollment form may be printed from the website upon completion of online enrollment.
 - By signing the form, you attest to understanding the risks of macitentan-containing products and agree to comply with the Macitentan-Containing Products REMS
3. **Determine the reproductive potential for female patients**
 - Prescribers should identify female patients (captured on the **Patient Enrollment Form**) as belonging to one of the following categories:
 - Female of reproductive potential (FRP)
 - or**
 - Female of non-reproductive potential (FNRP) (choose one of the options below)
 - Pre-pubertal female of non-reproductive potential
 - Post-menopausal female of non-reproductive potential
 - Female with other medical reasons for permanent, irreversible infertility

Definitions are provided in the section "Macitentan-Containing Products REMS Overview."

4. **Educate and counsel** all female patients about the risks of macitentan-containing products

- For all females, prescribers must:
 - Advise the patient that macitentan-containing products are only available through a restricted distribution program called the Macitentan-Containing Products REMS
 - Educate and counsel patients about the risks of macitentan-containing products
- For females of reproductive potential (FRP), prescribers must:
 - Review with her the **Guide for Female Patients**
 - Educate her about the risk of embryo-fetal toxicity; the need to use reliable contraception during macitentan-containing products treatment and for one month following treatment discontinuation and emergency contraception using the **Guide for Female Patients**
 - Advise the patient of the requirement for initial and monthly pregnancy tests to confirm they are not pregnant, so they can begin and continue to receive macitentan-containing products
 - Counsel her to immediately contact her healthcare provider if she misses a menstrual period or suspects she is pregnant
 - Counsel her that she must agree to be contacted prior to each shipment to confirm that a pregnancy test has been completed and receive counseling
- For females of non-reproductive potential (FNRP)
 - For a post-menopausal female or a female with other medical reasons for permanent, irreversible infertility, prescribers must provide the **Guide for Female Patients** and instruct her to read it
 - For pre-pubertal females, prescribers must:
 - Review with her and her parent/guardian the **Guide for Female Patients**
 - Educate her and her parent/guardian about the risk of serious birth defects
 - Counsel her and her parent/guardian to immediately contact her healthcare provider if she gets her menstrual period
- Prescribers must counsel any patient who fails to comply with the REMS requirements

5. **Enroll** female patients into the Macitentan-Containing Products REMS by completing the **Patient Enrollment Form**

- Enroll a patient **online**
 - For immediate patient enrollment, please go to **www.MacitentanREMS.com**
 - Confirm patient has agreed to comply with REMS requirements and has signed the form where indicated
 - Patients can sign electronically at the time of enrollment by typing their name into the signature box or signing with their finger or stylus on touchscreen devices. Patients can also request to receive an email at the email address entered during enrollment to allow for electronic signature.
 - Print the form and keep it with the patient's records
- Enroll a patient **by fax** using the printed form
 - Download the **Patient Enrollment Form** from **www.MacitentanREMS.com**
 - Confirm patient has agreed to comply with REMS requirements and has signed the form where indicated
 - Fax the completed form to the REMS Coordinating Center at 1-833-681-0003
 - Keep the original form with the patient's records

6. **Check patients' pregnancy status (for females of reproductive potential)**

- Order and review pregnancy tests for the patient:
 1. Prior to initiating treatment
 2. Monthly during treatment
 3. One (1) month after stopping treatment

7. **Monitor patients throughout treatment**

- For FRPs, prescribers must:
 - Order and review pregnancy tests monthly during treatment with macitentan-containing products and for one month after stopping treatment
 - Notify the patient and the REMS Coordinating Center if a patient's pregnancy test is positive
 - Monitor patients' reproductive status during treatment with macitentan-containing products and report any changes or misclassifications to the Macitentan-Containing Products REMS online at www.MacitentanREMS.com or by completing and submitting the **Change in Reproductive Potential Status and Pre-pubertal Annual Verification Form** or by contacting the REMS Coordinating Center at 1-888-572-2934 within 10 business days of becoming aware of the change
- For FNRPs, prescribers must:
 - Monitor patients' reproductive status during treatment with macitentan-containing products and report any changes or misclassifications to the Macitentan-Containing Products REMS online at www.MacitentanREMS.com or by completing and submitting the **Change in Reproductive Potential Status and Pre-pubertal Annual Verification Form** or by contacting the REMS Coordinating Center at 1-888-572-2934 within 10 business days of becoming aware of the change
 - For each pre-pubertal female who is at least 8 years of age and older, annually verify and report the reproductive status online or by completing and submitting the **Change in Reproductive Potential Status and Pre-pubertal Annual Verification Form** or by contacting the REMS Coordinating Center at 1-888-572-2934

Office Contacts

Prescribers may designate one or more Office Contacts to assist them with administrative aspects related to the Macitentan-Containing Products REMS. Prescribers may designate up to two Office Contacts via the **Prescriber Enrollment Form** and can designate additional Office Contacts via the Macitentan-Containing Products website or by calling the REMS Coordinating Center. A prescriber can add, edit, and delete Office Contacts via Macitentan-Containing Products REMS Website.

Office Contacts can perform the following tasks by calling the REMS Coordinating Center:

- Confirm a patient's enrollment status
- Update a patient's demographic information
- Confirm a patient's pregnancy test
- Respond to root cause analysis activities

Office Contacts can perform the following tasks via the Macitentan-Containing Products REMS Website:

- Initiate the **Patient Enrollment Form** and route it for patient and prescriber signature
- Update a patient's demographic information
- Update a patient's pregnancy test

Office Contacts **cannot** provide signature on behalf of the prescriber on the **Patient Enrollment Form** or the **Change in Reproductive Potential Status and Pre-Pubertal Annual Verification Form**, or authorize refills when required pregnancy testing is not confirmed.

Contraceptive Options for FRPs

All FRPs must use reliable contraception during macitentan-containing products treatment and for one month after stopping treatment. They should also have contraceptive counseling with either the prescriber or another designated healthcare provider trained in contraceptive counseling. Please refer to the following table for a complete list of acceptable contraceptive methods. A similar table can be found in the **Guide for Female Patients** and should be used to discuss acceptable birth control options with patients. The patient should be instructed to select one of the options listed.

- Educate and counsel females of reproductive potential about medical options in the event of unprotected sex or known or suspected contraceptive failure
- Remind patients to report any delay in getting a period or any other reason of suspected pregnancy during treatment to you immediately
- If pregnancy is suspected for any reason, a pregnancy test must be performed
- The prescriber must notify the REMS Coordinating Center at 1-888-572-2934 of any pregnancies that occur during treatment or within 1 month of discontinuation

Contraceptive Options for Females of Reproductive Potential

Acceptable birth control options

Option 1 One method from this list:	OR	Option 2 One method from this list:	OR	Option 3 One method from this list:	OR	Option 4 One method from this list:
Standard intrauterine device (Copper T 380A IUD)		Estrogen and progesterone oral contraceptives ("the pill")		Diaphragm with spermicide		Partner's vasectomy
Intrauterine system (LNg 20 IUS; progesterone IUS)		Estrogen and progesterone transdermal patch		Cervical cap with spermicide		PLUS One method from this list:
Progesterone implant		Vaginal ring		PLUS One method from this list:		Male condom
Tubal sterilization		Progesterone injection		Male condom		Diaphragm with spermicide
		PLUS One method from this list:				Cervical cap with spermicide
		Male condom				Estrogen and progesterone oral contraceptives ("the pill")
		Diaphragm with spermicide				Estrogen and progesterone transdermal patch
		Cervical cap with spermicide				Vaginal ring
						Progesterone Injection

Certified Pharmacies

Due to the risk of serious birth defects, macitentan-containing products are only available via certified pharmacies. For a list of certified pharmacies, please visit www.MacitentanREMS.com or call the REMS Coordinating Center at 1-888-572-2934.

Outpatient Pharmacy Certification

Only a limited number of certified pharmacies will dispense macitentan-containing products for outpatients. Prior to dispensing macitentan-containing products to any female, the pharmacy will confirm that the female and the prescriber who wrote the prescription are certified in the Macitentan-Containing Products REMS. A REMS Dispense Authorization (RDA) from the REMS Coordinating Center or the REMS Website must be obtained. If either the female is not enrolled or the prescriber is not certified, or an RDA has not been obtained, macitentan-containing products will not be dispensed. Females of reproductive potential will only be able to get a 30-day supply of macitentan-containing products at one time. The Medication Guide will be provided to all patients each time macitentan-containing products are dispensed. **The pharmacy must certify in the Macitentan-Containing Products REMS even if previously certified in the OPSUMIT REMS.** Only one outpatient pharmacy location per organization is required to certify; all outpatient pharmacy locations within the organization are not required to additionally certify. These locations will be considered certified under the primary pharmacy organization's certification.

Obtaining a REMS Dispense Authorization

The outpatient pharmacy must obtain an RDA from the Macitentan-Containing Products REMS website or the REMS Coordinating Center. When obtaining an RDA, the outpatient pharmacy must provide the patient's name, date of birth, the prescriber's NPI number, confirmation of a completed pregnancy test for FRP patients or prescriber authorization to refill, confirmation that counseling has been completed, manufacturer information, product/NDC code, and days' supply. If the patient is transitioning to a combination fixed-dose of macitentan with tadalafil, an outpatient pharmacy will need to request an RDA for each associated NDC.

If the days' supply for a FRP patient are greater than 30 days' supply, the system will require the outpatient pharmacy to provide a reason prior to obtaining an RDA. If the outpatient pharmacy does not provide a reason, they will not be able to obtain an RDA. The outpatient pharmacy must call the patient's prescriber to obtain the reason or correct the days' supply to 30 days.

Reasons to dispense greater than 30 days' supply to a FRP include:

- Travel Outside of the U.S.
- Public Health Emergency (e.g., pandemic, natural disaster)
- Replacement Shipment
- Other Reason Authorized by Prescriber
- Initial treatment with fixed-dose combination of macitentan with tadalafil in treatment naïve patient
- Transitioning from ERA monotherapy to combination fixed-dose of macitentan with tadalafil

The outpatient pharmacy can then request an RDA. If the request is rejected a notification will be presented to the pharmacy and will indicate which requirements have not been satisfied, an RDA number will not be provided, and the prescription must not be filled.

If the patient has not been counseled, then the outpatient pharmacy will be directed to counsel the patient per REMS requirements and record the completion of the counselling in the RDA request. If the monthly pregnancy test has not been confirmed, a pharmacy associate will contact the patient to determine if she has had the monthly pregnancy test. If the patient confirms the monthly pregnancy test, the pharmacy associate will record the confirmation in the Macitentan-Containing Products REMS website.

If unable to obtain confirmation from the patient that the pregnancy testing was completed, a pharmacy associate will call the patient's prescriber to obtain confirmation. If the prescriber confirms that the monthly pregnancy testing has been completed, the pharmacy associate will update the REMS system to indicate the completion of a pregnancy test.

If the prescriber cannot confirm that the pregnancy testing was completed, the pharmacy associate will remind the prescriber of his/her obligation to order and review monthly pregnancy tests and ask the prescriber if he/she authorizes the refill of macitentan-containing products without confirming the pregnancy test. The patient is eligible to receive macitentan-containing products only if the prescriber authorizes the refill of macitentan-containing products. If the prescriber authorizes the refill, the pharmacy associate will update the system on the Macitentan-Containing Products REMS website or by calling the REMS Coordinating Center to indicate that a pregnancy test has not been completed but, the prescriber has authorized the refill prior to obtaining an RDA.

If pregnancy testing confirmation or prescriber authorization for a refill is not received, the pharmacy may not request an RDA or fill the prescription.

As part of the RDA prescription information, the user will be required to determine if an FRP patient had a delay in treatment of five or more days. If this is true, the user must provide a reason for the delay in treatment prior to obtaining an RDA.

Reasons for an interruption in therapy include:

- Unknown
- Monthly Pregnancy Test is not complete
- Patient Noncompliance
- Scheduling or Transportation Issues
- Patient Health Issues
- Patient Misunderstanding
- Prescriber Error
- Monetary Issues
- Laboratory Error
- Change in Medication
- Treatment Restarted by Prescriber

The system will allow the outpatient pharmacy to obtain an RDA once all requirements have been met. The pharmacy, pharmacy participant, prescriber name, patient name, patient date of birth, manufacturer, NDC code, days' supply, reason for days' supply greater than 30 days (if applicable and for FRP patients only), did patient have a delay in treatment of five or more days, and reason for delay in treatment (if applicable), will be presented with the RDA number.

To be certified in the Macitentan-Containing Products REMS, an authorized representative of the outpatient pharmacy must:

- Read the macitentan-containing products Prescribing Information and the **Prescriber and Pharmacy Guide**
- Ensure training of dispensing staff on the Macitentan-Containing Products REMS procedures and materials, including the **Prescriber and Pharmacy Guide** prior to dispensing macitentan-containing products
- Establish processes and procedures to verify the female patient is enrolled, the reproductive status of the patient has not changed, and the prescriber is certified
- Agree to follow the REMS requirements by completing and submitting an **Outpatient Pharmacy Enrollment Form** to the Macitentan-Containing Products REMS
 - Authorized representatives can first complete the **Outpatient Pharmacy Enrollment Form**:
 - Online at www.MacitentanREMS.com (a completed enrollment form may be printed from the website)
 - By faxing the printed form to 1-833-681-0003

The REMS Coordinating Center will then complete the pharmacy's certification process after ensuring the pharmacy is contracted with a manufacturer in the Macitentan REMS Group and is able to support submitting daily product dispensing data.

Prior to dispensing, the outpatient pharmacy must:

- Obtain an RDA from the REMS website or the REMS Coordinating Center that verifies female patients are enrolled, the reproductive status has not changed, the prescriber is certified, and pregnancy test is completed for females of reproductive potential, or the prescriber authorizes the dispensing. The system will allow the outpatient pharmacy to obtain an RDA once all requirements have been met. The pharmacy, pharmacy participant, prescriber name, patient name, patient date of birth, manufacturer, NDC code, days' supply, reason for days' supply greater than 30 days (if applicable for FRP patients only), did patients have a delay in treatment of five or more days, and reason for delay in treatment (if applicable), will be presented with the RDA number.
- Not fill the prescription if an RDA cannot be obtained.

To maintain certification to dispense, the outpatient pharmacy must:

- Re-certify in the Macitentan-Containing Products REMS if the outpatient pharmacy designates a new authorized representative by completing, signing, and submitting a new **Outpatient Pharmacy Enrollment Form** as soon as the designated authorized representative changes.

At all times, the outpatient pharmacy must:

- Notify the REMS Coordinating Center if any patient becomes pregnant during macitentan-containing products treatment
- Not distribute, transfer, loan, or sell macitentan-containing products, except to certified dispensers
- For females of reproductive potential: Maintain and submit records of daily product dispensing data
- Maintain records that all processes and procedures are in place and are being followed
- Comply with audits carried out by the manufacturers or a third party acting on behalf of the manufacturers to ensure that all processes and procedures are in place and are being followed

Females of reproductive potential will be contacted each month by the pharmacy to arrange dispensing of macitentan-containing products. The pharmacy will:

- Ask if she has had a pregnancy test within the last month or verify that the prescriber authorizes the dispensing through the processes and procedures established as a requirement of the REMS.
- Counsel her on the need to use reliable contraception during macitentan-containing products treatment and for one month after stopping treatment
- Counsel her to inform her prescriber immediately if she misses a menstrual period or suspects that she may be pregnant, or if her reproductive status changes
- Dispense no more than a 30-days' supply
- Maintain and submit records of daily product dispensing data

Inpatient Pharmacy Certification

Inpatient pharmacies must agree to follow the REMS requirements, including:

- Dispense only to those patients under the supervision and care of a healthcare provider who is enrolled in the Macitentan-Containing Products REMS.
- Dispense to a female patient only after she has been enrolled in the Macitentan-Containing Products REMS or if she will be enrolled prior to discharge from this healthcare facility. A female who has not been enrolled by the certified prescriber will not have access to macitentan-containing products in the outpatient setting until such time that enrollment has been completed.
- Dispense no more than a fifteen- (15-) day temporary supply of macitentan-containing products upon discharge of any patient.
- Not distribute, transfer, loan, or sell macitentan-containing products, except to dispensers certified in the Macitentan-Containing Products REMS.

To be certified in the Macitentan-Containing Products REMS, an authorized representative of the inpatient pharmacy must:

- Read the macitentan-containing products Prescribing Information and the **Prescriber and Pharmacy Guide**
- Put processes and procedures in place to ensure the Macitentan-Containing Products REMS requirements are met
- Ensure training of dispensing staff on the Macitentan-Containing Products REMS procedures and materials, including the **Prescriber and Pharmacy Guide** prior to dispensing macitentan
- Agree to follow the REMS requirements by completing an **Inpatient Pharmacy Enrollment Form** online or submitting a completed form via fax to the Macitentan-Containing Products REMS Coordinating Center at 1-833-681-0003.

– Authorized representatives can complete the **Inpatient Pharmacy Enrollment Form**:

- Online at **www.MacitentanREMS.com** (a completed enrollment form may be printed from the website)
- By fax at 1-833-681-0003

To maintain certification to dispense, the inpatient pharmacy must:

- Re-certify by enrolling in the Macitentan-Containing Products REMS if the inpatient pharmacy designates a new authorized representative by completing, signing, and submitting a new **Inpatient Pharmacy Enrollment Form** as soon as the designated authorized representative changes.

At all times, the inpatient pharmacy must:

- Notify the Macitentan-Containing Products REMS at 1-888-572-2934 if any patient becomes pregnant during macitentan-containing products treatment
- Develop a process to track compliance with the conditions above and provide information about its compliance to the Macitentan-Containing Products REMS
- Agree that this pharmacy may be audited by the FDA, the Macitentan-Containing Products REMS, or a designated third party

How can an inpatient pharmacy verify a patient enrollment and prescriber certification before dispensing?

Before dispensing to a female inpatient, the inpatient pharmacy must verify that the patient is under the supervision and care of a certified prescriber, and that she is enrolled or will be enrolled in the Macitentan-Containing Products REMS prior to discharge. This may be verified online at **www.MacitentanREMS.com** or by phone by calling the REMS Coordinating Center.

If an inpatient pharmacy needs macitentan-containing products and is not certified in the Macitentan-Containing Products REMS, please go to **www.MacitentanREMS.com** for immediate online enrollment and certification or contact the REMS Coordinating Center, Monday through Friday 8:00 AM to 8:00 PM ET, at 1-888-572-2934 for assistance in enrolling.

To learn more about the serious risks associated with macitentan-containing products, please refer to the full Prescribing Information including BOXED WARNING, the **Prescriber and Pharmacy Guide**, and the **Guide for Female Patients**. These materials are available at **www.MacitentanREMS.com**.

If you have questions about Macitentan-Containing Products REMS enrollment and certification, or if you would like more information about macitentan-containing products, you can reach the REMS Coordinating Center by calling toll-free at 1-888-572-2934, Monday through Friday, 8:00AM – 8:00PM ET.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

You can reach the Macitentan-Containing Products REMS by calling toll free at 1-888-572-2934.

Monday – Friday

8:00 AM – 8:00 PM ET

For more information about the Macitentan-Containing Products REMS, please visit

www.MacitentanREMS.com.

Macitentan-Containing
Products

REMS

Macitentan-Containing Products REMS

(Risk Evaluation and Mitigation Strategy)

Guide for Female Patients

Information to help you throughout your treatment with macitentan-containing
products

Macitentan-Containing
Products

REMS

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What are macitentan-containing products?

Macitentan-containing products are prescription medicines used to treat pulmonary arterial hypertension (PAH), which is high blood pressure in the arteries of your lungs.

Macitentan-containing products can improve your ability to exercise, improve some of your symptoms, and help slow down the progression of your disease. Macitentan-containing products can also lower your chance of being hospitalized for PAH.

It is not known if macitentan-containing products are safe and effective in children.

What are the serious risks of macitentan-containing products?

Macitentan-containing products can cause **serious birth defects** if taken during pregnancy. Women must not be pregnant:

- When they start taking macitentan-containing products,
- While taking macitentan-containing products, or
- Within one month of stopping macitentan-containing products

What is the Macitentan-Containing Products REMS (Risk Evaluation and Mitigation Strategy)?

Because of the risk of serious birth defects when taking macitentan-containing products, the Food and Drug Administration (FDA) has required a special program called a Risk Evaluation and Mitigation Strategy (REMS). The purpose of the Macitentan-Containing Products REMS is to make sure the benefits of macitentan-containing products outweigh the risks. All females must enroll in the Macitentan-Containing Products REMS to receive macitentan-containing products.

How do I enroll in the Macitentan-Containing Products REMS?

Your healthcare provider will complete your enrollment online at www.MacitentanREMS.com OR by faxing a completed enrollment form to the REMS Coordinating Center.

There are several steps you must take:

1. Read this **Guide for Female Patients**. Ask your healthcare provider any questions you have about taking macitentan-containing products and the Macitentan-Containing Products REMS.
2. Make sure you understand:
 - The benefits and risks of macitentan-containing products
 - How to enroll and take part in the Macitentan-Containing Products REMS
3. Complete and sign the **Patient Enrollment Form** with your healthcare provider. Your healthcare provider will fill out most of the enrollment form for you. For additional information, please see the section titled '**What are the Macitentan-Containing Products REMS requirements for me?**' on page 4.

How do I change prescribers in the Macitentan-Containing Products REMS?

You can change prescribers in the Macitentan-Containing Products REMS by requesting your new prescriber to submit a new Patient Enrollment Form via fax to the REMS Coordinating Center.

What are the Macitentan-Containing Products REMS requirements for me?

Females Who **Cannot** Get Pregnant

You are considered a female who is **not** able to get pregnant if you:

- Have not yet entered puberty, **or**
- Do not have a uterus, **or**
- Have gone through menopause. (Menopause means that you have not had a menstrual period for at least 12 months for natural reasons, or that you have had your ovaries removed.), **or**
- Are infertile for other medical reasons and this infertility is permanent and cannot be reversed.

To receive macitentan-containing products, you must:

- Enroll in the Macitentan-Containing Products REMS by completing the **Patient Enrollment Form**
 - Your prescriber will help you complete this form
 - You must understand your requirements in the Macitentan-Containing Products REMS and provide your signature:
 - electronically (if enrolling online), **or**
 - on the form itself (if enrolling by paper)
- Tell your prescriber if you become pregnant or your ability to become pregnant changes
- Receive counseling from your prescriber on the risk of serious birth defects (only if you are premenopausal)
- Be monitored every year to see if your ability to become pregnant changes and tell your prescriber if your ability to become pregnant changes (only if you are over the age of 8)

Note:

- If you are a parent or caregiver of a female child who started taking macitentan-containing products before reaching puberty, you should check your child regularly to see if she is developing signs of puberty. Tell your prescriber right away if you notice that she is developing breast buds or pubic hair. Your prescriber should decide if your child has reached puberty. Your child may reach puberty before having her first menstrual period.

Females Who **Can** Get Pregnant

You are considered a female who can get pregnant if you:

- Have entered puberty, even if you have not started your period, and
- Have a uterus, and
- Have not gone through menopause (have not had a period for at least 12 months for natural reasons, or have had your ovaries removed)

To receive macitentan-containing products, you must:

- Enroll in the Macitentan-Containing Products REMS by completing the **Patient Enrollment Form**
 - Your prescriber will help you complete this form
 - You must understand your requirements in the Macitentan-Containing Products REMS and provide your signature:
 - electronically (if enrolling online), **or**
 - on the form itself (if enrolling by paper)
 - Have a negative pregnancy test:
 - before starting macitentan-containing products,
 - each month for as long as you are being treated with macitentan-containing products, and
 - for one month after you stop taking macitentan-containing products
- Your healthcare provider will order the pregnancy tests for you. You may not receive your macitentan-containing product refill on time if you do not confirm with the pharmacy that you have had your monthly pregnancy test
- Use reliable birth control at all times when taking macitentan-containing products and for one month after stopping macitentan-containing products. Your birth control options are listed on page 6.
 - Do not have unprotected sex

Talk to your healthcare provider right away if you have unprotected sex, if you think your birth control has failed, or if you think you are pregnant. If so, your healthcare provider may discuss medical options with you (e.g., emergency contraception). Do not wait until your next appointment to tell your healthcare provider if you miss your menstrual period or if you think you are pregnant.

Macitentan-containing products are not available at your local pharmacy. You must receive macitentan-containing products through a certified outpatient pharmacy.

Your pharmacy will contact you every month to provide counseling and to ask if you have completed a pregnancy test before shipping your macitentan-containing products to your home or another shipping address you choose.

What are my birth control options?

If you are a female who can get pregnant, your healthcare provider will talk with you about your birth control options before starting macitentan-containing products. Ask your healthcare provider if you have any questions. Tell your healthcare provider if you want to change your birth control.

You must choose one of the 4 options listed below. More than one birth control method might be needed every time you have sex.

Acceptable birth control options

Option 1 One method from this list:	OR	Option 2 One method from this list:	OR	Option 3 One method from this list:	OR	Option 4 One method from this list:
Standard intrauterine device (Copper T 380A IUD)		Estrogen and progesterone oral contraceptives ("the pill")		Diaphragm with spermicide		Partner's vasectomy
Intrauterine system (LNg 20 IUS: progesterone IUS)		Estrogen and progesterone transdermal patch		Cervical cap with spermicide		PLUS One method from this list:
Progesterone implant		Vaginal ring		PLUS One method from this list:		Male condom
Tubal sterilization		Progesterone injection		Male condom		Diaphragm with spermicide
		PLUS One method from this list:				Cervical cap with spermicide
		Male condom				Estrogen and progesterone oral contraceptives ("the pill")
		Diaphragm with spermicide				Estrogen and progesterone transdermal patch
		Cervical cap with spermicide				Vaginal ring
						Progesterone Injection

How will I receive macitentan-containing products?

Macitentan-containing products are available only through certified outpatient pharmacies.

Before your first prescription is filled, the pharmacy you selected will call you to schedule a shipment of macitentan-containing products that will come right to your home or another shipping address you choose.

For females who can get pregnant, the pharmacy will contact you **every month** to ask if you have completed a pregnancy test before the pharmacy can ship your macitentan-containing product. It is important that you can be contacted to avoid delays in your refills.

A Medication Guide will be included with each macitentan-containing product shipment.

Read the Medication Guide each time you receive it. Important information may have been added or changed.

For a list of certified pharmacies, please call the REMS Coordinating Center at **1-888-572-2934**.

Steps to treatment with macitentan-containing products

Use this checklist to start with macitentan-containing products.

FIRST:

- Review the **Guide for Female Patients** with your healthcare provider
- Make sure you understand the risks and benefits of taking macitentan-containing products
- For females who can get pregnant, complete a pregnancy test
- Enroll in the Macitentan-Containing Products REMS

NEXT:

- Expect a call from the pharmacy you selected to schedule your first shipment

EVERY MONTH:

- Read the Medication Guide that comes with every shipment

For females who **can** get pregnant:

- Use reliable birth control method(s) agreed upon with your healthcare provider—during treatment and for one month after you stop taking macitentan-containing products
- Complete the monthly pregnancy test ordered by your healthcare provider
- Expect your pharmacy to call you every month to ask if you had a pregnancy test in the last month before it reorders your macitentan-containing product. The refill may not be done on time if you've not had your pregnancy test
- Do not get pregnant. Tell your healthcare provider right away if you:
 - Have unprotected sex
 - Think that your birth control failed
 - Miss a menstrual period
 - Think you are pregnant

You can reach the Macitentan-Containing Products REMS by calling toll free at 1-888-572-2934.

**Monday – Friday
8:00 AM to 8:00 PM ET**

**For more information about the Macitentan-Containing Products REMS, please visit
*www.MacitentanREMS.com***

Macitentan-Containing
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REMS

Macitentan-Containing Products REMS Change in Reproductive Potential Status and Pre-pubertal Annual Verification Form

**THIS FORM SHOULD NOT BE USED TOGETHER WITH THE ENROLLMENT FORM.
USE IT ONLY TO REPORT A CHANGE IN REPRODUCTIVE STATUS OR FOR PRE-PUBERTAL ANNUAL VERIFICATION**



Prescribers must complete this form to:

- 1) Change the reproductive status of any female patient within 10 business days of awareness of the change in reproductive status.
- 2) Complete annual verification of the reproductive potential status for pre-pubertal females 8 years of age or older.

Complete this form online at www.MacitentanREMS.com OR fax this completed form to 1-833-681-0003.

Contact the Macitentan-Containing Products REMS at 1-888-572-2934 with any questions.

Patient Information (please print; * required field)

First name *	MI	Last name *
Address *		
City *	State*	ZIP *
Birth date *	Phone	

Prescriber Information (please print)

First name *	MI	Last name *
NPI # *		
Address		
City	State	ZIP
Phone # *	Fax	
Office contact and email address (optional)		

Definitions of Reproductive Potential Status

Females of Reproductive Potential

- Females of reproductive potential include girls who have entered puberty and all females who have a uterus and have not passed through menopause (as defined below).
- For the purposes of this REMS, puberty includes those girls who are at least Tanner Stage 3 and have not yet had a menses (premenarchal).
- For the purposes of this REMS, females who have undergone **tubal sterilization** are classified as females of **reproductive** potential.

Females of Non-Reproductive Potential

- Pre-pubertal females: Females who are at Tanner Stages 1 and 2 are not considered to be of reproductive potential.
- Post-menopausal females: Females who have passed through menopause. Menopause is defined as 12 months of spontaneous amenorrhea (not amenorrhea induced by a medical condition or medical therapy) or post-surgical from bilateral oophorectomy.
- Females with other medical reasons for permanent, irreversible infertility.

Select the most appropriate reason for submitting this form.

(For reference, please see the Definitions of Reproductive Potential Status)

Change in Status *

- **Based on definitions of reproductive potential status, patient is (please check one):**
 - Female of Reproductive Potential
 - Female of Non-Reproductive Potential – Patient is pre-pubertal
 - Female of Non-Reproductive Potential – Patient is post-menopausal
 - Female of Non-Reproductive Potential – Other medical reasons for permanent, irreversible infertility
- **Reason for change in classification (please check one):**
 - Physiological transition
 - Medical/surgical (please specify): _____
 - Other (please specify): _____
- **Annual Verification**
 - Patient remains a Pre-pubertal Female (8 years of age or older)

Continued on next page

Prescriber Acknowledgement (REQUIRED)

By signing, I certify that the patient's reproductive status as noted above is accurate, and that I will comply with the REMS requirements for my patient's reproductive potential status.

Prescriber Signature *

Title (MD/PA/NP, etc.)

Date *

Please visit www.MacitentanREMS.com or call 1-888-572-2934 for more information about the Macitentan-Containing Products REMS.

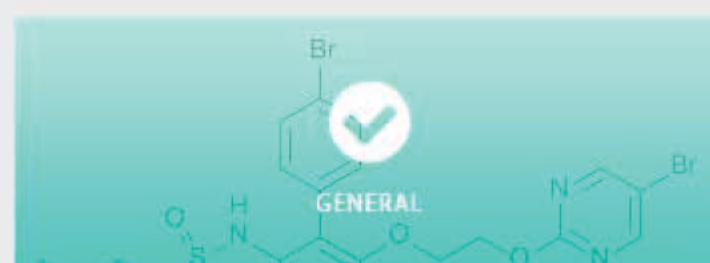
Macitentan-Containing Products

REMS

PUBLIC PORTAL

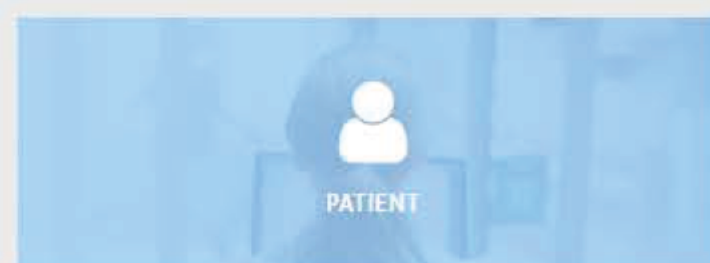
A Risk Evaluation and Mitigation Strategy (REMS) is a program required by the Food and Drug Administration (FDA) to manage serious risks associated with a drug product. The Macitentan-Containing Products REMS is for females only. Male patients are not required to enroll in the Macitentan-Containing Products REMS. The goal of the Macitentan-Containing Products REMS is to mitigate the risk of embryo-fetal toxicity associated with macitentan-containing products by:

1. Ensuring prescribers are educated on the following:
 - the risks of embryo-fetal toxicity
2. Ensuring prescribers are educated on and adhere to the following:
 - counseling patients about these risks and the need for monthly monitoring
 - enrolling patients in the Macitentan-Containing Products REMS
 - monitoring patients at baseline and monthly
3. Ensuring that pharmacies are educated on the following:
 - the risks of embryo-fetal toxicity
4. Ensuring that pharmacies are educated on and adhere to the following:
 - confirming that the appropriate patient monitoring and counseling has occurred before dispensing macitentan-containing products
5. Ensuring that patients are informed about:
 - the risks of embryo-fetal toxicity
 - appropriate baseline and monthly patient monitoring
 - appropriate contraception



General

Additional information including a list of participating companies and products



Patient

Information, tools and materials for patients taking macitentan-containing products



Pharmacy

REMS Dispense Authorization, resources, forms, enrollment, and educational materials for pharmacies



Prescriber

Resources, forms, enrollment, patient management, and educational materials for macitentan-containing products prescribers

Macitentan-Containing Products REMS Overview:

- All healthcare providers must certify by enrolling in the Macitentan-Containing Products REMS and comply with requirements to prescribe macitentan-containing products
- All female patients must be enrolled in the Macitentan-Containing Products REMS to receive macitentan-containing products
- Females of Reproductive Potential and Pre-pubertal Females of Non-Reproductive Potential are required to be counseled on the risks of macitentan-containing products
- Females of Reproductive Potential are required to get monthly pregnancy testing
- A limited number of certified pharmacies will dispense macitentan-containing products for outpatients. They must certify by enrolling in the Macitentan-Containing Products REMS and agree to the REMS requirements
- Pharmacies that supply inpatient use of macitentan-containing products must also be certified in the Macitentan-Containing Products REMS and agreeing to the REMS requirements

Macitentan is an endothelin receptor antagonist (ERA) indicated for the treatment of pulmonary arterial hypertension (PAH, WHO Group I) to reduce the risks of disease progression and hospitalization for PAH.

Effectiveness was established in a long-term study in PAH patients with predominantly WHO Functional Class II-III symptoms treated for an average of 2 years. Patients had idiopathic and heritable PAH (57%), PAH caused by connective tissue disorders (31%), and PAH caused by congenital heart disease with repaired shunts (8%).

OPSYNVI™ is a combination of macitentan-containing products, an endothelin receptor antagonist (ERA), and tadalafil, a phosphodiesterase 5 inhibitor (PDE5i) indicated for the long-term treatment of pulmonary arterial hypertension (PAH, WHO Group I) in adult patients of WHO functional class (FC) II-III (1.1).

Tadalafil is a phosphodiesterase 5 (PDE5) inhibitor indicated for the treatment of pulmonary arterial hypertension (PAH, WHO Group 1) to improve exercise ability.

Efficacy of OPSYNVI was established in a study in PAH patients with WHO Functional Class II-III treated for 16-weeks. Patients treated with OPSYNVI had idiopathic and heritable PAH (54.2%), PAH caused by connective tissue disorders (33.6%), heritable PAH (3.7%), PAH associated with HIV infection (3.7%), PAH associated with congenital heart disease (2.8%), Drug- and -toxin induced (0.9%) and PAH associated with congenital heart disease (0.9%).

PRODUCTS

Product Name	Company	Telephone	NDC Code
Placebo A	Company 1	1-800-555-5555	55555-555-55, 10 mg blister of 15 tablets
Placebo B	Company 2	1-800-444-4444	44444-444-44, 10 mg bottle of 30 tablets

Macitentan-Containing
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REMS

[PRIVACY POLICY](#) | [TERMS OF USE](#) | [CONTACT US](#)

Report pregnancies to the Macitentan-Containing Products REMS by calling 1-888-572-2934.
Report adverse events to FDA by visiting www.fda.gov/medwatch or call 1-800-FDA-1088.

Contact Us

 8:00 AM to 8:00 PM ET
Monday - Friday

 1-888-572-2934

 1-833-681-0003

General FAQs

> Expand All

- > What type of information is collected by the Macitentan-Containing Products REMS and who will see it?
- > Why aren't I receiving emails from the Macitentan-Containing Products REMS?
- > What if I need help using the website?
- > What browser types and versions does the Macitentan-Containing Products REMS website support?
- > How does the Macitentan-Containing Products REMS website use cookies?
- > What do I do if I can't view a document on the website?
- > How do I report a problem with the Macitentan-Containing Products REMS website?
- > How do I obtain a username and password for the Macitentan-Containing Products REMS website?
- > What if I do not receive the verification email after I created my account?
- > What do I do if I forgot my password?
- > What do I do if I forgot my username?
- > What do I do if my user account is locked?
- > How do I change my username and/or password?
- > What is two-factor authentication (2FA)?

Prescriber FAQs

- > How do patients enroll in the Macitentan-Containing Products REMS?
- > How do I complete a patient transfer?
- > How do prescribers certify by enrolling in the Macitentan-Containing Products REMS?
- > What are the Macitentan-Containing Products REMS requirements for prescribers?
- > How do I find a pharmacy to fill a macitentan-containing products prescription for outpatient use?
- > Do healthcare providers who prescribe macitentan-containing products have to certify by enrolling in the Macitentan-Containing Products REMS?
- > What if a patient gets pregnant during treatment with macitentan-containing products or within one month of discontinuation of treatment?
- > What is an RDA?

Pharmacy FAQs

- > How does a patient enroll in the Macitentan-Containing Products REMS?
- > How does a pharmacy certify in the Macitentan-Containing Products REMS?
- > What happens if the pharmacy's authorized representative leaves or changes?
- > Do pharmacies need to recertify annually in the Macitentan-Containing Products REMS?
- > What are the Macitentan-Containing Products REMS requirements for pharmacies?
- > How are pharmacies classified in the Macitentan-Containing Products REMS?
- > What is a REMS Dispense Authorization (RDA)?

How does a pharmacy enroll in a REMS Dispense Authorization (RDA)?

Patient FAQs

- › What is macitentan?
- › What are the serious risks of macitentan-containing products?
- › What is the Macitentan-Containing Products REMS (Risk Evaluation and Mitigation Strategy)?
- › Am I considered a female who cannot get pregnant?
- › I am a female who cannot get pregnant, what must I do to receive macitentan-containing products?
- › Am I considered a female who can get pregnant?
- › I am a female who can get pregnant, what must I do to receive macitentan-containing products?
- › Do male patients taking macitentan-containing products need to enroll?
- › Can Veterans Affairs (VA) patients enroll in the Macitentan-Containing Products REMS by phone or online?
- › What are my birth control options while taking macitentan-containing products?
- › How will I receive my macitentan-containing products?
- › What should I do if I get pregnant while taking macitentan-containing products?
- › How do I enroll in the Macitentan-Containing Products REMS?
- › Do patients need to enroll in the Macitentan-Containing Products REMS if already enrolled in the Opsumit REMS?
- › Is this REMS mandatory?
- › If I am unable to get pregnant, do I still need to enroll?
- › What is an RDA?
- › What are the patient requirements for the Macitentan-Containing Products REMS?
- › Where can patients fill macitentan-containing products prescriptions?
- › What does it mean to transfer prescribers?
- › If I transfer prescribers, will my previous prescriber still be able to see my information in the REMS system?
- › Will a transfer cause an interruption in my treatment?
- › How does a transfer work?

Wholesaler FAQs

- › What are the requirements of the Macitentan-Containing Products REMS for wholesalers?
- › How do wholesalers confirm that the pharmacy is authorized to receive macitentan-containing products?
- › How can I verify if a pharmacy is certified in the Macitentan-Containing Products REMS through the daily certification files available via secure file transfer protocol (sFTP)?

Prescriber

- › How do patients enroll in the Macitentan-Containing Products REMS?
- › How do I complete a patient transfer?
- › How do prescribers certify by enrolling in the Macitentan-Containing Products REMS?
- › What are the Macitentan-Containing Products REMS requirements for prescribers?
- › How do I find a pharmacy to fill a macitentan-containing products prescription for outpatient use?
- › Do prescribers need to be certified in the Macitentan-Containing Products REMS if already certified in the Opsumit REMS?
- › Do healthcare providers who prescribe macitentan-containing products have to certify by enrolling in the Macitentan-Containing Products REMS?
- › What if a patient gets pregnant during treatment with macitentan-containing products or within one month of discontinuation of treatment?
- › What is an RDA?

Find A Pharmacy



Find a pharmacy participating in the Macitentan-Containing Products REMS

Certify



Prescribers must certify by enrolling in the Macitentan-Containing Products REMS and comply with the Macitentan-Containing Products REMS requirements to prescribe macitentan-containing products

Materials for Prescribers

Change in Reproductive Potential Status and Pre-Pubertal Annual Verification Form



Patient Enrollment Form



Prescriber Enrollment and Agreement Form



Prescriber FAQs

Patient

- > What is macitentan?
- > What are the serious risks of macitentan-containing products?
- > What is the Macitentan-Containing Products REMS (Risk Evaluation and Mitigation Strategy)?
- > Am I considered a female who cannot get pregnant?
- > I am a female who cannot get pregnant, what must I do to receive macitentan-containing products?
- > Am I considered a female who can get pregnant?
- > I am a female who can get pregnant, what must I do to receive macitentan-containing products?
- > Do male patients taking macitentan-containing products need to enroll?
- > Can Veterans Affairs (VA) patients enroll in the Macitentan-Containing Products REMS by phone or online?
- > What are my birth control options while taking macitentan-containing products?

Find A Pharmacy



Find a pharmacy participating in the Macitentan-Containing Products REMS

Materials for Female Patients

Guide for Female Patients



Patient FAQs

Pharmacy

- › How does a patient enroll in the Macitentan-Containing Products REMS?
- › How does a pharmacy certify in the Macitentan-Containing Products REMS?
- › What happens if the pharmacy's authorized representative leaves or changes?
- › Do pharmacies need to recertify annually in the Macitentan-Containing Products REMS?
- › What are the Macitentan-Containing Products REMS requirements for pharmacies?
- › How are pharmacies classified in the Macitentan-Containing Products REMS?
- › What is a REMS Dispense Authorization (RDA)?
- › How does a pharmacy obtain a REMS Dispense Authorization (RDA)?

Find A Pharmacy



Find a pharmacy participating in the Macitentan-Containing Products REMS

Certify



Pharmacies that dispense macitentan must certify by enrolling in the Macitentan-Containing Products REMS.

Materials for Pharmacies

[Outpatient Pharmacy Enrollment Form](#)[Inpatient Pharmacy Enrollment Form](#)[Prescriber and Pharmacy Guide](#)[Pharmacy FAQs](#)

Macitentan-Containing Products REMS Pharmacy Locator

PHARMACY NAME	PHONE NUMBER	FAX	NPI	ADDRESS	PHARMACY TYPE
Abbott Group	(847) 289-1763	(901) 546-3381	7589632145	607 Apple Lane	Outpatient
Aguilar LLC	(682) 313-7849	(509) 598-2170	8564752314	1025 Green Avenue	Inpatient
Allen-Pollard	(367) 420-9667	(734) 584-1097	1547826584	4551 Locust Court	Inpatient
Allison, Bradshaw and Stark	(913) 536-8872	(701) 865-5255	1476985324	3366 Bond Street	Outpatient
Andersen Inc	(631) 237-7549	(647) 094-4532	2789653247	1939 Irving Road	Inpatient
Andersen, Friedman and Foley	(938) 321-5932	(662) 743-6822	6987452159	432 Virgil Street	Inpatient
Archer-Yang	(253) 478-2336	(718) 874-7501	3698745217	896 Cherry Camp Road	Outpatient
Arias LLC	(650) 857-1397	(423) 658-1116	4598632574	859 Cambridge Place	Inpatient
Arnold, Sparks and Walton	(909) 205-8448	(250) 915-2419	7856954725	3302 Rosemont Avenue	Inpatient
Arnold-Mcconnell	(706) 853-1029	(707) 723-9178	9875231458	885 Florence Street	Outpatient

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[Next >](#)

Login

Welcome. Please log in.

Enter your username



Enter your password



[Forgot your password?](#)

LOGIN

Macitentan-Containing
Products

REMS

PRESCRIBER PORTAL

 Prescriber Certification

Instructions

Healthcare providers who prescribe macitentan-containing products (prescribers) must certify by enrolling in the Macitentan-Containing Products REMS. To become certified, the prescriber must first read the **Prescribing Information (PI)** and the **Prescriber and Pharmacy Guide**, and then agree to follow the Macitentan-Containing Products REMS requirements by completing the **Prescriber Enrollment and Agreement Form**. Select the button below to continue with online certification **OR** fax a completed **Prescriber Enrollment and Agreement Form** to 1-833-681-0003.

Overview of online certification:

- 1 Prescriber Information** - Prescribers will enter an individual National Provider Identifier (NPI) number. This will be used to obtain most of the information needed for the enrollment form. The prescriber will be asked to provide information about another person who can be contacted on behalf of the prescriber.
- 2 Primary Office Practice/Clinical Information** - The prescriber will be asked to provide primary office information.
- 3 Secondary Office Practice/Clinical Information** - The prescriber will be asked to provide secondary office information.
- 4 Create Password** - The prescriber will be asked to enter a password to create the program account. Upon creation of the account, the prescriber will receive an email with a link. Upon clicking on the link in the email, the prescriber will be asked to log in and complete the certification.
- 5 Agreement** - The prescriber will be asked to provide their signature. By signing, the prescriber signifies their understanding of the risks associated with macitentan-containing products treatment and their obligation as a macitentan-containing products prescriber to educate female patients about these risks, counsel them on risk reduction, monitor them appropriately, and report adverse events to the REMS Coordinating Center.
- 6 Complete** - The certification will be completed upon agreeing and providing a signature.

[START →](#)

 Prescriber Certification1
PRESCRIBER
INFORMATION2
PRIMARY OFFICE
PRACTICE/CLINICAL
INFORMATION3
SECONDARY OFFICE
PRACTICE/CLINICAL
INFORMATION4
PASSWORD5
AGREEMENT6
COMPLETE

Prescriber Information

Please provide an individual NPI number



1023092293

FIND



NPI Information

Gary Olsen

Mailing Address
12433 S Fort St
Draper, UT 84020Phone
8015761086

★ = Primary Specialty



Email



test@yopmail.com

test@yopmail.com

Professional Designation



DO

[← PREVIOUS](#)[RESTART](#)[NEXT →](#)

 Prescriber Certification


Primary Office Practice/Clinical Information

Office practice/clinic name

Specialty

Affiliated hospital

Office Address

 Use my NPI location address

Office Contact

Name

Email

Phone

Office Phone

Extension

Fax

Preferred method of contact

 Email Phone Fax

[← PREVIOUS](#)
[RESTART ↻](#)
[NEXT →](#)

 Prescriber Certification

Secondary Office Practice/Clinical Information

Office practice/clinic name

 Office practice/clinic name

Specialty

Specialty

Affiliated hospital

 Affiliated hospital

Office Address

 Use my NPI location address Address Line 1

Address Line 2

City

State



Zip Code

Office Contact

Name

 First Name

Last Name

Email

 Email

Confirm Email

Phone

 (nnn) nnn-nnnn

Office Phone

 (nnn) nnn-nnnn

Extension

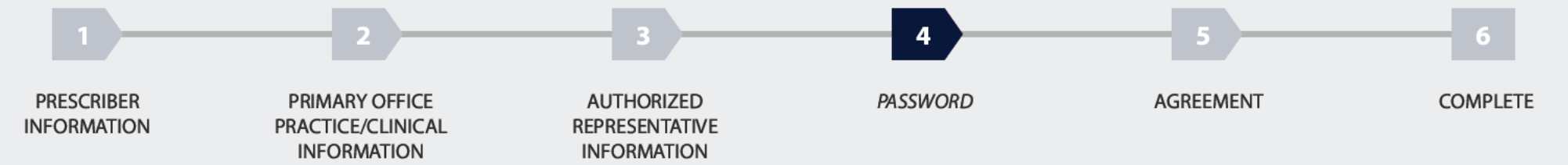
nnn..

Fax

 (nnn) nnn-nnnn

Preferred method of contact

 Email Phone Fax PREVIOUSRESTART NEXT 

 Prescriber Certification

Password

Please provide your username

Please create your password

- Two-Factor Authentication Opt-In
- Two-Factor Authentication Opt-Out

Two-Factor Authentication**Why Opt In for 2FA?**

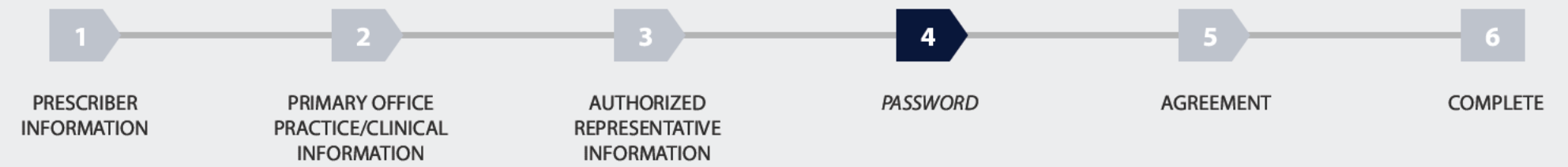
- **Enhanced Security:** 2FA adds an extra layer of defense, ensuring that only authorized users can access your account, even if your password is compromised.
- **Protect Patient Confidentiality:** Safeguard your patients' sensitive information from unauthorized access, preserving their trust in your practice.
- **Regulatory Compliance:** Maintain compliance with healthcare regulations like HIPAA by implementing robust security measures.

Note:

- Users who opt in to 2FA will need to obtain their verification code via email each time the user logs into their account. You will be able to change your 2FA selection in your user profile screen later if you choose to do so.

NEXT →

Prescriber Certification



Password

Please provide your username

Please create your password

- Two-Factor Authentication Opt-In
- Two-Factor Authentication Opt-Out

Opt Out? Consider the Risks.

If you choose to opt out of 2FA, please be aware of the following risks.

- **Increased Vulnerability:** Without 2FA, your account is more susceptible to unauthorized access, potentially exposing your patients' PHI to malicious actors.
- **Potential Data Breach:** In the event of a security breach, your patients' sensitive information could be compromised, leading to legal and financial consequences.
- **Loss of Trust:** Patients entrust you with their confidential information. A breach could erode their trust in your practice.

Note: You will be able to change your 2FA selection in your user profile screen later if you choose to do so.

Two-Factor Authentication

Why Opt In for 2FA?

- **Enhanced Security:** 2FA adds an extra layer of defense, ensuring that only authorized users can access your account, even if your password is compromised.
- **Protect Patient Confidentiality:** Safeguard your patients' sensitive information from unauthorized access, preserving their trust in your practice.
- **Regulatory Compliance:** Maintain compliance with healthcare regulations like HIPAA by implementing robust security measures.

NEXT →

 Prescriber Certification

1

PRESCRIBER
INFORMATION

2

PRIMARY OFFICE
PRACTICE/CLINICAL
INFORMATION

3

SECONDARY
OFFICE
PRACTICE/CLINICAL
INFORMATION

4

ALIAS/ID

5

AGREEMENT

6

COMPLETE

Password

You must confirm your email to continue

An email has been sent to you at the following address:

test@yopmail.com

I have checked my junk mail, and waited a few minutes

 Resend Email

Login

Welcome. Please log in.

Enter your username



Email



Enter your password



Password



[Forgot your password?](#)

LOGIN

Enter Verification Code

XXXXX

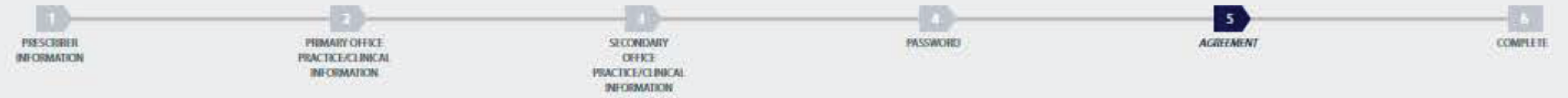


VERIFY

 Gary Dean Olsen DO
NPI: 1023092293

Program Status: Pending Execution of REMS Agreement

 Prescriber Certification



Agreement

Please read and accept the following terms:

Macitentan-Containing Products REMS Prescriber Agreement:

By signing below, you signify your understanding of the risks of macitentan-containing product treatment and your obligation as a prescriber of macitentan-containing products to educate your female patients about the Macitentan-Containing Products REMS (Risk Evaluation and Mitigation Strategy), monitor them appropriately, and report any pregnancies to the REMS Coordinating Center. Specifically, you attest to the following:

- I have reviewed the **Prescribing Information** and the **Prescriber and Pharmacy Guide** and agree to comply with the Macitentan-Containing Products REMS requirements.
- For all Females, I will:
 - assess the patient's reproductive status using the definitions in the **Prescriber and Pharmacy Guide** and document and submit the results using the **Patient Enrollment Form**.
 - counsel the female patient that macitentan-containing products are only available through a restricted distribution program called the Macitentan-Containing Products REMS.
 - enroll all female patients by completing and submitting the **Patient Enrollment Form**.
- For Females of Reproductive Potential, I will:
 - counsel the Females of Reproductive Potential about the risk of embryo-fetal toxicity, the need to use reliable contraception during treatment and for one month following treatment discontinuation, and emergency contraception using the **Guide for Female Patients**.
 - assess the patient's pregnancy status by ordering and reviewing a pregnancy test before the start of treatment, monthly during treatment, and for one month after stopping treatment.
 - counsel the patient if she is not complying with the required testing or if she is not using appropriate contraception, and to contact her prescriber if she misses a menstrual period or suspects that she is pregnant.
- For Pre-pubertal Females I will:
 - counsel the Pre-Pubertal Female patient and her parent/guardian on the risk of embryo-fetal toxicity and to immediately contact her prescriber if she begins to menstruate using the **Guide for Female Patients**.
 - regularly assess the reproductive status of each Pre-Pubertal Female during their treatment with macitentan-containing products.
 - document the reproductive potential status of Pre-Pubertal Females who are at least 8 years or older and submit to the REMS at least annually using the **Change in Reproductive Potential Status and Pre-pubertal Annual Verification Form**.
- At all times, I will:
 - report any change or misclassification in reproductive status to the REMS by submitting a **Change in Reproductive Potential Status and Pre-pubertal Annual Verification Form** within 10 business days of becoming aware of the change.
 - report any pregnancies to the REMS at 1-888-572-2934.

I understand and agree to all the terms above

Prescriber Signature:

Please use your mouse to sign your name, Gary Dean Olsen, in the box below:

SAVE CLEAR

NEXT →



Gary Dean Olsen DO

NPI: 1023092293

Program Status: Enrolled as of 8/16/2023



Prescriber Certification

1
PRESCRIBER
INFORMATION2
PRIMARY OFFICE
PRACTICE/CLINICAL
INFORMATION3
SECONDARY OFFICE
PRACTICE/CLINICAL
INFORMATION4
PASSWORD5
AGREEMENT6
COMPLETE

Complete

Gary Dean Olsen DO, your certification in the Macitentan-Containing Products REMS is complete.

You may choose from the following options or navigate to your desired function utilizing the prescriber menu at the top of the page.



MANAGE PATIENTS

Manage Patients

- Manage your enrolled patients
- Change patient's reproductive potential status



PREFERENCES

Preferences

Update your personal preferences.



1023092293



Gary Dean Olsen

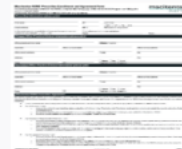
12433 S Fort St, Draper, UT, 84020



PRINT ENROLLMENT FORM

Print enrollment form

Print or download a PDF copy of your completed enrollment form.



 Helene Presskreischer MD
NPI: 1386704617

Program Status: **Enrolled as of 9/22/2023** ✓

Manage Patients

PATIENTS

Prescriber ↑↓	Patient Name ↑↓	REMS ID	Date of Birth	Classification	Prescriber Signature	Patient Signature	Status	Actions

Key:  Re-send for Patient's Signature  Discard Patient  Prescriber Signature  Patient Signature  Monthly Pregnancy Test  Reproductive Potential Status  Re-Enroll Patient  Patient Detail

← Previous Page 1 of 1 Next →

New Patient Actions

 ENROLL A PATIENT

Prescriber Actions

 MANAGE OFFICE

Materials for Prescribers

Patient Enrollment Form 

Change in Reproductive Potential Status and Pre-Pubertal Annual Verification Form 

Prescriber and Pharmacy Guide 

Prescriber Enrollment and Agreement Form 

Prescriber FAQs



Gary Dean Olsen DO

NPI: 1023092293

Program Status: **Enrolled as of 8/16/2023**



Patient Enrollment

Instructions

All female patients taking macitentan-containing products must be enrolled in the Macitentan-Containing Products REMS.

- 1 Patient Information** - Enter information about the patient such as name, address, phone number, date of birth, primary language, and email address.
- 2 Alternate Contact** - The patient may enter information about an emergency contact that the REMS Coordinating Center can contact in the event of an emergency. Legal guardian contact information is required for a patient that is under the age of 18 years old.
- 3 Reproductive Potential Status** - Enter the reproductive potential status of the patient. For a female of reproductive potential, indicate if a negative pregnancy test has been confirmed. Certify that for female patients, you have provided the appropriate counseling on Macitentan-Containing Products REMS materials and will continue to fulfill the required obligations under the Macitentan-Containing Products REMS.
- 4 Patient Agreement** - The patient and/or parent/legal guardian will receive an email to complete their attestation.

START



Gary Dean Olsen DO

NPI: 1023092293

Program Status: **Enrolled as of 8/16/2023**

Patient Enrollment



PATIENT

ALTERNATE
CONTACTALTERNATE
ESSENTIAL
STATUSPATIENT
AGREEMENT

Patient Information

Name



Jane

M.I.

M.I.

Smith

Address



100 Main Street

Address Line 2

New York

NY

10001

Date of Birth



10/20/1990

Primary Language



Primary Language

Email



test@yopmail.com

test@yopmail.com

Primary Phone



6105006000

Alternate Phone



6108009000

Best time to call



Morning



Afternoon



Evening

[← PREVIOUS](#)[RESTART ↻](#)[NEXT →](#)



Gary Dean Olsen DO

NPI: 1023092293

Program Status: Enrolled as of 8/16/2023



Patient Enrollment



Alternate Contact

Emergency Contact Name



First Name

Last Name

Relationship



Mother, Father...

Phone



(nnn) nnn-nnnn

← PREVIOUS

RESTART ↻

NEXT →



Gary Dean Olsen DO

NPI: 1023092293

Program Status: **Enrolled as of 8/16/2023** 

Patient Enrollment



PREGNANT

ALTERNATE
CONTACTREPRODUCING
POTENTIAL
STATUSPATIENT
AGREEMENT

Alternate Contact

Legal Guardian Name



First Name

Last Name

Relationship



Parent/Guardian

Email



Email

Confirm Email

Phone



(nnn) nnn-nnnn

If the enrolling patient is a minor, a parent or guardian will need to complete this page.

Emergency Contact Name



First Name

Last Name

Relationship



Mother, Father...

Phone



(nnn) nnn-nnnn

PREVIOUS

RESTART

NEXT



Gary Dean Olsen DO

NPI: 1023092293

Program Status: **Enrolled as of 8/16/2023**

Patient Enrollment

1
INTENT2
ALTERNATE
EXERCISE3
REPRODUCTIVE
POTENTIAL
STATUS4
INTENT
AGREEMENT

Reproductive Potential Status

Select the female patient's current reproductive status below

Females of Reproductive Potential:

Females of Reproductive Potential

- Females of reproductive potential include girls who have entered puberty and all females who have a uterus and have not passed through menopause. Menopause is defined as 12 months of spontaneous amenorrhea (not amenorrhea induced by a medical condition or medical therapy) or post-surgical from bilateral oophorectomy.
- For the purposes of this REMS, puberty includes those girls who are at least Tanner Stage 3 and have not yet had a menses (premenarchal).
- For the purposes of this REMS, females who have undergone **tubal sterilization** are classified as females of **reproductive** potential.

Females of Non-Reproductive Potential:

- Pre-pubertal Female:** includes females who are at Tanner Stages 1 and 2 and are not considered to be of reproductive potential
- Post-menopausal Female** - females who have passed through menopause. Menopause is defined as 12 months of spontaneous amenorrhea (not amenorrhea induced by a medical condition or medical therapy) or postsurgical from bilateral oophorectomy
- Other medical reasons for permanent, irreversible infertility.

Pregnancy Test

A negative pregnancy test has been confirmed prior to prescribing macitentan

- Yes
- No

Prescriber Requirements

- For all Females:**
 - I acknowledge that I have counseled the patient (and parent/guardian when appropriate) the macitentan-containing products are only available through a restricted distribution program under an FDA-required REMS.
 - I will evaluate the patient and agree to document any change or misclassification in reproductive potential status by submitting a **Change in Reproductive Potential Status and Pre-pubertal Annual Verification Form** within 10 business days of becoming aware of a change
- For Females of Reproductive Potential:**
 - I acknowledge that I have counseled the patient (and parent/guardian when appropriate) on the risks of macitentan-containing products, including the risk of serious birth defects, and that I have reviewed the **Guide for Female Patients** with the patient (and parent/guardian when appropriate).
 - I will order and review tests prior to initiation of macitentan-containing product treatment, monthly during treatment and for one month after stopping treatment in accordance with the Macitentan-Containing Products REMS.
- For Pre-pubertal Females:**
 - I acknowledge that I have counseled the patient and parent/guardian on the risks of macitentan-containing products, including the risk of serious birth defects, and that I have reviewed the **Guide for Female Patients** with the patient and parent/guardian.
 - I will evaluate the patient's reproductive potential status annually for Pre-pubertal Females who are at least eight years of age and older, and agree to report any change or misclassification in reproductive potential status on a **Change in Reproductive Potential Status and Pre-pubertal Annual Verification Form** within 10 business days of becoming aware of a change.

Certification



I certify that the above therapy ordered is medically necessary and agree to follow the "Prescriber Requirements" as outlined above. Further, I hereby authorize the Macitentan-Containing Products REMS sponsors and/or their designated representative(s), to act on my behalf for the limited purposes of providing this prescription to the certified outpatient pharmacy for patient treatment purposes.

[← PREVIOUS](#)[RESTART](#)[SUBMIT](#)



Gary Dean Olsen DO

NPI: 1023092293

Program Status: Enrolled as of 8/16/2023



Patient or Parent/Guardian Signature

1

PATIENT

2

ALTERNATE
CONTACT

3

REPRODUCTIVE
POTENTIAL
STATUS

4

PATIENT
AGREEMENT

Thank you for completing the required information in order to enroll your patient in the Macitentan-Containing Products REMS. An email was sent to the patient or parent/guardian for them to agree to the Macitentan-Containing Products REMS requirements in order to completed their enrollment

[MANAGE PATIENTS](#)

Dear Jenna Smith,

Your prescriber has started your enrollment in the Macitentan-Containing Products REMS. You may now complete the enrollment by signing the agreement.

Click the button below to complete your enrollment.

Continue Enrollment

If you have any questions, you may call the Macitentan-Containing Products REMS at 1-888-572-2934, Monday through Friday, 8:00 AM to 8:00 PM EST.

Sincerely,

The Macitentan-Containing Products REMS

Phone: 1-888-572-2934

Fax: 1-833-681-0003

www.MacitentanREMS.com

Report pregnancies to the Macitentan-Containing Products REMS by calling 1-888-572-2934.

Report adverse events to FDA by visiting www.fda.gov/medwatch or call 1-800-FDA-1088.

 **Helene Presskreischer MD**
NPI: 1386704617

Program Status: **Enrolled as of 9/22/2023** ✓

Manage Patients

PATIENTS

Prescriber ↑↓	Patient Name ↑↓	REMS ID	Date of Birth	Classification	Prescriber Signature	Patient Signature	Status	Actions
Helene Presskreischer	Jenny Smith	2875382	12/3/1987	FRP (Female of Reproductive Potential)	✓	✓	Enrolled	      
Helene Presskreischer	Anna Jones	9370927	2/3/1981	FRP (Female of Reproductive Potential)	✓	✓	Enrolled	      
Helene Presskreischer	Regina George	7382321	1/3/1982	FRP (Female of Reproductive Potential)	✗	✗	Pending	      

Key:  Re-send for Patient's Signature  Disenroll Patient  Prescriber Signature  Patient Signature  Monthly Pregnancy Test  Reproductive Potential Status  Re-Enroll Patient  Patient Detail

< Previous Page 1 of 1 Next >

New Patient Actions

 ENROLL A PATIENT

Prescriber Actions

 MANAGE OFFICE

Materials for Prescribers

- [Patient Enrollment Form](#) 
- [Change in Reproductive Potential Status and Pre-Pubertal Annual Verification Form](#) 
- [Prescriber and Pharmacy Guide](#) 
- [Prescriber Enrollment and Agreement Form](#) 
- [Prescriber FAQs](#)

Helene Presskreischer MD
NPI: 138670

Program Status: Enrolled as of 9/22/2023

Prescriber Signature

Patient Name: Regina George

REMS ID: 7382321

Date of Birth: 1/3/1982

Classification: Please confirm the female patient's current reproductive status below.

Females of Reproductive Potential:

Females of Reproductive Potential

- Females of reproductive potential include girls who have entered puberty and all females who have a uterus and have not passed through menopause. Menopause is defined as 12 months of spontaneous amenorrhea (not amenorrhea induced by a medical condition or medical therapy) or post-surgical from bilateral oophorectomy.
- For the purposes of this REMS, puberty includes those girls who are at least Tanner Stage 3 and have not yet had a menses (premenarche).
- For the purposes of this REMS, females who have undergone tubal sterilization are classified as females of reproductive potential.

Pregnancy Test

A negative pregnancy test has been confirmed prior to prescribing macitentan

- Yes
 No

Females of Non-Reproductive Potential:

- Pre-pubertal Female: includes females who are at Tanner Stages 1 and 2 and are not considered to be of reproductive potential
- Post-menopausal Female: females who have passed through menopause. Menopause is defined as 12 months of spontaneous amenorrhea (not amenorrhea induced by a medical condition or medical therapy) or postsurgical from bilateral oophorectomy
- Other medical reasons for permanent, irreversible infertility.

Prescriber Requirements

For All Females:

- I acknowledge that I have counseled the patient (and parent/guardian when appropriate) that macitentan-containing products are only available through a restricted distribution program under an FDA-required REMS.
- I will evaluate the patient and agree to document any change or misclassification in reproductive potential status by submitting a *Change in Reproductive Potential Status and Pre-Pubertal Annual Verification Form* within 10 business days of becoming aware of the change

For Females of Reproductive Potential

- I acknowledge that I have counseled the patient (and parent/guardian when appropriate) on the risks of macitentan-containing products, including the risk of serious birth defects, and that I have reviewed the *Guide for Female Patients* with the patient (and parent/guardian when appropriate).
- I will order and review pregnancy tests prior to initiation of macitentan-containing product treatment, monthly during treatment and for one month after stopping treatment in accordance with the Macitentan REMS

For Pre-Pubertal Females

- I acknowledge that I have counseled the patient and parent/guardian on the risks of macitentan-containing products, including the risk of serious birth defects, and that I have reviewed the *Guide for Female Patients* with the patient and parent/guardian.
- I will evaluate the patient's reproductive potential status, verify reproductive potential status annually for Pre-pubertal Females who are at least eight years of age and older, and agree to report any change or misclassification in reproductive potential status on a *Change in Reproductive Potential Status and Pre Pubertal Annual Verification Form* within 10 business days of becoming aware of the change

Certification

I certify that the above therapy ordered is medically necessary and agree to follow the "Prescriber Requirements" as outlined above. Further, I hereby authorize the Macitentan REMS sponsors and/or their designated representative(s), to act on my behalf for the limited purposes of providing this prescription to the certified outpatient pharmacy for patient treatment purposes.

CANCEL

SUBMIT



Gary Dean Olsen DO

NPI: 1023092293

Program Status: **Enrolled as of 8/16/2023** ✓



Jane Smith

Date of Birth: 10/20/1990

REMS ID: 0045068

Patient Information



Jane Smith



100 Main Street
New York, 10001



10/20/1990



Female



(888) 888-8888



test@yopmail.com

Patient Events



Counseled

8/16/2023



Pregnancy Test Confirmed

8/16/2023



Reproductive Potential Status

8/16/2023



Enrollment Date

8/16/2023



Prescriber Signature

8/16/2023



Patient Signature

8/16/2023

Actions

MONTHLY PREGNANCY TEST

PRINT COMPLETED ENROLLMENT FORM

REPRODUCTIVE POTENTIAL STATUS

DISENROLL PATIENT

Materials for Prescribers

Change in Reproductive Potential Status and Pre-Pubertal Annual Verification Form



Patient Enrollment Form



Prescriber Enrollment and Agreement Form



Prescriber FAQs



Gary Dean Olsen DO

NPI: 1023092293

Program Status: Enrolled as of 8/16/2023 ✓



Jane Smith

Date of Birth: 10/20/1990

Monthly Pregnancy Test

Pregnancy Test

- Monthly Pregnancy Test Obtained

i Information

Confirm that a pregnancy test has been obtained within the last month for this patient.

The prescriber must notify the Macitentan-Containing Products REMS Coordinating Center (by phone at 1-888-572-2934) of any pregnancies that occur during treatment or within one month of discontinuation.

COMPLETE



Gary Dean Olsen DO

NPI: 1023092293

Program Status: Enrolled as of 8/16/2023



Jane Smith

Date of Birth: 10/20/1990

Change in Reproductive Potential Status and Pre-Pubertal Annual Verification

Select the female patient's current reproductive status below

Females of Reproductive Potential:

Females of Reproductive Potential

- Females of reproductive potential include girls who have entered puberty and all females who have a uterus and have not passed through menopause. Menopause is defined as 12 months of spontaneous amenorrhea (not amenorrhea induced by a medical condition or medical therapy) or post-surgical from bilateral oophorectomy.
- For the purposes of this REMS, puberty includes those girls who are at least Tanner Stage 3 and have not yet had a menses (premenarchal).
- For the purposes of this REMS, females who have undergone **tubal sterilization** are classified as females of **reproductive** potential.

Females of Non-Reproductive Potential:

- Pre-pubertal Female:** includes females who are at Tanner Stages 1 and 2 are not considered to be of reproductive potential
- Post-menopausal Female** - females who have passed through menopause. Menopause is defined as 12 months of spontaneous amenorrhea (not amenorrhea induced by a medical condition or medical therapy) or postsurgical from bilateral oophorectomy
- Other medical reasons for permanent, irreversible infertility

Reason for change in classification

- Physiological transition
- Medical/Surgical (Please specify below)
- Other (Please specify below)

Please Specify

Annual Verification for Pre-Pubertal Status

- Patient remains a Pre-pubertal Female (8 years of age or older)

Information

To change a patient's reproductive status:

1. Select the patient's current reproductive status within 10 business days of awareness of the change
2. Select the Reason for the patient's change in classification
3. Complete the annual verification of the reproductive potential status for pre-pubertal females 8 years of age or older, if applicable

COMPLETE



Gary Dean Olsen DO

NPI: 1023092293

Program Status: **Enrolled as of 8/16/2023**



Jane Smith

Date of Birth: 10/20/1990

Disenroll Patient

Disenroll Reason

Discontinued Therapy

Patient Information

I have verified the patient's name and date of birth above and would like to disenroll the patient.

Information

Used to disenroll a patient. If applicable, report pregnancies to the Macitentan-Containing Products REMS by calling 1-888-572-2934. Report adverse events to FDA by visiting www.fda.gov/medwatch or call 1-800-FDA-1088. A representative may reach out for additional questions.

DISENROLL PATIENT

Helene Presskreischer MD
NPI: 1386704617

Program Status: **Enrolled as of 9/22/2023**

Manage Office

Office Name

9073250972
 159 Tower Ave,
Needham, MA 02494

OFFICE CONTACTS

REFRESH

Name	Phone	Email	Receive Communications	Current Status	Actions
Mary Smith	3253221124	at_prescriber1@yopmail.com	☐ Opt-in	Active	

Add Office Contact Edit Office Contact Remove Office Contact

Material for Prescribers

Patient Enrollment Form

Change in Reproductive Potential Status and Pre-Pubertal Annual Verification Form

Prescriber and Pharmacy Guide

Prescriber Enrollment and Agreement Form

Prescriber FAQs

Add Office Contact



Office Contact Information

Please enter Office Contact First Name, Last Name, Email Address, and click "SEARCH"

* First Name

* Last Name

* Email Address

* Required field

SEARCH



No results match your search criteria. Add new Office Contact information in blank fields below

FIRST NAME	LAST NAME	EMAIL	PHONE NUMBER
Jane	Williams	williams_jane@mail.com	

NEW SEARCH

SUBMIT

By clicking "Submit", the Prescriber confirms they are granting administrative rights to the Office Contact(s). The Prescriber understands they must review and sign all paperwork prior to submitting it to the REMS.

Add Office Contact



Office Contact Information

Please enter Office Contact First Name, Last Name, Email Address, and click "SEARCH"

* First Name

* Last Name

* Email Address

* Required field

SEARCH



Results found. Please select an Office Contact to affiliate

FIRST NAME	LAST NAME	EMAIL	PHONE NUMBER	AFFILIATE SELECTED OFFICE CONTACT	OPT-IN TO NOTIFICATIONS
Jane	Williams	williams_jane@mail.com	281-119-7593	☒	☐

NEW SEARCH

SUBMIT

By clicking "Submit", the Prescriber confirms they are granting administrative rights to the Office Contact(s). The Prescriber understands they must review and sign all paperwork prior to submitting it to the REMS.

Macitentan-Containing
Products

REMS

OFFICE CONTACT PORTAL

 **Office Contact:** Rebecca Stagg Program Status: **Active as of 9/22/2023**

Manage Patients

PATIENTS									
Prescriber ↑↓	Patient Name ↑↓	REMS ID	Date of Birth	Classification	Prescriber Signature	Patient Signature	Status	Actions	
Monica Creek	Jenny Smith	2875382	12/3/1987	FRP (Female of Reproductive Potential)	✓	✓	Enrolled	   	
Anna Willett	Anna Jones	9370927	2/3/1981	FRP (Female of Reproductive Potential)	✓	✓	Enrolled	   	
Bobby Jones	Regina George	7382321	1/3/1982	FRP (Female of Reproductive Potential)	✗	✗	Pending	   	

Key:  Prescriber Signature  Patient Signature  Monthly Pregnancy Test  Re-Enroll Patient  Patient Detail

New Patient Actions

 **ENROLL A PATIENT**

Materials for Prescribers

- Patient Enrollment Form* 

- Change in Reproductive Potential Status and Pre-Pubertal Annual Verification Form* 

- Prescriber and Pharmacy Guide* 

- Prescriber Enrollment and Agreement Form* 

- Prescriber FAQs

 **Office Contact:** Rebecca Stagg

Program Status: **Active as of 9/22/2023** 

  Patient Enrollment

Select a Prescriber:

—None— 

START 

 Office Contact: Rebecca Stagg  Nib Thao MD
NPI: 1841320475Program Status: Active as of 9/22/2023   Patient Enrollment

Instructions

All female patients taking macitentan-containing products must be enrolled in the Macitentan-Containing Products REMS.

- 1 Patient Information** – Enter information about the patient such as name, address, phone number, date of birth, primary language, and email address.
- 2 Alternate Contact** – The patient may enter information about an emergency contact that the REMS Coordinating Center can contact in the event of an emergency. Legal guardian contact information is required for a patient that is under the age of 18 years old.
- 3 Reproductive Potential Status** – Enter the reproductive potential status of the patient. For a female of reproductive potential, indicate if a negative pregnancy test has been confirmed. Certify that for female patients, you have provided the appropriate counseling and Macitentan-Containing Products REMS materials and will continue to fulfill the required obligations under the Macitentan-Containing Products REMS.
- 4 Prescriber/Patient Agreement** – The prescriber will receive the Prescriber Agreement. The patient and/or parent/legal guardian will receive an email to complete their attestation.

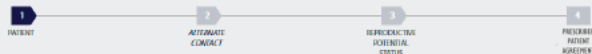
[← PREVIOUS](#)[NEXT →](#)

 **Office Contact:** Rebecca Stagg

 **Nib Thao MD**
NPI: 1841520475

 **Patient Enrollment**

Program Status: **Active as of 9/22/2023** 



Patient Information

Name M.I.

 Jane M.I.

Smith

Address

 100 Main Street

Address Line 2

New York NY 10001

Date of Birth

 10/20/1990 

Primary Language

 Primary Language

Email

 test@yopmail.com

test@yopmail.com

Primary Phone

 6105006000

Alternate Phone

 6108009000

Best time to call

 Morning Afternoon Evening

[← PREVIOUS](#) [RESTART ↻](#)

[NEXT →](#)

**Office Contact:** Rebecca Stagg

Nib Thao MD

NPI: 1041520425



Patient Enrollment

Program Status: **Active as of 9/22/2023**1
PATIENT2
ALTERNATE
CONTACT3
REPRODUCTIVE
POTENTIAL
STATUS4
PRESCRIBER
PARENT
AGREEMENT

Alternate Contact

Emergency Contact Name



First Name

Last Name

Relationship



Mother, Father...

Phone

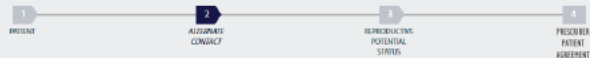


(nnn) nnn-nnnn

← PREVIOUS

RESTART ↻

NEXT →

 **Office Contact:** Rebecca Stagg **Nib Thao MD**
NPI: 1841520475  Patient EnrollmentProgram Status: **Active** as of 9/22/2023 

Alternate Contact

Legal Guardian Name

 First Name

Last Name

Relationship

 Parent/Guardian

Email

 Email

Confirm Email

Phone

 (nnn) nnn-nnnn

Emergency Contact Name

 First Name

Last Name

Relationship

 Mother, Father...

Phone

 (nnn) nnn-nnnn If the enrolling patient is a minor, a parent or guardian will need to complete this page. PREVIOUSRESTART NEXT 

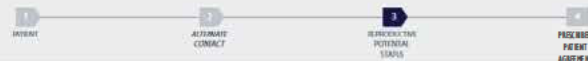
REMS

Office Contact: Rebecca Staggs

Nib Thao MD
NPI: 1881520475

Patient Enrollment

Program Status: Active as of 9/22/2023



Reproductive Potential Status

Select the female patient's current reproductive status below

Females of Reproductive Potential:

 Females of Reproductive Potential

- Females of reproductive potential include girls who have entered puberty and all females who have a uterus and have not passed through menopause. Menopause is defined as 12 months of spontaneous amenorrhea (not amenorrhea induced by a medical condition or medical therapy) or post-surgical from bilateral oophorectomy.
- For the purposes of this REMS, puberty includes those girls who are at least Tanner Stage 3 and have not yet had a menses (premenarchal).
- For the purposes of this REMS, females who have undergone tubal sterilization are classified as females of reproductive potential.

Females of Non-Reproductive Potential:

- Pre-pubertal Female: includes females who are at Tanner Stages 1 and 2 and are not considered to be of reproductive potential
- Post-menopausal Female - females who have passed through menopause. Menopause is defined as 12 months of spontaneous amenorrhea (not amenorrhea induced by a medical condition or medical therapy) or postsurgical from bilateral oophorectomy
- Other medical reasons for permanent, irreversible infertility.

Pregnancy Test

A negative pregnancy test has been confirmed prior to prescribing macitentan

- Yes
- No

Prescriber Requirements

For all Females:

- I acknowledge that I have counseled the patient (and parent/guardian when appropriate) the macitentan-containing products are only available through a restricted distribution program under an FDA-required REMS.
- I will evaluate the patient and agree to document any change or misclassification in reproductive potential status by submitting a Change in Reproductive Potential Status and Pre-pubertal Annual Verification Form within 10 business days of becoming aware of a change.

For Females of Reproductive Potential:

- I acknowledge that I have counseled the patient (and parent/guardian when appropriate) on the risks of macitentan-containing products, including the risk of serious birth defects, and that I have reviewed the Guide for Female Patients with the patient (and parent/guardian when appropriate).
- I will order and review tests prior to initiation of macitentan-containing product treatment, monthly during treatment and for one month after stopping treatment in accordance with the Macitentan-Containing Products REMS.

For Pre-pubertal Females:

- I acknowledge that I have counseled the patient and parent/guardian on the risks of macitentan-containing products, including the risk of serious birth defects, and that I have reviewed the Guide for Female Patients with the patient and parent/guardian.
- I will evaluate the patient's reproductive potential status annually for Pre-pubertal Females who are at least eight years of age and older, and agree to report any change or misclassification in reproductive potential status on a Change in Reproductive Potential Status and Pre-pubertal Annual Verification Form within 10 business days of becoming aware of a change.

← PREVIOUS | RESTART ↻

SUBMIT

**Office Contact:** Rebecca Stagg

Nib Thao MD

NPI: 184 152 0475



Patient or Parent/Guardian Signature

Program Status: **Active as of 9/22/2023** ✓

1

PATIENT

2

ALTERNATE
CONTACT

3

REPRODUCTIVE
POTENTIAL
STATUS

4

PRESCRIBER
PATIENT
AGREEMENT

Thank you for completing the required information in order to enroll your patient in the Macitentan-Containing Products REMS. An email was sent to the prescriber for their review and attestation and to the patient or parent/guardian for them to agree to the Macitentan-Containing Products REMS requirements in order to complete their enrollment.

[MANAGE PATIENTS](#)

 **Office Contact:** Rebecca Stagg

  **Nib Thao MD**
NPI: 1841520475

  **Jackie Daniels**
Date of Birth: **11/28/1994**
REMS ID: **0049392**

Program Status: **Active as of 9/22/2023**

Monthly Pregnancy Test

Pregnancy Test

Monthly Pregnancy Test Obtained

Information

Confirm that a pregnancy test has been obtained within the last month for this patient.

The prescriber must notify the Macitentan-Containing Products REMS Coordinating Center {by calling 1-888-572-2934} of any pregnancies that occur during treatment or within one month of discontinuation.

COMPLETE

 **Office Contact:** Rebecca Stagg

  **Nib Thao MD**
NPI: 1841520475

  **Jackie Daniels**
Date of Birth: **11/28/1994**
REMS ID: **0049392**

Program Status: **Active as of 9/22/2023**

Patient Information

-  Jackie Daniels
-  87 Test Ave
Knoxville, TN 37909
-  11/28/1994  FRP (Female of Reproductive Potential)
-  (970) 970-9732
-  Jackie Daniels@yopmail.com

Patient Events

-  Counseled 10/3/2023
-  Pregnancy Test Confirmed 10/3/2023
-  Reproductive Potential Status 10/3/2023
-  Enrollment Date 10/3/2023
-  Prescriber Signature 10/3/2023
-  Patient Signature 10/3/2023

Actions

 MONTHLY PREGNANCY TEST

Materials for Prescribers

- Patient Enrollment Form* 
- Change in Reproductive Potential Status and Pre-Pubertal Annual Verification Form* 
- Prescriber and Pharmacy Guide* 
- Prescriber Enrollment and Agreement Form* 
- Prescriber FAQs

Macitentan-Containing
Products

REMS

OUTPATIENT PHARMACY PORTAL

Pharmacy Certification by Enrollment

Pharmacy Type Selection

Carefully select a pharmacy type from the list below. Each type of pharmacy in the Macitentan-Containing Products REMS has specific requirements.



OUTPATIENT PHARMACY

Outpatient Pharmacy

SELECT →



INPATIENT PHARMACY

Inpatient Pharmacy

SELECT →

 Pharmacy Certification by
Enrollment

The Macitentan-Containing Products REMS is a limited distribution network and requires that outpatient pharmacies are contracted with a manufacturer in order to become certified.

Has your pharmacy finalized contracting with a manufacturer of the Macitentan-Containing Product REMS?

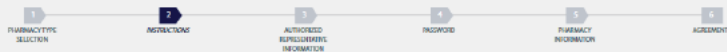
YES

NO

 Pharmacy Certification by
Enrollment

We are unable to move forward with the enrollment process at this time.
Should your status with the manufacturers change in the future, we can initiate the enrollment process.

OK

 Outpatient Pharmacy
Enrollment

Instructions

Pharmacies that dispense macitentan-containing products must be specially certified by enrolling in the Macitentan-Containing Products REMS. To become certified, an authorized representative must review the **Prescribing Information (PI)** and the **Prescriber and Pharmacy Guide**, and then complete the Outpatient Pharmacy Enrollment Form. All Outpatient Pharmacy enrollments completed online will be submitted to the REMS Coordinating Center for review to determine whether the Outpatient Pharmacy can be certified. Select the start button below to continue with online enrollment **OR** fax a completed **Outpatient Pharmacy Enrollment Form** to 1-833-681-0003.

Overview of online enrollment:

- 1 Pharmacy Type Selection** - An authorized representative must select the specific pharmacy type for the pharmacy being certified.
- 2 Instructions To Complete Enrollment** - Directions for the authorized representative to follow in completing the enrollment and certification process.
- 3 Authorized Representative Information** - The authorized representative will be asked to provide their name, title, and credentials. The authorized representative will also be asked to provide an email, phone, and fax number.
- 4 Create Password** - The authorized representative will be asked to enter a password to create a program account. Upon creation of the account, the authorized representative will receive an email with a link. Upon clicking on the link in the email, the authorized representative will be asked to log in and complete certification.
- 5 Pharmacy Information** - The authorized representative will enter the pharmacy's organizational National Provider Identifier (NPI) number. This will be used to obtain most of the information needed for the enrollment form.
- 6 Agreement** - The authorized representatives will be asked to provide their signature. By signing, the authorized representative agrees that the pharmacy will comply to the Macitentan-Containing Products REMS requirements for an Outpatient Pharmacy. The authorized representative will submit the enrollment form to the REMS Administrator for review.

The REMS Coordinating Center will complete the pharmacy's certification process after ensuring the pharmacy has met the appropriate requirements and is able to support submitting daily product dispensing data.

START →



Pharmacy Enrollment

1

PHARMACY TYPE
SELECTION

2

INSTRUCTIONS

3

AUTHORIZED
REPRESENTATIVE
INFORMATION

4

PASSWORD

5

PHARMACY
INFORMATION

6

AGREEMENT

Authorized Representative Information

Name



Maria

Lopez

Position/Title

Pharmacist

Credentials



PharmD

Email



mblopez@yopmail.com

mblopez@yopmail.com

Phone



9854461238

Fax



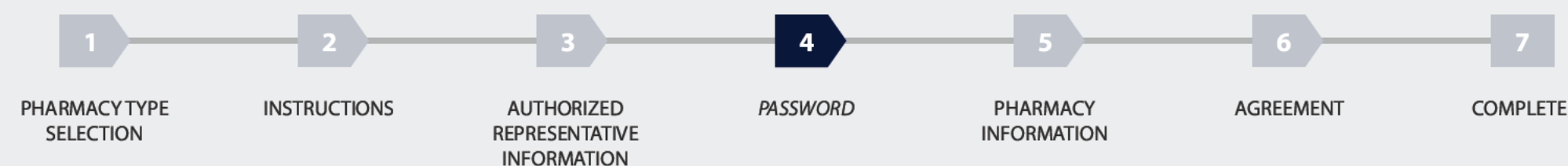
(nnn) nnn-nnnn

← PREVIOUS

RESTART ↻

NEXT →

Pharmacy Certification by Enrollment



Password

Enter your username

Please create your password

- Two-Factor Authentication Opt-In
- Two-Factor Authentication Opt-Out

Two-Factor Authentication

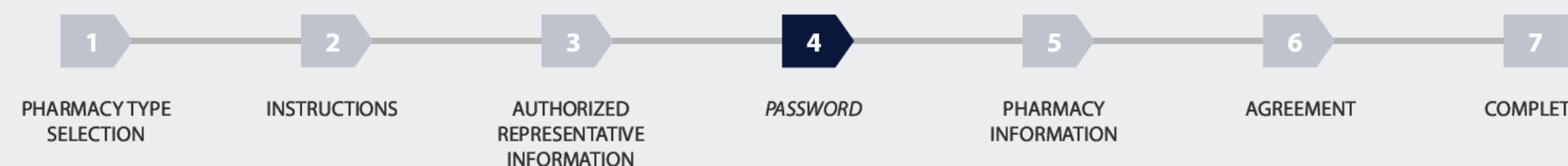
Why Opt In for 2FA?

- **Enhanced Security:** 2FA adds an extra layer of defense, ensuring that only authorized users can access your account, even if your password is compromised.
- **Protect Patient Confidentiality:** Safeguard your patients' sensitive information from unauthorized access, preserving their trust in your practice.
- **Regulatory Compliance:** Maintain compliance with healthcare regulations like HIPAA by implementing robust security measures.

Note:

- Users who opt in to 2FA will need to obtain their verification code via email each time the user logs into their account. You will be able to change your 2FA selection in your user profile screen later if you choose to do so.

 Pharmacy Certification by Enrollment



Password

Enter your username



Please create your password

Two-Factor Authentication Opt-In

Two-Factor Authentication Opt-Out

Opt Out? Consider the Risks.

If you choose to opt out of 2FA, please be aware of the following risks:

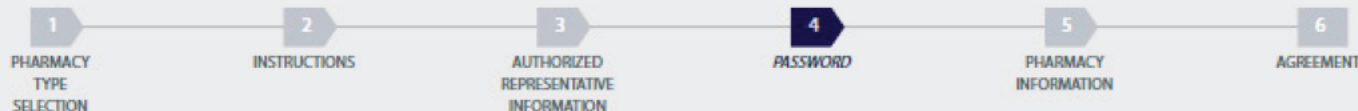
- **Increased Vulnerability:** Without 2FA, your account is more susceptible to unauthorized access, potentially exposing your patients' PHI to malicious actors.
- **Potential Data Breach:** In the event of a security breach, your patients' sensitive information could be compromised, leading to legal and financial consequences.
- **Loss of Trust:** Patients entrust you with their confidential information. A breach could erode their trust in your practice.

Note: You will be able to change your 2FA selection in your user profile screen later if you choose to do so.

Two-Factor Authentication

Why Opt In for 2FA?

- **Enhanced Security:** 2FA adds an extra layer of defense, ensuring that only authorized users can access your account, even if your password is compromised.
- **Protect Patient Confidentiality:** Safeguard your patients' sensitive information from unauthorized access, preserving their trust in your practice.
- **Regulatory Compliance:** Maintain compliance with healthcare regulations like HIPAA by implementing robust security measures.

 Pharmacy Certification by Enrollment

Password

You must confirm your email to continue

An email has been sent to you at the following address:

mblopez@yopmail.com

I have checked my junk mail, and waited a few minutes

 Resend Email

Login

Welcome. Please log in.

Enter your username



Email



Enter your password



Password



[Forgot your password?](#)

LOGIN

Enter Verification Code

XXXXX



VERIFY

 Pharmacy Enrollment1
PHARMACY TYPE
SELECTION2
INSTRUCTIONS3
AUTHORIZED
REPRESENTATIVE
INFORMATION4
PASSWORD5
PHARMACY
INFORMATION6
AGREEMENT

Pharmacy Information



OUTPATIENT PHARMACY

Outpatient Pharmacy

Please provide an organizational NPI number



1003120387

FIND



NPI Information

Memorial Medical Group LLC Family Practice

Mailing Address

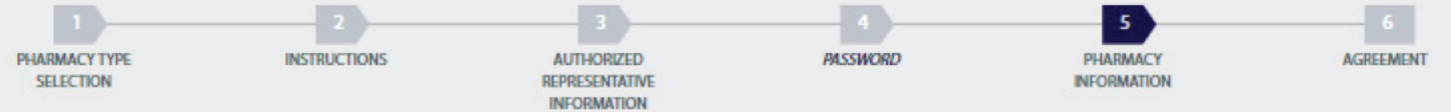
4600 Memorial Dr Ste 160

Belleville, IL 62226

(★ = Primary)

★ - Pharmacy

NEXT →

 Pharmacy Enrollment

Pharmacy Information

Mailing Address



4600 Memorial Dr Ste 160

Address Line 2

Belleville

IL ▾

62226

Phone



(nnn) nnn-nnnn

Fax



(nnn) nnn-nnnn

← PREVIOUS

NEXT →



Outpatient Pharmacy Agreement

Please read and accept the following terms:

I am the authorized representative designated by my outpatient pharmacy to coordinate the activities of the Macitentan-Containing Products REMS. **Therefore, I must:**

- Carry out the certification process and oversee implementation of and compliance with the REMS on behalf of the pharmacy.
- Review the Prescribing Information and **Prescriber and Pharmacy Guide**.
- Certify by enrolling in the REMS by completing the **Outpatient Pharmacy Enrollment Form** and submitting it to the REMS.
- Train all relevant staff involved in dispensing on the REMS requirements, procedures, and REMS materials.

Before dispensing, the outpatient pharmacy must:

- Obtain a REMS Dispense Authorization (RDA) from the Macitentan-Containing Products REMS Coordinating Center or the Macitentan-Containing Products REMS website that verifies female patients are enrolled, the reproductive status has not changed, the prescriber is certified, and pregnancy test is completed for females of reproductive potential - or the prescriber authorizes the dispensing.
- Counsel females of reproductive potential on the risk of embryo-fetal toxicity, the need to use reliable contraception during treatment and for one month after stopping treatment, to get monthly pregnancy tests, and to inform her prescriber immediately if she misses a menstrual period or suspects she is pregnant.
- Dispense no more than a 30-days' supply for females of reproductive potential.

To maintain certification to dispense:

- Have a new authorized representative certify by enrolling in the REMS by completing the **Outpatient Pharmacy Enrollment Form** if the authorized representative changes.

At all times, the outpatient pharmacy must:

- Report pregnancies to the REMS.
- Not distribute, transfer, loan, or sell macitentan-containing products, except to certified dispensers.
- Maintain and submit records of daily product dispensing data for all females.
- Maintain records that all processes and procedures are in place and being followed.
- Comply with audits carried out by the manufacturers or a third party acting on behalf of the manufacturers to ensure that all processes and procedures are in place and are being followed.

As the authorized representative, I will ensure that all pharmacy dispensing staff are trained on the Macitentan-Containing Products REMS requirements prior to dispensing macitentan-containing products

Authorized Representative Signature:

Please use your mouse to sign your name, Maria Lopez in the box below:

SAVE CLEAR

SUBMIT

 Pharmacy Enrollment

Congratulations on completing your Outpatient Pharmacy Enrollment in order to certify in the Macitentan-Containing Products REMS.

The REMS Coordinating Center will complete the pharmacy's certification process after ensuring the pharmacy has met the appropriate requirements and is able to support submitting daily dispensing data.

OK



Memorial Medical Group LLC Family Practice

NPI: 1003120387

Program Status: **Enrolled as of 8/22/2023**



Pharmacy Certification by Enrollment

Complete

Maria Lopez PharmD, as an authorized representative you have successfully completed the pharmacy certification for Memorial Medical Group LLC Family Practice.

You may choose from the following options or navigate to your desired function utilizing the pharmacy menu at the top of the page.



OUTPATIENT PHARMACY

Outpatient Pharmacy



MANAGE PHARMACY

Manage Staff Pharmacists

- Manage Staff Pharmacists
- Obtain a patient REMS Dispense Authorization (RDA)



PREFERENCES

Preferences

Update your personal preferences



PRINT ENROLLMENT FORM

Print enrollment form

Print or download a PDF copy of your completed enrollment form.





Memorial Medical Group LLC Family Practice
NPI: 1003120387

Program Status: **Enrolled as of 8/22/2023** [✔](#)

Manage Pharmacy

Outpatient Pharmacy

📞 985-466-5124
4600 MEMORIAL DR STE 160
🏠 PHARMACY ENROLLMENTS
BELLEVILLE, IL 62226

ASSIGNED PHARMACISTS

REFRESH

Name ↑↓	Current Status ↑↓	Status Date ↑↓	Actions
Maria Lopez	Active	8/22/2023	
Authorized Representative Pharmacy Staff Resend Invite			Remove Pharmacy Staff

Patient Actions

- ENTER PATIENTS INFORMATION
- OBTAIN AN RDA

Pharmacy Actions

- INVITE AUTHORIZED REPRESENTATIVE
- INVITE PHARMACY STAFF
- PRESCRIBER LOCATOR

Materials for Pharmacies

- [Outpatient Pharmacy Enrollment Form](#)
- [Inpatient Pharmacy Enrollment Form](#)
- [Prescriber and Pharmacy Guide](#)
- [Pharmacy FAQs](#)



Memorial Medical Group LLC Family Practice

NPI: 1003120387

Program Status: **Enrolled as of 8/22/2023**

Enter Patient Information

To view and update Patient Information:

1. Enter the patient's information and click Search.
2. Verify patient's current reproductive potential status classification, last pregnancy test confirmation date, and last counseling confirmation date.
3. Confirm patient's pregnancy test.
4. Confirm patient's counseling.

Patient Information

First Name	M.I.	Last Name	Date of Birth
First Name	M.I.	Last Name	Date Of Birth

CANCEL **RESTART**

SEARCH

Information

Memorial Medical Group LLC Family Practice
NPI: 1003120387

Program Status: Enrolled as of 8/22/2023

Enter Patient Information

To view and update Patient Information:

1. Enter the patient's information and click Search.
2. Verify patient's current reproductive potential status classification, last pregnancy test confirmation date, and last counseling confirmation date.
3. Confirm patient's pregnancy test.
4. Confirm patient's counseling.

Patient Information

First Name	M.I.	Last Name	Date of Birth
Jane	M.I.	Smith	10/20/1990

REMS ID: 0045068

Most Recent Shipment Date:

Most Recent Days' Supply:

Prescriber Name: Gary Olsen

Reproductive Potential Status: FRP (Female of Reproductive Potential)

Reproductive Potential Status Date: 8/16/2023

Last Pregnancy Test Confirmation Date: 8/16/2023

Last Counseling Confirmation Date:

Monthly Pregnancy Test

Smith, Jane - DOB: 10/20/1990

Counseling

Smith, Jane - DOB: 10/20/1990

CANCEL

SUBMIT

Information

Patient is enrolled in REMS



Memorial Medical Group LLC Family Practice
NPI: 1003120387

Program Status: Enrolled as of 8/22/2023

Obtain a REMS Dispense Authorization (RDA)

Prescriber Information

Prescriber

Patient Information

First Name

M.I.

Last Name

Date of Birth

CANCEL

RESTART ↺

VERIFY

i Information



Memorial Medical Group LLC Family Practice

NPI: 1003120387

Program Status: Enrolled as of 8/22/2023 ✓

Obtain a REMS Dispense Authorization (RDA)

Prescriber Information

Prescriber

1236489454

Patient Information

First Name

Jenny

M.I.

A

Last Name

Patient

Date of Birth

8/3/2006



CANCEL

RESTART ↻

VERIFY

i Information

✗ Prescriber is not certified in REMS

✗ Patient is not enrolled in REMS



Memorial Medical Group LLC Family Practice

NPI: 1003120387

Program Status: Enrolled as of 8/22/2023

Obtain a REMS Dispense Authorization (RDA)

Prescriber Information

DR. RONALD BINGHAM

Patient Information

First Name	M.I.	Last Name	Date of Birth
Allison	M.I.	Patient	8/23/1973

 Counseling Patient, Allison - DOB: 8/23/1973 Monthly Pregnancy Test Patient, Allison - DOB: 8/23/1973 Prescriber Refill Authorization Patient, Allison - DOB: 8/23/1973

PRESCRIPTION INFORMATION

Manufacturer	NDC Code	Days' Supply
--None--	--None--	30

CANCEL

SUBMIT

 Information Prescriber is certified in REMS Patient is enrolled in REMS

Patient ID: 0044861

Patient Reproductive Status: FNRP (Patient is post-menopausal)



Memorial Medical Group LLC Family Practice

NPI: 1003120387

Program Status: Enrolled as of 8/22/2023

Obtain a REMS Dispense Authorization (RDA)

Prescriber Information

DR. RONALD BINGHAM

Patient Information

First Name	M.I.	Last Name	Date of Birth
Rose	M.I.	Patient	7/14/2000

Counseling

 Patient, Rose - DOB: 7/14/2000

Monthly Pregnancy Test

 Patient, Rose - DOB: 7/14/2000

Prescriber Refill Authorization

 Patient, Rose - DOB: 7/14/2000

PRESCRIPTION INFORMATION

Manufacturer	NDC Code	Days' Supply
Actelion Pharmaceuticals	66215-501-30, 10 mg bottle of 30 tablets	30

CANCEL

SUBMIT

Information

 Prescriber is certified in REMS Patient is enrolled in REMS

Patient ID: 0044723

Patient Reproductive Status: FRP (Female of Reproductive Potential)



Memorial Medical Group LLC Family Practice

NPI: 1003120387

Program Status: Enrolled as of 8/22/2023

Obtain a REMS Dispense Authorization (RDA)

Prescriber Information

DR. RONALD BINGHAM

Patient Information

First Name

Rose

M.I.

M.I.

Last Name

Patient

Date of Birth

7/14/2000

Counseling

 Patient, Rose - DOB: 7/14/2000

Monthly Pregnancy Test

 Patient, Rose - DOB: 7/14/2000

Prescriber Refill Authorization

 Patient, Rose - DOB: 7/14/2000**i** Information Prescriber is certified in REMS Patient is enrolled in REMS

Patient ID: 0044723

Patient Reproductive Status: FRP (Female of Reproductive Potential)

PRESCRIPTION INFORMATION

Manufacturer

Actelion Pharmaceuticals

NDC Code

66215-501-30, 10 mg bottle of 30 tablets

Days' Supply

30

CANCEL

SUBMIT



Memorial Medical Group LLC Family Practice

NPI: 1003120387

Program Status: Enrolled as of 8/22/2023

Obtain a REMS Dispense Authorization (RDA)

Prescriber Information

DR. RONALD BINGHAM

Patient Information

First Name	M.I.	Last Name	Date of Birth
Rose	M.I.	Patient	7/14/2000

Counseling

 Patient, Rose - DOB: 7/14/2000

Monthly Pregnancy Test

 Patient, Rose - DOB: 7/14/2000

Prescriber Refill Authorization

 Patient, Rose - DOB: 7/14/2000

PRESCRIPTION INFORMATION

Manufacturer	NDC Code	Days' Supply	Reason for Days' Supply >30 (For FRP ONLY)
Actelion Pharmaceuticals	66215-501-30, 10 mg bottle of 30 tablets	45	--None--

CANCEL

SUBMIT

Information

 Prescriber is certified in REMS Patient is enrolled in REMS

Patient ID: 0044723

Patient Reproductive Status: FRP (Female of Reproductive Potential)

Memorial Medical Group LLC Family Practice
NPI: 1003120387

Program Status: Enrolled as of 8/22/2023

Obtain a REMS Dispense Authorization (RDA)

Prescriber Information

DR. RONALD BINGHAM

Patient Information

First Name	M.I.	Last Name	Date of Birth
Kiana	M.I.	Patient	8/23/2000

Counseling

Patient, Kiana - DOB: 8/23/2000

Monthly Pregnancy Test

Patient, Kiana - DOB: 8/23/2000

Prescriber Refill Authorization

Patient, Kiana - DOB: 8/23/2000

PRESCRIPTION INFORMATION

Manufacturer	NDC Code	Days' Supply	Reason for Days' Supply >30 (For FRP ONLY)
Actelion Pharmaceuticals	66215-501-30, 10 mg bottle of 30 tablets	45	--None--
# Days of Interruption	Reason for Treatment Interruption*		
29	Unknown		

* An evaluation of dispensing delays which resulted in an actual treatment interruption (defined as a delay in treatment of five or more days).

CANCEL

SUBMIT

Information

- Prescriber is certified in REMS
- Patient is enrolled in REMS

Patient ID: 0045152
Patient Reproductive Status: FRP (Female of Reproductive Potential)

Memorial Medical Group LLC Family Practice
NPI: 1003120387

Program Status: Enrolled as of 8/22/2023

Obtain a REMS Dispense Authorization (RDA)

Prescriber Information

DR. RONALD BINGHAM

Patient Information

First Name	M.I.	Last Name	Date of Birth
Kiana	M.I.	Patient	8/23/2000

Counseling

Patient, Kiana - DOB: 8/23/2000

Monthly Pregnancy Test

Patient, Kiana - DOB: 8/23/2000

Prescriber Refill Authorization

Patient, Kiana - DOB: 8/23/2000

PRESCRIPTION INFORMATION

Manufacturer	NDC Code	Days' Supply	Reason for Days' Supply >30 (For FRP ONLY)
Actelion Pharmaceuticals	66215-501-30, 10 mg bottle of 30 tablets	45	-None-
# Days of Interruption	Reason for Treatment Interruption*		
29	-None-		

* An evaluation of dispensing delays which resulted in an actual treatment interruption (defined as a delay in treatment of five or more days).

CANCEL **SUBMIT**

Information

- Prescriber is certified in REMS
- Patient is enrolled in REMS

Patient ID: 0045152
Patient Reproductive Status: FRP (Female of Reproductive Potential)

- Patient counseling is not recorded
- Pregnancy test or Prescriber Refill Authorization not recorded
- Reasons for days' supply >30 days for FRP is not selected
- Reason for treatment interruption is not selected



Memorial Medical Group LLC Family Practice

NPI: 1003120387

Program Status: Enrolled as of 8/22/2023 ✓

Obtain a REMS Dispense Authorization (RDA)

- ✓ A prescription has been recorded for the following
REMS Dispense Authorization (RDA)

RDA-8383144

**Pharmacy:** Memorial Medical Group LLC Family Practice**Authorized Representative:** Maria Lopez**Prescriber Name:** Ronald Bingham**Patient Name:** Patient, Rose**Date of Birth:** 7/14/2000**Manufacturer:** Actelion Pharmaceuticals**NDC Code:** 66215-501-30, 10 mg bottle of 30 tablets**Days' Supply:** 30

i Information

[OBTAIN ANOTHER RDA](#)



Memorial Medical Group LLC Family Practice.

NPI: 1003120387

Program Status: Enrolled as of 8/22/2023 ✓

Invite Authorized Pharmacist

Name



First Name

Last Name

Position/Title

--None--

Credentials



--None--

Email



Email

Confirm Email

- As the authorized pharmacist, I agree that I am responsible for all the pharmacists at this pharmacy.

SEND INVITE

Dear Alejandro Rodgers,

Your pharmacy's authorized representative has invited you to be an authorized representative for your pharmacy. You may create credentials in the Macitentan-Containing Products REMS website to allow you to perform activities on behalf of your pharmacy.

Please select the button below to continue.

Continue

If you have any questions, you may call the Macitentan-Containing Products REMS at 1-888-572-2934, Monday through Friday, 8:00 AM to 8:00 PM EST.

Sincerely,

The Macitentan-Containing Products REMS

Phone: 1-888-572-2934

Fax: 1-833-681-0003

www.MacitentanREMS.com

Report pregnancies to the Macitentan-Containing Products REMS by calling 1-888-572-2934.

Report adverse events to FDA by visiting www.fda.gov/medwatch or call 1-800-FDA-1088.



Memorial Medical Group LLC Family Practice.

NPI: 1003120387

Program Status: Enrolled as of 8/22/2023 ✓

Invite Staff Pharmacist

Name



First Name

Last Name

Position/Title

--None--



Credentials



--None--



Email



Email

Confirm Email

- As the authorized pharmacist, I agree that I am responsible for all the pharmacists at this pharmacy.

SEND INVITE

Dear Brad Johnson,

Your pharmacy's authorized representative has invited you to create credentials in the Macitentan-Containing Products REMS website to allow you to perform activities on behalf of the pharmacy.

Please select the button below to continue.

Continue

If you have any questions, you may call the Macitentan-Containing Products REMS at 1-888-572-2934, Monday through Friday, 8:00 AM to 8:00 PM EST.

Sincerely,

The Macitentan-Containing Products REMS

Phone: 1-888-572-2934

Fax: 1-833-681-0003

www.MacitentanREMS.com

Report pregnancies to the Macitentan-Containing Products REMS by calling 1-888-572-2934.
Report adverse events to FDA by visiting www.fda.gov/medwatch or call 1-800-FDA-1088.

Macitentan-Containing Products REMS Prescriber Locator

PRESCRIBER NAME	NPI	REMS STATUS	REMS ID	PHONE NUMBER
Able Williams	1161567212	Certified	0045055	(765) 813-8837
Adam H Adler	1801105309	Certified	0044524	(741) 852-9630
Angela Elizabeth Aakhus	1326330127	Certified	0044646	(765) 432-1234
Anne White	1003815234	Certified	0044944	(812) 432-5896
Anthonia D Adewole	1598907925	Certified	0044674	(313) 744-3523
Anuhya Perry	1866254231	Certified	0044625	(623) 944-1576
Aviva Abosch	1023062999	Certified	0044839	(768) 901-4561
Azin Abazari	1164625133	Certified	0045076	(768) 901-4123
Barry Allen	1111110111	Certified	0044522	(704) 581-3204
Bethany Jane Abde	1215331566	Certified	0044955	(123) 456-9874

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Macitentan-Containing
Products

REMS

INPATIENT PHARMACY PORTAL

Pharmacy Certification by Enrollment

Pharmacy Type Selection

Carefully select a pharmacy type from the list below. Each type of pharmacy in the Macitentan-Containing Products REMS has specific requirements.



OUTPATIENT PHARMACY

Outpatient Pharmacy

SELECT →

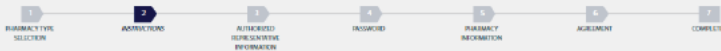


INPATIENT PHARMACY

Inpatient Pharmacy

SELECT →

Inpatient Pharmacy Certification by Enrollment



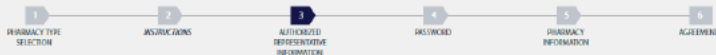
Instructions

Pharmacies that dispense macitentan-containing products must be specially certified by enrolling in the Macitentan-Containing Products REMS. To become certified, an authorized representative must review the [Prescribing Information \(PI\)](#) and the [Prescriber and Pharmacy Guide](#), and then complete the [Inpatient Pharmacy Enrollment Form](#). Select the start button below to continue with online enrollment OR fax a completed [Inpatient Pharmacy Enrollment Form](#) to 1-833-681-0003.

Overview of online enrollment and certification:

- 1 Pharmacy Type Selection** - An authorized representative must select the specific pharmacy type for the pharmacy being certified.
- 2 Instructions To Complete Enrollment** - Directions for the authorized representative to follow in completing the enrollment and certification process.
- 3 Authorized Representative Information** - The authorized representative will be asked to provide their name, title, and credentials. The authorized representative will also be asked to provide an email, phone, and fax number.
- 4 Create Password** - The authorized representative will be asked to enter a password to create a program account. Upon creation of the account, the authorized representative will receive an email with a link. Upon clicking on the link in the email, the authorized representative will be asked to log in and complete the certification.
- 5 Pharmacy Information** - The authorized representative will enter the pharmacy's organizational National Provider Identifier (NPI) number. This will be used to obtain most of the information needed for the enrollment form.
- 6 Agreement** - The authorized representatives will be asked to provide their signature. By signing, the authorized representative agrees that the pharmacy will comply to the Macitentan-Containing Products REMS requirements for the pharmacy type.
- 7 Complete** - The certification will be completed upon agreeing and providing a signature.

[START](#) →

Pharmacy Certification by
Enrollment

Authorized Representative Information

Name



Nick

Wentz

Position/Title

Hospital pharmacist

Credentials



PharmD

Email



testaccount9@yopmail.com

testaccount9@yopmail.com

Phone



6108009000

Fax



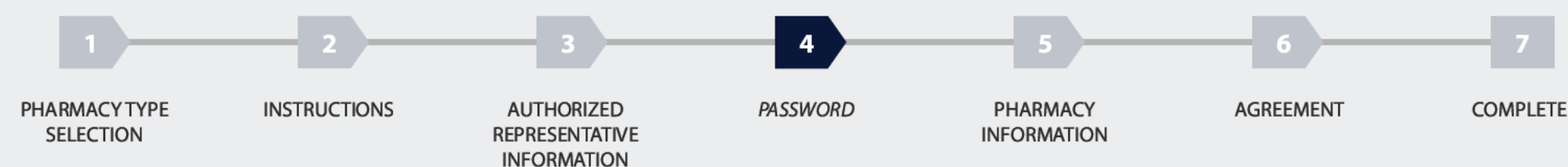
6105009000

← PREVIOUS

RESTART ↻

NEXT →

Pharmacy Certification by Enrollment



Password

Enter your username

Please create your password

Two-Factor Authentication Opt-In

Two-Factor Authentication Opt-Out

Two-Factor Authentication

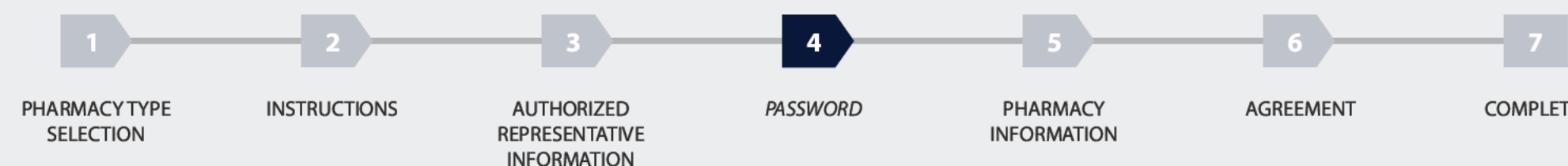
Why Opt In for 2FA?

- **Enhanced Security:** 2FA adds an extra layer of defense, ensuring that only authorized users can access your account, even if your password is compromised.
- **Protect Patient Confidentiality:** Safeguard your patients' sensitive information from unauthorized access, preserving their trust in your practice.
- **Regulatory Compliance:** Maintain compliance with healthcare regulations like HIPAA by implementing robust security measures.

Note:

- Users who opt in to 2FA will need to obtain their verification code via email each time the user logs into their account. You will be able to change your 2FA selection in your user profile screen later if you choose to do so.

 Pharmacy Certification by Enrollment



Password

Enter your username



Please create your password

Two-Factor Authentication Opt-In

Two-Factor Authentication Opt-Out

Opt Out? Consider the Risks.

If you choose to opt out of 2FA, please be aware of the following risks:

- **Increased Vulnerability:** Without 2FA, your account is more susceptible to unauthorized access, potentially exposing your patients' PHI to malicious actors.
- **Potential Data Breach:** In the event of a security breach, your patients' sensitive information could be compromised, leading to legal and financial consequences.
- **Loss of Trust:** Patients entrust you with their confidential information. A breach could erode their trust in your practice.

Note: You will be able to change your 2FA selection in your user profile screen later if you choose to do so.

Two-Factor Authentication

Why Opt In for 2FA?

- **Enhanced Security:** 2FA adds an extra layer of defense, ensuring that only authorized users can access your account, even if your password is compromised.
- **Protect Patient Confidentiality:** Safeguard your patients' sensitive information from unauthorized access, preserving their trust in your practice.
- **Regulatory Compliance:** Maintain compliance with healthcare regulations like HIPAA by implementing robust security measures.

Pharmacy Certification by Enrollment



Password

You must confirm your email to continue

An email has been sent to you at the following address:

testaccount9@yopmail.com

I have checked my junk mail, and waited a few minutes

[Resend Email](#)

Login

Welcome. Please log in.

Enter your username



Email



Enter your password



Password



Forgot your password?

LOGIN

Enter Verification Code

XXXXXX



VERIFY

Pharmacy Certification by Enrollment



Pharmacy Information



Inpatient Pharmacy

Please provide an organizational NPI number



FIND



NPI Information

Walgreens Pharmacy #09290

Mailing Address

2500 Grant St
Gary, IN 46404

(★ = Primary)

★ Pharmacy

Inpatient Pharmacy Type

Other

Other (please specify)

Inpatient Pharmacist Position/Title

Head of Pharmacy and Therapeutics (P&T) committee

NEXT →

Pharmacy Certification by Enrollment



Pharmacy Information

Mailing Address

 Address Line 1
Address Line 2
City IN Zip Code

Phone

 (nnn) nnn-xxxx

Fax

 (nnn) nnn-xxxx

Shipping Address

Use my mailing address

 Address Line 1
Address Line 2
City State Zip Code

Phone

 (nnn) nnn-xxxx

Fax

 (nnn) nnn-xxxx

← PREVIOUS

NEXT →

Pharmacy Enrollment



Inpatient Pharmacy Agreement

Please read and accept the following terms:

Authorized Representative Agreement

I am the authorized representative designated by my inpatient pharmacy to coordinate the activities of the Macitentan-Containing Products REMS. **Therefore, I must:**

- Carry out the certification process and oversee implementation of and compliance with the REMS on behalf of the pharmacy.
- Review the **Prescribing Information** and the **Prescriber and Pharmacy Guide**.
- Certify by enrolling in the REMS by completing the **Inpatient Pharmacy Enrollment Form** and submitting it to the REMS.
- Train all relevant staff involved in dispensing macitentan-containing products on the REMS requirements, procedures and REMS materials.
- Establish processes and procedures to verify the female patient is enrolled in the REMS or will be enrolled prior to discharge, her reproductive status, and the female patient is under the supervision and care of a certified prescriber.
- For females of reproductive potential: establish processes and procedures to verify pregnancy testing is complete and that the patient is counseled on the risk of embryo-fetal toxicity, the need to use reliable contraception during treatment and for one month after stopping treatment, to get monthly pregnancy tests, and to inform the prescriber immediately if she misses a menstrual period or suspects she is pregnant.

Before dispensing:

- Verify the female patient is under the supervision and care of a certified prescriber, and that she is enrolled or will be enrolled in the REMS prior to discharge, through the processes and procedures established as a requirement of the REMS.
- Verify pregnancy testing is complete, and that the patient is counseled on the risk of embryo-fetal toxicity, the need to use reliable contraception during treatment and for one month after stopping treatment, to get monthly pregnancy tests, and to inform the prescriber immediately if she misses a menstrual period or suspects she is pregnant, through the processes and procedures established as a requirement of the REMS for females of reproductive potential.

To maintain certification to dispense:

- Have a new authorized representative certify by enrolling in the REMS by completing the **Inpatient Pharmacy Enrollment Form** if the authorized representative changes.

At discharge:

- Dispense no more than a 15-day's supply of macitentan-containing products.

At all times:

- Not distribute, transfer, loan, or sell macitentan-containing products, except to certified dispensers.
- Report any pregnancies to the REMS Coordinating Center.
- Maintain records that all processes and procedures are in place and are being followed.
- Comply with audits by the manufacturer or a third party acting on behalf of the manufacturer to ensure all processes and procedures are in place and being followed.

Note: If your inpatient pharmacy needs macitentan-containing products and is not certified in the Macitentan-Containing Products REMS, please go to www.MacitentanREMS.com for immediate online certification, or contact the REMS Coordinating Center at 1-888-572-2934 for assistance in certifying.

- I attest that I have read the Prescribing Information and Prescriber and Pharmacy Guide available at www.MacitentanREMS.com. I will ensure training of dispensing staff on the Macitentan-Containing Products REMS procedures and materials, including the Prescriber and Pharmacy Guide prior to dispensing macitentan-containing products. I agree that this pharmacy may be audited by the FDA, the Macitentan-Containing Products REMS sponsors, or a designated third party.

Authorized Representative Signature:

Please use your mouse to sign your name, Nick Wentz, in the box below:

SAVE

CLEAR

NEXT

REMS



Walgreens Pharmacy #09290

NPL: 1023023157

Program Status: **Enrolled as of 8/17/2023**Pharmacy Certification
by Enrollment1
PHARMACY
SELECTION2
INSTRUCTIONS3
AUTHORIZED
REPRESENTATIVE
INFORMATION4
PASSWORD5
PHARMACY
INFORMATION6
AGREEMENT7
COMPLETE

Complete

Nick Wentz PharmD, as an authorized representative you have successfully completed the pharmacy certification for Walgreens Pharmacy #09290.

You may choose from the following options or navigate to your desired function utilizing the pharmacy menu at the top of the page.



INPATIENT PHARMACY

Inpatient Pharmacy



MANAGE PHARMACY

Manage Staff Pharmacists

- Manage Staff Pharmacists
- Verify Prescriber Certification and Patient Enrollment



PREFERENCES

Preferences

Update your personal preferences



PRINT ENROLLMENT FORM

Print enrollment form

Print or download a PDF copy of your completed enrollment form.





Walgreens Pharmacy #09290.

NPI: 1023023157

Program Status: Enrolled as of 8/17/2023

Invite Authorized Pharmacist

Name



First Name

Last Name

Position/Title

--None--

Credentials



--None--

Email



Email

Confirm Email

As the authorized pharmacist, I agree that I am responsible for all the pharmacists at this pharmacy.

SEND INVITE

Dear Lee Morgan,

Your pharmacy's authorized representative has invited you to be an authorized representative for your pharmacy. You may create credentials in the Macitentan-Containing Products REMS website to allow you to perform activities on behalf of your pharmacy.

Please select the button below to continue.

Continue

If you have any questions, you may call the Macitentan-Containing Products REMS at 1-888-572-2934, Monday through Friday, 8:00 AM to 8:00 PM EST.

Sincerely,

The Macitentan-Containing Products REMS

Phone: 1-888-572-2934

Fax: 1-833-681-0003

www.MacitentanREMS.com

Report pregnancies to the Macitentan-Containing Products REMS by calling 1-888-572-2934.

Report adverse events to FDA by visiting www.fda.gov/medwatch or call 1-800-FDA-1088.



Walgreens Pharmacy #09290.
NPI: 1023023157

Program Status: **Enrolled as of 8/17/2023**

Invite Staff Pharmacist

Name



First Name

Last Name

Position/Title

-None-

Credentials



-None-

Email



Email

Confirm Email

As the authorized pharmacist, I agree that I am responsible for all the pharmacists at this pharmacy.

SEND INVITE

Dear Shawn Staff,

Your pharmacy's authorized representative has invited you to create credentials in the Macitentan-Containing Products REMS website to allow you to perform activities on behalf of the pharmacy.

Please select the button below to continue.

Continue

If you have any questions, you may call the Macitentan-Containing Products REMS at 1-888-572-2934, Monday through Friday, 8:00 AM to 8:00 PM EST.

Sincerely,

The Macitentan-Containing Products REMS

Phone: 1-888-572-2934

Fax: 1-833-681-0003

www.MacitentanREMS.com

Report pregnancies to the Macitentan-Containing Products REMS by calling 1-888-572-2934.

Report adverse events to FDA by visiting www.fda.gov/medwatch or call 1-800-FDA-1088.

Macitentan-Containing Products REMS Prescriber Locator

PRESCRIBER NAME	NPI	REMS STATUS	REMS ID	PHONE NUMBER
Able Williams	1161567212	Certified	0045055	(765) 813-8837
Adam H Adler	1801105309	Certified	0044524	(741) 852-9630
Angela Elizabeth Aakhus	1326330127	Certified	0044646	(765) 432-1234
Anne White	1003815234	Certified	0044944	(812) 432-5896
Anthonia D Adewole	1598907925	Certified	0044674	(313) 744-3523
Anuhya Perry	1866254231	Certified	0044625	(623) 944-1576
Aviva Abosch	1023062999	Certified	0044839	(768) 901-4561
Azin Abazari	1164625133	Certified	0045076	(768) 901-4123
Barry Allen	1111110111	Certified	0044522	(704) 581-3204
Bethany Jane Abde	1215331566	Certified	0044955	(123) 456-9874

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BRAFORD PHARMACY, L.L.C.
NPI: 2111111121

Program Status: **Enrolled as of 3/15/2020**

Verify Prescriber Certification and Patient Enrollment

Enter the prescriber's individual NPI#

1111111153

Enter the patient's name and date of birth

First Name

Jenn

M. I.

A

Last Name

Patient

Date of Birth

06/13/1970

VERIFY

Information

Verify the female patient is under the supervision and care of a certified prescriber, and that she is enrolled or will be enrolled in the REMS Program prior to discharge

Macitentan-Containing Products REMS Prescriber Locator

Search by Prescriber Name or NPI Number

PRESCRIBER NAME

NPI

REMS STATUS

REMS ID

PHONE NUMBER



Walgreens Pharmacy #09290

NPI: 1023023157

Program Status: Enrolled as of 8/17/2023 ✓

Verify Prescriber Certification and Patient Enrollment

Prescriber

RONALD BINGHAM

Patient Information

First Name

Hazel

M.I.

M.I

Last Name

Myra

Date of Birth

7/4/2000



←PREVIOUS

CONTINUE

i Information

- ✓ Prescriber is certified in REMS
- ✓ Patient is enrolled in REMS

Patient ID: 0044536 📄

Reproductive Status: FRP (Female of Reproductive Potential)

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

NORMAN L STOCKBRIDGE
03/22/2024 03:46:40 PM