

## Welcome to the Adempas REMS (Risk Evaluation and Mitigation Strategy)

The Adempas REMS is a program to tell patients and healthcare providers about the serious risks of birth defects while taking Adempas. This program is required by the Food and Drug Administration (FDA). All females must enroll in the Adempas REMS to receive Adempas. REMS stands for Risk Evaluation and Mitigation Strategy.

Bayer Pharmaceuticals has worked with the FDA to develop the Adempas REMS to educate prescribers and patients about the risk of embryo-fetal toxicity. The REMS will require that females agree to follow the REMS requirements to be enrolled in the Adempas REMS in order to receive Adempas® (riociguat).

### Adempas REMS Overview

- Females must not be pregnant when they start taking Adempas, become pregnant during treatment, or become pregnant for one month after stopping Adempas treatment.
- All healthcare providers must enroll in the Adempas REMS and agree to the REMS requirements to prescribe Adempas.
- All female patients must enroll in the Adempas REMS and agree to the REMS requirements to receive Adempas.
- A limited number of certified pharmacies will dispense Adempas for outpatients. They must enroll in the Adempas REMS and agree to the REMS requirements to provide Adempas for outpatient use.
- Inpatient pharmacies must enroll in the Adempas REMS and agree to the REMS requirements to stock Adempas for inpatient use.

### Changes to the Adempas Risk Evaluation and Mitigation Strategy (REMS) February 2020

- Revised Form: [Adempas REMS Patient Enrollment and Consent Form](#)
- Revised Form: [Adempas REMS Prescriber Enrollment and Agreement Form](#)

Click below to learn more about the Adempas REMS



To learn more about the serious risks associated with Adempas, please refer to the *Prescribing Information* including Boxed Warning, *Spanish Prescribing Information*, *Adempas Medication Guide*, *Spanish Adempas Medication Guide*, *Prescriber and Pharmacy Guide*, *Guide for Female Patients* and the *Spanish Guide for Female Patients*.

## INDICATIONS

- Adempas is indicated for the treatment of adults with persistent/recurrent chronic thromboembolic pulmonary hypertension (CTEPH) (WHO Group 4) after surgical treatment, or inoperable CTEPH, to improve exercise capacity and WHO functional class.
- Adempas is indicated for the treatment of adults with pulmonary arterial hypertension (PAH) (WHO Group 1) to improve exercise capacity, improve WHO functional class, and to delay clinical worsening.

Efficacy was shown in patients on Adempas monotherapy or in combination with endothelin receptor antagonists or prostanoids. Studies establishing effectiveness included predominately patients with WHO functional class II-III and etiologies of idiopathic or heritable PAH (61%) or PAH associated with connective tissue diseases (25%).

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit [www.fda.gov/medwatch](http://www.fda.gov/medwatch), or call 1-800-FDA-1088. BAYER, the Bayer Cross and ADEMPAS are registered trademarks of Bayer.

[Privacy Policy](#) [Conditions of Use](#) [Contact us](#) [California Transparency in Supply Chains](#)

This site is intended for US residents only.  
Copyright © 2013 Bayer Pharmaceuticals, Inc. All rights reserved.  
Version 1.7.0.42

## PRESCRIBER OVERVIEW

Due to the risk of embryo-fetal toxicity, Adempas is available only through the Adempas REMS ([Risk Evaluation and Mitigation Strategy](#)).

The goal of the Adempas REMS is to mitigate the risk of embryo-fetal toxicity associated with Adempas 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 ADEMPAS 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 Adempas
5. Ensuring that patients are informed about:
  - the risks of embryo-fetal toxicity
  - appropriate baseline and monthly patient monitoring
  - appropriate contraception

In order to prescribe and receive Adempas, prescribers and females must enroll in the Adempas REMS and agree to comply with the requirements of the program.

Only a limited number of certified pharmacies will dispense Adempas to outpatients.

### To enroll in the Adempas REMS, prescribers must:

- Read the Adempas [Prescribing Information \(PI\)](#) and the [Prescriber and Pharmacy Guide](#)
- Agree to follow the REMS requirements by completing and submitting a [Prescriber Enrollment and Agreement Form](#)
- Complete and submit the [Prescriber Enrollment and Agreement Form](#):
  - [Online](#)
  - [By fax](#) at 1-855-662-5200
  - [By calling the Adempas REMS](#) at 1-855-4ADEMPAS (1-855-423-3672)
- Receive an enrollment confirmation from the Adempas REMS verifying that enrollment has been completed

[Prescriber Roles  
& Responsibilities](#)

### PDFs for Download

#### Materials for Healthcare Providers

-  [Prescriber and Pharmacy Guide for the Adempas REMS](#)
-  [Adempas REMS Prescriber Enrollment and Agreement Form](#)
-  [Adempas REMS Patient Enrollment and Consent Form](#)
-  [Spanish Adempas REMS Patient Enrollment and Consent Form](#)
-  [Adempas REMS Change in Reproductive Potential Status and Pre-pubertal Annual Verification Form](#)
-  [Adempas REMS Inpatient Pharmacy Enrollment Form](#)

#### Materials for Patients

-  [Adempas REMS Guide for Female Patients](#)
-  [Spanish Adempas REMS Guide for Female Patients](#)

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit [www.fda.gov/medwatch](http://www.fda.gov/medwatch), or call 1-800-FDA-1088. BAYER, the Bayer Cross and ADEMPAS are registered trademarks of Bayer.

[Privacy Policy](#) [Conditions of Use](#) [Contact us](#) [California Transparency in Supply Chains](#)

This site is intended for US residents only.  
Copyright © 2013 Bayer Pharmaceuticals, Inc. All rights reserved.  
Version 1.7.0.42

## PRESCRIBER ROLES AND RESPONSIBILITIES

### 1. Enroll in the Adempas REMS

- Prior to writing an Adempas prescription for a patient, a healthcare provider must enroll in the Adempas REMS.
  - **Read** the Adempas *Prescribing Information (PI)* and the *Prescriber and Pharmacy Guide* to understand the risks of Adempas and the Adempas REMS requirements.
  - **Agree** to follow the Adempas REMS requirements by completing and submitting a *Prescriber Enrollment and Agreement Form*
    - Complete and submit the *Prescriber Enrollment and Agreement Form*:
      - [Online](#)
      - [By fax at 1-855-662-5200](#)
      - [By calling the Adempas REMS at 1-855-4ADEMPAS \(1-855-423-3672\)](#)
  - **Receive** an enrollment confirmation from the Adempas REMS verifying that enrollment has been complete.

### 2. Determine the reproductive potential status of female patients

#### 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).

#### 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.

### 3. Educate and Counsel Patients

- For all females, prescribers must:
  - Advise the patient that Adempas is only available through a restricted distribution program called the Adempas REMS.
  - Assess the patient's reproductive status using the definitions in the *Prescriber and Pharmacy Guide*. Document and submit the results to the REMS using the *Patient Enrollment and Consent Form*.
- For Females of Reproductive Potential, prescribers must:
  - Review with her the *Guide for Female Patients*.
  - Counsel the patient on the risk of embryo-fetal toxicity, the need to use effective contraception during Adempas treatment and for one month following treatment discontinuation, and the need to consider medical options in the event of unprotected sexual intercourse or known or suspected contraception failure, and to immediately contact her healthcare provider if she misses a menstrual period or suspects that she is pregnant 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 Adempas.
  - Counsel the patient if she is not complying with the required testing or if she is not using effective contraception.
  - Counsel her to immediately contact her healthcare provider if she misses a menstrual period or suspects she is pregnant.
- For Females of Non-Reproductive Potential
  - 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*.
    - Counsel her and her parent/guardian about the risk of embryo-fetal toxicity.
    - 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 program requirements.

### 4. Check Pregnancy Status (in Females of Reproductive Potential)

- Order a pregnancy test.
- Review the pregnancy test results prior to the initiation of Adempas to ensure the result is negative.
- Notify the patient of negative pregnancy test results prior to the initiation of Adempas.

### 5. Enroll Female Patients in the Adempas REMS

- All female patients must be enrolled in the Adempas REMS in order to receive Adempas.
- Confirm that the patient has agreed to comply with the Adempas REMS requirements.
  - Complete with the patient the designated section of the *Patient Enrollment and Consent Form* and submit it to the Adempas REMS.
  - Prescribers can complete the *Patient Enrollment and Consent Form*:
    - [Online](#)
    - [By fax at 1-855-662-5200](#)

### 6. Monitor Patients

- For Females of Reproductive Potential, prescribers must:
  - Order and review pregnancy tests monthly during treatment with Adempas and for one month after stopping treatment.
  - Notify the patient and Bayer if a patient's pregnancy test is positive.
  - Monitor patients' reproductive status during treatment with Adempas and report any changes or misclassifications to the Adempas REMS by completing and submitting the *Change in Reproductive Potential Status and Pre-pubertal Annual Verification Form* within 10 business days of becoming aware of the change.
- For Females of Non-Reproductive Potential and Pre-Pubertal Females, prescribers must:
  - Monitor patients' reproductive status during treatment with Adempas and report any changes or misclassifications to the Adempas REMS by completing and submitting the *Change in Reproductive Potential Status and Pre-pubertal Annual Verification Form* within 10 business days of becoming aware of the change.
    - Prescribers can complete the *Change in Reproductive Potential Status and Pre-pubertal Annual Verification Form*:
      - [Online](#)
      - [By fax at 1-855-662-5200](#)
  - For each Pre-Pubertal Female who is at least 8 years of age and older, annually verify and report the reproductive status by completing and submitting the *Change in Reproductive Potential Status and Pre-pubertal Annual Verification Form*.

### 7. Report Pregnancies

- Prescribers must also report any pregnancies associated with the use of Adempas to Bayer at 1-888-842-2937 or send the information to [DrugSafety.GPV.US@bayer.com](mailto:DrugSafety.GPV.US@bayer.com).

## PDFs for Download

### Materials for Healthcare Providers

-  [Prescriber and Pharmacy Guide for the Adempas REMS](#)
-  [Adempas REMS Prescriber Enrollment and Agreement Form](#)
-  [Adempas REMS Patient Enrollment and Consent Form](#)
-  [Spanish Adempas REMS Patient Enrollment and Consent Form](#)
-  [Adempas REMS Change in Reproductive Potential Status and Pre-pubertal Annual Verification Form](#)
-  [Adempas REMS Inpatient Pharmacy Enrollment Form](#)

### Materials for Patients

-  [Adempas REMS Guide for Female Patients](#)
-  [Spanish Adempas REMS Guide for Female Patients](#)

## INFORMATION FOR FEMALE PATIENTS

Adempas<sup>®</sup> is a prescription medicine to treat adults with:

- **chronic thromboembolic pulmonary hypertension (CTEPH)**
  - treated with surgery but who continue to have high pulmonary blood pressure (persistent) or it comes back after surgery (recurrent), **or**
  - that cannot be treated with surgery

CTEPH is a type of high blood pressure in the arteries of your lungs caused by blood clots that narrow or block blood flow. Adempas can improve your ability to exercise and can help to improve some of your symptoms.

- **pulmonary arterial hypertension (PAH)**

PAH is a type of high blood pressure in the arteries of your lungs. Adempas can improve your ability to exercise, improve some of your symptoms, and help slow down the worsening of your physical condition.

It is unknown if Adempas is safe and effective in children.

Because of the serious risks of birth defects while taking Adempas, the FDA (Food and Drug Administration) requires a program called REMS. REMS stands for **R**isk **E**valuation and **M**itigation **S**trategy. The purpose of this program is to make sure that patients and prescribers understand the risks. All females must enroll in the Adempas REMS to receive Adempas.

### Females Who Cannot Get Pregnant:

You are considered a female who cannot get pregnant if you have not yet entered puberty, or you do not have a uterus, or you have gone through menopause (have not had a period for at least 12 months for natural reasons, or have had your ovaries removed).

To receive Adempas, you must:

- Enroll in the Adempas REMS by completing the **Patient Enrollment and Consent Form**.
- Receive counseling from your prescriber on the risk of serious birth defects (Pre-menopausal only)
- Tell your prescriber if you become pregnant or your ability to become pregnant changes
- If you are over the age of 8: Be monitored every year to see if your ability to become pregnant changes and tell your prescriber if your ability to become pregnant changes

If you are the parent or caregiver of a female child who started taking Adempas before reaching puberty, you should check your child regularly to see if she is developing signs of puberty. Tell your doctor right away if you notice that she is developing breast buds or pubic hair. Your doctor 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 is able to get pregnant if you have entered puberty, even if you have not started your period, and you have a uterus, and have not gone through menopause (have not had a period for at least 12 months for natural reasons or you have had your ovaries removed).

### If you are a female who can get pregnant, to receive Adempas you must:

- Talk to your healthcare provider about the risks and benefits of Adempas.
- Read:
  - The [Guide for Female Patients](#), [Spanish Guide for Female Patients](#)
- Make sure you understand the risks and benefits of taking Adempas
- Have a pregnancy test before you start taking Adempas to be sure you are not pregnant
- Have a pregnancy test before you receive your refill each month
- Use effective forms of birth control during Adempas treatment and for one month after stopping treatment with Adempas
- Immediately notify your healthcare provider if you miss a menstrual period or suspect you are pregnant

For more information on Adempas, the Adempas REMS and effective forms of birth control, download the [Guide for Female Patients](#), [Spanish Guide for Female Patients](#).

To learn more about the serious risks associated with Adempas, please refer to the [Prescribing Information](#) including Boxed Warning, [Spanish Prescribing Information](#).

#### PDFs for Download

##### Materials for Patients

-  [Adempas REMS Guide for Female Patients](#)
-  [Spanish Adempas REMS Guide for Female Patients](#)

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit: [www.fda.gov/medwatch](http://www.fda.gov/medwatch), or call 1-800-FDA-1088. BAYER, the Bayer Cross and ADEMPAS are registered trademarks of Bayer.

[Privacy Policy](#) [Conditions of Use](#) [Contact us](#) [California Transparency in Supply Chains](#)

This site is intended for US residents only.  
Copyright © 2013 Bayer Pharmaceuticals, Inc. All rights reserved.  
Version 1.7.0.42

## CERTIFIED OUTPATIENT PHARMACY OVERVIEW

Due to the risk of embryo-fetal toxicity, Adempas is available only through the Adempas REMS.

Adempas will be dispensed to outpatients by a limited number of certified pharmacies. Prior to dispensing Adempas the pharmacy will confirm that the prescriber who wrote the prescription is enrolled, and if the patient is a female that she is enrolled in the Adempas REMS. If either the female or prescriber is not enrolled, Adempas will not be dispensed.

### For all female patients, outpatient pharmacies will:

- Contact the Adempas REMS Coordinating Center to determine if the patient has received sample medication from the prescriber
- Verify the female patient is enrolled, the reproductive status has not changed, and the prescriber is certified through processes and procedures established as a requirement of the REMS.

### For Females of Reproductive Potential, outpatient pharmacies will:

- Counsel her on the risk of embryo-fetal toxicity
- Contact her each month to arrange the dispensing of Adempas
- Ask the patient if she has had a pregnancy test within the last month or that the prescriber has authorized the refill through processes and procedures established as part of the REMS requirements
- Counsel her on the need to use effective contraception during Adempas treatment and for one month after stopping treatment
- Counsel her to get monthly pregnancy tests
- Counsel her to inform her prescriber immediately if she misses a menstrual period or suspects that she may be pregnant
- Dispense no more than 30-days' supply

All outpatient pharmacists must report any pregnancies associated with the use of Adempas to Bayer at 1-888-842-2937 or send the information to [DrugSafety.GPV.US@bayer.com](mailto:DrugSafety.GPV.US@bayer.com)

Females of Reproductive Potential will only be able to get a 30-day supply of Adempas at one time.

To learn more about the serious risks associated with Adempas, please refer to the [Prescribing Information](#) including Boxed Warning, [Spanish Prescribing Information](#), and the [Prescriber and Pharmacy Guide](#).

### PDFs for Download

#### Materials for Healthcare Providers

-  [Prescriber and Pharmacy Guide for the Adempas REMS](#)
-  [Adempas REMS Prescriber Enrollment and Agreement Form](#)
-  [Adempas REMS Patient Enrollment and Consent Form](#)
-  [Spanish Adempas REMS Patient Enrollment and Consent Form](#)
-  [Adempas REMS Change in Reproductive Potential Status and Pre-pubertal Annual Verification Form](#)
-  [Adempas REMS Inpatient Pharmacy Enrollment Form](#)

#### Materials for Patients

-  [Adempas REMS Guide for Female Patients](#)
-  [Spanish Adempas REMS Guide for Female Patients](#)

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit [www.fda.gov/medwatch](http://www.fda.gov/medwatch), or call 1-800-FDA-1088. BAYER, the Bayer Cross and ADEMPAS are registered trademarks of Bayer.

[Privacy Policy](#) [Conditions of Use](#) [Contact us](#) [California Transparency in Supply Chains](#)

This site is intended for US residents only.  
Copyright © 2013 Bayer Pharmaceuticals, Inc. All rights reserved.  
Version 1.7.0.42

## CERTIFIED INPATIENT PHARMACY OVERVIEW

Due to the risk of embryo-fetal toxicity, Adempas is available only through the Adempas REMS.

In order to stock Adempas, inpatient pharmacies must enroll and be certified in the Adempas REMS.

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

- Establish processes and procedures to ensure the REMS requirements are met.
- Complete training in the Adempas REMS by reading the *Prescriber and Pharmacy Guide*.
- Assign an authorized representative to assume responsibility for the training of dispensing staff on the Adempas REMS requirements and Adempas REMS materials prior to dispensing Adempas.
- Assume responsibility for the training of all relevant staff in dispensing on the Adempas REMS requirements, procedures, and Adempas REMS materials prior to dispensing Adempas, using the *Prescriber and Pharmacy Guide*.
- 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 effective contraception, to get monthly pregnancy tests, and to inform the prescriber of a pregnancy immediately.

Before dispensing:

- Verify the female patient is under the supervision and care of a certified prescriber, her reproductive status, 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.
- For females of reproductive potential: Verify pregnancy testing is complete, and that the patient is counseled on the risk of embryo-fetal toxicity, the need to use effective 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 REMS.

At discharge:

- Verify the female patient is enrolled in the REMS through the processes and procedures established as a requirement of the REMS.
- Dispense no more than a 15-day temporary supply of Adempas to any female patient upon discharge from the healthcare facility.

At all times:

- Not distribute, transfer, loan, or sell Adempas.
- Report any pregnancies associated with the use of Adempas to Bayer at 1-888-842-2937, or send the information to [DrugSafety.GPV.US@bayer.com](mailto:DrugSafety.GPV.US@bayer.com).
- 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.
- Maintain records of all processes and procedures including compliance with those processes and procedures.

To be certified in the Adempas REMS, an authorized representative of the inpatient pharmacy must:

- Complete training in the Adempas REMS by reading the *Adempas Prescribing Information (PI)*, and the *Prescriber and Pharmacy Guide for the Adempas REMS* to understand the risks of Adempas and the Adempas REMS requirements.
- Agree to follow the REMS requirements by completing and submitting an *Inpatient Pharmacy Enrollment Form* to the Adempas REMS.
  - Authorized representatives can complete the *Inpatient Pharmacy Enrollment Form*:
    - [Online](#)
    - [By fax](#) at 1-855-662-5200
    - [By calling the Adempas REMS](#) at 1-855-4ADEMPAS (1-855-423-3672)
- If an inpatient pharmacy needs Adempas and is not certified in the Adempas REMS, the inpatient pharmacy can contact the Adempas REMS Program Coordinating Center at 1-855-4ADEMPAS (1-855-423-3672) for assistance in obtaining up to a 15-day supply of Adempas for a specific inpatient while initiating enrollment.

To learn more about the serious risks associated with Adempas, please refer to the *Prescribing Information* including Boxed Warning, *Spanish Prescribing Information*, *Prescriber and Pharmacy Guide* and the *Guide for Female Patients*.

### PDFs for Download

#### Materials for Healthcare Providers

-  [Prescriber and Pharmacy Guide for the Adempas REMS](#)
-  [Adempas REMS Prescriber Enrollment and Agreement Form](#)
-  [Adempas REMS Patient Enrollment and Consent Form](#)
-  [Spanish Adempas REMS Patient Enrollment and Consent Form](#)
-  [Adempas REMS Change in Reproductive Potential Status and Pre-pubertal Annual Verification Form](#)
-  [Adempas REMS Inpatient Pharmacy Enrollment Form](#)

#### Materials for Patients

-  [Adempas REMS Guide for Female Patients](#)
-  [Spanish Adempas REMS Guide for Female Patients](#)

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit [www.fda.gov/medwatch](http://www.fda.gov/medwatch), or call 1-800-FDA-1088. BAYER, the Bayer Cross and ADEMPAS are registered trademarks of Bayer.

[Privacy Policy](#) [Conditions of Use](#) [Contact us](#) [California Transparency in Supply Chains](#)

This site is intended for US residents only.  
Copyright © 2013 Bayer Pharmaceuticals, Inc. All rights reserved.  
Version 1.7.0.42

User Name:

Submit

Login is available for enrolled prescribers and office contacts designated by prescribers only.

To learn more about the serious risks associated with Adempas, please refer to the [Prescribing Information](#) including Boxed Warning, [Spanish Prescribing Information](#), and the [Prescriber and Pharmacy Guide](#).

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit [www.fda.gov/medwatch](http://www.fda.gov/medwatch), or call 1-800-FDA-1088.  
BAYER, the Bayer Cross and ADEMPAS are registered trademarks of Bayer.

[Privacy Policy](#) [Conditions of Use](#) [Contact us](#) [California Transparency in Supply Chains](#)

This site is intended for US residents only.  
Copyright © 2013 Bayer Pharmaceuticals, Inc. All rights reserved.  
Version 1.7.0.42

**Phone: 1-855-4ADEMPAS (1-855-423-3672)**  
**Fax: 1-855-662-5200**

*Hours of Operation: Monday- Friday 8:00 AM - 8:00 PM Eastern*

To report any adverse events, product technical complaints, medication errors, or pregnancies associated with the use of Adempas, contact:

Bayer at 1-888-842-2937, or send the information to [DrugSafety.GPV.US@bayer.com](mailto:DrugSafety.GPV.US@bayer.com).

To learn more about the serious risks associated with Adempas, please refer to the [Prescribing Information](#) including Boxed Warning, [Spanish Prescribing Information](#), and the [Prescriber and Pharmacy Guide](#).

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit [www.fda.gov/medwatch](http://www.fda.gov/medwatch), or call 1-800-FDA-1088.  
BAYER, the Bayer Cross and ADEMPAS are registered trademarks of Bayer.

[Privacy Policy](#) [Conditions of Use](#) [Contact us](#) [California Transparency in Supply Chains](#)

This site is intended for US residents only.  
Copyright © 2013 Bayer Pharmaceuticals, Inc. All rights reserved.  
Version 1.7.0.42

## Adempas REMS Patient Enrollment and Consent Form

## 1 Patient Information

|                      |   |                      |
|----------------------|---|----------------------|
| * First Name:        | Middle Initial:   | * Last Name:         |
| <input type="text"/> | <input type="text"/>                                    | <input type="text"/> |
| * Address Line 1:    | Address Line 2:   |                      |
| <input type="text"/> | <input type="text"/>                                    |                      |
| * City:              | * State:  | * Zip code:          |
| <input type="text"/> | <input type="text" value="Please Select"/>              | <input type="text"/> |
| * Birthdate:         | * Gender:   |                      |
| <input type="text"/> | <input type="radio"/> Male <input type="radio"/> Female |                      |

## Contact Information

|                       |  |   |
|-----------------------|--|---|
| * Preferred Phone:    | Can we leave a message on this phone?:             | Preferred Time to Contact:                              |
| <input type="text"/>  | <input type="radio"/> Yes <input type="radio"/> No | <input type="radio"/> Day <input type="radio"/> Evening |
| Cell/Alternate Phone: | * Email:   |   |
| <input type="text"/>  | <input type="text"/>                               |   |

## Alternate Contact Information

|  |                      |                      |
|--|----------------------|----------------------|
| Alternate Contact Name:                                    | Phone:               | Relationship:        |
| <input type="text"/>                                       | <input type="text"/> | <input type="text"/> |
| <input type="checkbox"/> 1 mg Adempas Sample Dispensed**   | Date:                |                      |
|  | <input type="text"/> |                      |
| <input type="checkbox"/> 0.5 mg Adempas Sample Dispensed** | Date:                |                      |
|  | <input type="text"/> |                      |

\*\* Adempas Sample should only be dispensed as a 30-day supply.

## 2 Statement of Medical Necessity

The following does not suggest approved uses or indications.

- \* Diagnosis:
- I27.0 Primary pulmonary hypertension     I27.21 Secondary pulmonary hypertension     I27.24 Chronic thromboembolic pulmonary hypertension (Inoperable)  
 I27.24 Chronic thromboembolic pulmonary hypertension (Persistent/Recurrent)     OTHER (please specify)

Therapy Status:

Initial Therapy (monotherapy or in combination)     Add-on therapy     Transition from other therapy

## 3 Female Patient Agreement

**For all Females:** I understand that Adempas is only available through a restricted distribution program under an FDA-required Risk Evaluation and Mitigation Strategy (REMS).  
**For Females Who Can Get Pregnant:** I have been counseled on the risks of Adempas, including the risk of serious birth defects. I have read the *Guide for Female Patients*. Before treatment initiation, I understand that I will receive counseling from the prescriber on: the risk of serious birth defects, the need to use effective contraception during Adempas treatment and for one month after stopping Adempas treatment, my medical options in the event of unprotected sexual intercourse or known or suspected contraception failure, and to immediately contact my prescriber if I miss a menstrual period or suspect that I am pregnant. Before each prescription, I will receive counseling by the pharmacy or the prescriber who dispenses Adempas on the risk of serious birth defects, the need to use effective contraception during Adempas treatment and for one month after stopping Adempas treatment, to get monthly pregnancy tests, and to report a pregnancy immediately. Ensure that I have completed pregnancy testing before I started Adempas, monthly before each refill, and for one month after stopping Adempas. I understand that I may be contacted by Bayer and/or its agents and contractors to obtain information about my pregnancy. I will communicate with the pharmacy to confirm completion of pregnancy testing.  
**For Pre-Pubertal Females:** I have been counseled on the risks of Adempas, including the risk of serious birth defects, and that I have read the *Guide for Female Patients*. I understand that I must immediately contact my healthcare provider if I get my menstrual period.  
**For Post-Menopausal Females:** I have received and read the *Guide for Female Patients* and that I will inform my prescriber if there is a change in my reproductive status.  
**For Females with other medical reasons for permanent, irreversible infertility:** I have received and read the *Guide for Female Patients* and that I will inform my prescriber if there is a change in my reproductive status.

## 4 Prescriber Information

|                         |  |                      |
|-------------------------|--|----------------------|
| * First Name:           | * Last Name:                                     | * NPI Number:        |
| <input type="text"/>    | <input type="text"/>                             | <input type="text"/> |
| Practice/Facility Name: |  |                      |
| <input type="text"/>    |  |                      |
| Address Line 1:         | Address Line 2:                                  |                      |
| <input type="text"/>    | <input type="text"/>                             |                      |
| City:                   | State:   | Zip code:            |
| <input type="text"/>    | <input type="text" value="-- Please Select --"/> | <input type="text"/> |
| Phone:                  | * Email:   | State License #:     |
| <input type="text"/>    | <input type="text"/>                             | <input type="text"/> |

## 5 Prescriber Authorization

For female patients, please indicate the patient's current reproductive status below.

- \* Reproductive Status:
- Female of Reproductive Potential  
 Female of Non-Reproductive Potential

I certify that the information provided is accurate to the best of my knowledge. I certify that for female patients, I have provided the appropriate counseling and Adempas REMS materials, and I will continue to fulfill my obligations under the Adempas REMS Program. I understand that I may not delegate signature authority.

Definitions:

**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).

**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 postsurgical from bilateral oophorectomy.
- Females with other medical reasons for permanent, irreversible infertility.

**Prescriber Obligations under the Adempas REMS**

**For All Females, I will:**

- determine the reproductive potential status of all female patients using the definitions provided in the *Prescriber and Pharmacy Guide*.
- advise all females that Adempas is only available through a restricted distribution program called the Adempas REMS.
- enroll all female patients into the Adempas REMS by completing the *Patient Enrollment and Consent Form* and submitting it to the REMS.

**For Females of Reproductive Potential, I will:**

- counsel Females of Reproductive Potential (FRP) on Adempas risks, including serious birth defects; and review the *Guide for Female Patients* with the patient.
- counsel each FRP to immediately contact her prescriber if she misses a menstrual period or suspects pregnancy.
- order and review pregnancy tests for FRPs before the start of treatment, monthly during treatment, and for one month after stopping treatment.
- counsel each FRP to use effective contraception during Adempas treatment and for one month after stopping treatment and discuss her medical options in the event of unprotected sexual intercourse or known or suspected contraceptive failure using the *Guide for Female Patients*.
- counsel each FRP during treatment if she is not complying with the required testing or if she is not using effective contraception, and to immediately 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 (PPF) patient on the Adempas risks, including serious birth defects and to immediately contact her prescriber if she begins to menstruate.
- Review the *Guide for Female Patients* with the patient.
- for PPF, regularly assess the reproductive status of each pre-pubertal female during their treatment with Adempas.

To report any adverse events, product technical complaints, medication errors or pregnancies associated with the use of Adempas, contact: Bayer at 1-888-842-2937, or send the information to DrugSafety.GPV.US@bayer.com.

Red Asterisk \* - Required field for submitting enrollment form

CANCEL CONTINUE TO SIGN

## 5 Prescriber Authorization

For female patients, please indicate the patient's current reproductive status below.

\* Reproductive Status:

- Female of Reproductive Potential
- Female of Non-Reproductive Potential

\* If this patient is a Female of Reproductive Potential has a pregnancy test been completed prior to prescribing Adempas?:

- Yes
- No

I certify that the information provided is accurate to the best of my knowledge. I certify that for female patients, I have provided the appropriate counseling and Adempas REMS materials, and I will continue to fulfill my obligations under the Adempas REMS. I understand that I may not delegate signature authority.

Reference ID: 4709629

Definitions:

## 5 Prescriber Authorization

For female patients, please indicate the patient's current reproductive status below.

**\* Reproductive Status:**

- Female of Reproductive Potential
- Female of Non-Reproductive Potential

**\* Female of Non-Reproductive Potential:**

- Pre-Pubertal Female
- Post-Menopausal Female
- Female with other medical reasons for permanent, irreversible infertility

I certify that the information provided is accurate to the best of my knowledge. I certify that for female patients, I have provided the appropriate counseling and Adempas REMS materials, and I will continue to fulfill my obligations under the Adempas REMS. I understand that I may not delegate signature authority.

Reference ID: 4709629

## Adempas REMS (Risk Evaluation and Mitigation Strategy) Program Prescriber Enrollment and Agreement Form

In order to prescribe Adempas, prescribers must enroll in the Adempas REMS by completing this form. In order to receive samples of Adempas, prescribers must be enrolled in the Adempas REMS and agree to comply with the requirements for a Sample Dispensing Prescriber, detailed in the agreement below.

Access this form online at [www.adempasREMS.com](http://www.adempasREMS.com), fax this form to 1-855-662-5200 or call the Adempas REMS Program at 1-855-4ADEMPAS (1-855-423-3672).

### Prescriber Information (\* indicates required field)

First Name: JOHN  
 Middle Name:   
 Last Name: SMITH

NPI: 1234567890  
 State License #:

\*Specialty:  Cardiology  
 Pulmonology  
 Other

\*Credentials:  MD  
 DO  
 NP  
 PA  
 Other with prescriptive authority

Facility Name:   
 \*Address 1: 13795 KENWOOD DR  
 Address 2:   
 \*City: BAXTER  
 \*State: MN  
 \*ZipCode: 56425-8504  
 \*Phone Number: 435-313-0686  
 \*Fax Number:   
 \*Email:

Preferred Method of Contact:

Phone Number:   
 Email:   
 Fax Number:

### Office Contact

Primary Contact

First Name:   
 Last Name:   
 Email ( Required if office contact is provided ):

Secondary Contact

First Name:   
 Last Name:   
 Email ( Required if office contact is provided ):

### Prescriber REMS Agreement

By signing below, you signify your understanding of the risks of Adempas treatment and your obligation as an Adempas prescriber to educate your female patients about the Adempas REMS, monitor them appropriately, and report any pregnancies to the Adempas REMS. Specifically, you attest to the following:

- I have reviewed the *Adempas Prescribing Information*, and the *Prescriber and Pharmacy Guide*.
- For all Females, I will:
  - determine the reproductive potential status of all female patients using the definitions provided in the *Prescriber and Pharmacy Guide*.
  - advise all females that Adempas is only available through a restricted distribution program called the Adempas REMS.
  - enroll all female patients into the Adempas REMS by completing the *Patient Enrollment Form* and submitting it to the REMS.
- For Females of Reproductive Potential, I will:
  - counsel Females of Reproductive Potential (FRP) on Adempas risks, including serious birth defects; and review the *Guide for Female Patients* with the patient.
  - counsel each FRP to immediately contact her prescriber if she misses a menstrual period or suspects pregnancy.
  - order and review pregnancy tests for FRPs before the start of treatment, monthly during treatment, and for one month after stopping treatment.
  - counsel each FRP to use effective contraception during Adempas treatment, and for one month after stopping treatment, and discuss her medical options in the event of unprotected sexual intercourse or known or suspected contraceptive failure using the *Guide for Female Patients*.
  - counsel each FRP during treatment if she is not complying with the required testing or if she is not using effective contraception, and to immediately 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 (PPF) patient on the Adempas risks, including serious birth defects; and review the *Guide for Female Patients* with the patient.
  - for PPF, regularly assess the reproductive status of each pre-pubertal female during their treatment with Adempas.
  - at least annually document the reproductive potential status for Pre-Pubertal Females who are at least 8 years of age and older by submitting a *Change in Reproductive Potential Status and Pre-pubertal Annual Verification Form*.
- At all times, I will:
  - report any change or misclassification in reproductive 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.
  - provide documentation of compliance with program requirements.
  - notify Bayer of any pregnancies at 1-888-842-2937 or send the information to [DrugSafety.GPV.US@bayer.com](mailto:DrugSafety.GPV.US@bayer.com).

\*Signature:

Please Validate your Submission by Re-entering your NPI Number, and pressing 'Submit Enrollment!':

### Prescriber REMS Agreement for Those Who Dispense

I will:

- follow the requirements of a prescriber as I have attested to on the *Prescriber Enrollment and Agreement Form* above
- dispense Adempas to female patients only if the *Patient Enrollment and Consent Form* has been signed and submitted
- report dispensing Adempas to the REMS using the *Patient Enrollment and Consent Form*
- order and review a pregnancy test for FRP prior to dispensing Adempas
- not distribute, transfer, loan or sell Adempas
- maintain records of all processes and procedures including compliance with those processes and procedures
- comply with audits

Signature:

Please Validate your Submission by Re-entering your NPI Number, and pressing 'Submit Enrollment!':

Submit Enrollment

To report any adverse events, product technical complaints, medication errors or pregnancies associated with the use of Adempas, contact:  
 Bayer at 1-888-842-2937, or send the information to [DrugSafety.GPV.US@bayer.com](mailto:DrugSafety.GPV.US@bayer.com)

# Adempas REMS Enrollment - In-Patient Pharmacy...

## Adempas Risk Evaluation and Mitigation Strategy (REMS) Program Inpatient Pharmacy Enrollment Form

Due to a risk of fetal exposure and adverse fetal outcomes in females of reproductive potential prescribed Adempas, Adempas is available only through the Adempas REMS. The Adempas REMS is a component of a Risk Evaluation and Mitigation Strategy (REMS). In order for inpatients to receive Adempas, females as well as inpatient pharmacies that wish to stock this product, must enroll in the Adempas REMS and agree to comply with the requirements of the program.

Access this form online at [www.adempasREMS.com](http://www.adempasREMS.com), fax this form to 1-855-662-5200 or call the Adempas REMS Program at 1-855-4ADEMPAS (1-855-423-3672).

### Inpatient Pharmacy Information (\* indicates required field)

|                     |                     |
|---------------------|---------------------|
| * Type of Facility: | -- Please Select -- |
| NPI:                | 1234567890          |
| * Facility Name:    |                     |
| * Address Line 1:   | 4408 16TH AVE       |
| Address Line 2:     |                     |
| * City:             | BROOKLYN            |
| * State:            | NY                  |
| * Zip code:         | 11204-1012          |
| * Phone:            | 718-871-6700        |
| * Fax:              | 718-871-3043        |

### Ship To Information (\* indicates required field)

|                         |                     |
|-------------------------|---------------------|
| * Ship to Address:      | -- Please Select -- |
| * Ship to Contact Name: |                     |

### Authorized Representative Information (\* indicates required field)

|                 |                     |
|-----------------|---------------------|
| * First Name:   |                     |
| Middle Initial: |                     |
| * Last Name:    |                     |
| Position/Title: | -- Please Select -- |
| Phone:          |                     |
| Fax:            |                     |
| * Email:        |                     |

### Inpatient Pharmacy / Authorized Representative Acknowledgement

This inpatient pharmacy will:

- establish processes and procedures to ensure the REMS requirements are met.
- complete training in the Adempas REMS by reading the *Prescriber and Pharmacy Guide*.
- assume responsibility for the training of all relevant staff in dispensing on the Adempas REMS requirements, procedures, and Adempas REMS materials prior to dispensing Adempas, using the *Prescriber and Pharmacy Guide*.
- 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 effective contraception, to get monthly pregnancy tests, and to inform the prescriber of a pregnancy immediately.
- before dispensing: verify the female patient is under the supervision and care of a certified prescriber, her reproductive status, 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.
- for females of reproductive potential: verify pregnancy testing is complete, and that the patient is counseled on the risk of embryo-fetal toxicity, the need to use effective 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 REMS.

At Discharge:

- verify the female patient is enrolled in the REMS through the processes and procedures established as a requirement of the REMS.
- dispense no more than a 15-day temporary supply of Adempas to any female patient upon discharge from the healthcare facility.

At all times:

- do not distribute, transfer, loan, or sell Adempas.
- report any pregnancies associated with the use of Adempas to Bayer at 1-888-842-2937 or send the information to [DrugSafety.GPV.US@bayer.com](mailto:DrugSafety.GPV.US@bayer.com).
- 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.
- maintain records of all processes and procedures including compliance with those processes and procedures.

Note: If your inpatient pharmacy needs Adempas and is not certified in the Adempas REMS, contact the Adempas REMS Coordinating Center at 1-855-4ADEMPAS (1-855-423-3672) for assistance in obtaining up to a 15-day supply of Adempas for a specific inpatient while initiating enrollment.

\* Authorized Representative Signature:

Cancel

Submit

To report any adverse events, product technical complaints, medication errors or pregnancies associated with the use of Adempas, contact:  
Bayer at 1-888-842-2937, or send the information to [DrugSafety.GPV.US@bayer.com](mailto:DrugSafety.GPV.US@bayer.com).