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

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 Program to receive Adempas. REMS stands for Risk Evaluation and Mitigation Strategy.

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

Adempas REMS Program 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 Program and agree to the REMS requirements to prescribe Adempas.
- All female patients must enroll in the Adempas REMS Program 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 Program and agree to the REMS requirements to provide Adempas for outpatient use.
- Inpatient pharmacies must enroll in the Adempas REMS Program and agree to the REMS requirements to stock Adempas for inpatient use.

Click below to learn more about the Adempas REMS Program


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%).
PRESCRIBER

Due to the risk of fetal harm, Adempas is available only through the Adempas REMS (Risk Evaluation and Mitigation Strategy) Program.

The goals of the Adempas Risk Evaluation and Mitigation Strategy (REMS) are:

1. To inform prescribers, patients, and pharmacists about the serious risk of teratogenicity and safe-use conditions for Adempas
2. To minimize the risk of fetal exposure and adverse fetal outcomes in Females of Reproductive Potential prescribed Adempas
   a. Females who are pregnant must not be prescribed Adempas
   b. Females taking Adempas must not become pregnant

In order to prescribe and receive Adempas, prescribers and females must enroll in the Adempas REMS Program 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 Program, prescribers must:

- Read the Adempas Full Prescribing Information (PI), Adempas Medication Guide, and the Prescriber Guide for the Adempas REMS Program
- Agree to follow the REMS requirements by completing and submitting an Adempas REMS Prescriber Enrollment and Agreement Form to the Adempas REMS Program
- Complete the Adempas REMS Prescriber Enrollment and Agreement Form:
  - Online
  - By fax at 1-855-662-5200
  - By calling the Adempas REMS Program at 1-855-4ADEMPAS (1-855-423-6722)
- Receive an enrollment confirmation from the Adempas REMS Program verifying that enrollment has been completed
PREScriBER ROLES AND RESPONSIBILITIES

1. Enroll in the Adempas REMS Program
   - Prior to writing an Adempas prescription for a patient, a healthcare provider must enroll in the Adempas REMS Program.
   - Review the Adempas REMS Program Fact Sheet and the Adempas REMS Program Patient Information Guide.
   - Complete the Adempas REMS Program Enrollment Form online at www.adempas.remsprogram.com or by calling 1-866-842-2580.

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 the REMS, puberty includes those girls who are at least Tanner Stage 2 and have not yet had a menstrual period.
   - Females of Non-Reproductive Potential
     - Females of non-reproductive potential include females who are at Tanner Stage 1 and are not considered to be of reproductive potential.
     - Females of non-reproductive potential include males who have passed through menopause (as defined below).

3. Educate and Counsel Patients
   - For all females, prescribers must:
     - Discuss the potential for adverse effects of Adempas.
     - Discuss the need for use of contraception during treatment with Adempas.
     - Discuss the need for nutrition and exercise during treatment with Adempas.
     - Discuss the need for counseling and counseling referral.
     - Discuss the need for opioid use disorder and counseling referral.
     - Discuss the need for mental health counseling and counseling referral.
     - Discuss the need for reproductive counseling and counseling referral.
     - Discuss the need for developmental counseling and counseling referral.
     - Discuss the need for genetic counseling and counseling referral.

4. Check Pregnancy Status (in Females of Reproductive Potential)
   - Order a pregnancy test.
   - Review the pregnancy test results prior to the initiation of Adempas.
   - Notify the patient of negative pregnancy test results prior to the initiation of Adempas.

5. Enroll Female Patients in the Adempas REMS Program
   - All female patients must be enrolled in the Adempas REMS Program in order to receive Adempas.
   - Confirm that the patient has agreed to comply with the Adempas REMS Program requirements.
   - Complete the Adempas REMS Program Enrollment Form and submit it to the Adempas REMS Program.

6. Monitor Patients
   - For patients on Adempas, prescribers must:
     - Order and review pregnancy tests monthly during treatment with Adempas and for one month after stopping treatment.
     - Notify the patient and patient’s health care provider if the patient is pregnant.
     - Follow the Adempas REMS Program and provide all necessary follow-up.

7. Report Pregnancies
   - Prescribers must also report any pregnancies associated with the use of Adempas by calling 1-866-842-2580, or online on the REMS website.
INFORMATION FOR FEMALE PATIENTS

Adempas® 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 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 Risk Evaluation and Mitigation Strategy. The purpose of this program is to make sure that patients and prescribers understand the risks. All females must enroll in the Adempas REMS Program to receive Adempas.

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 Adempas Medication Guide, Spanish Adempas Medication Guide and

- Have a pregnancy test before you start taking Adempas
- Have a pregnancy test before you receive your refill each month
- Use reliable 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 Program, and reliable forms of birth control, download the Adempas REMS Guide for Females Who Can Get Pregnant, Spanish Adempas REMS Guide for Females Who Can Get Pregnant.

To learn more about the serious risks associated with Adempas, please refer to the Full Prescribing Information including Boxed Warnings, Spanish Full Prescribing Information, Adempas Medication Guide and the Spanish Adempas Medication Guide.
CERTIFIED OUTPATIENT PHARMACY OVERVIEW

Due to the risk of teratogenicity, Adempas is available only through the Adempas REMS Program. Adempas will be dispensed to outpatients by a limited number of certified pharmacies. The pharmacist 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 Program. If either the female or prescriber is not enrolled, Adempas will not be dispensed.

For Females of Reproductive Potential, pharmacies will:

- Ask the patient if she has had a pregnancy test within the last month
- Counsel her on the need to use reliable contraception during Adempas 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

Females of Reproductive Potential and Pre-Pubertal Females will only be able to get a 30 day supply of Adempas at one time. The Adempas Medication Guide will be provided to all patients each time Adempas is dispensed.

To learn more about the serious risks associated with Adempas, please refer to the Full Prescribing Information including Boxed Warning, Spanish Full Prescribing Information, Adempas Medication Guide, Spanish Adempas Medication Guide and the Prescriber Guide for the Adempas REMS Program.
CERTIFIED INPATIENT PHARMACY OVERVIEW

Due to the risk of teratogenicity, Adempas is available only through the Adempas REMS Program. In order to stock Adempas, inpatient pharmacies must enroll and be certified in the Adempas REMS Program.

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

- establish systems, protocols, or other measures to ensure the REMS requirements are met.
- dispense only after contacting the Adempas REMS Program Coordinating Center to confirm the REMS requirements are met.
- not transfer Adempas to any pharmacy, practitioner or healthcare setting not certified by the Adempas REMS Program.
- confirm the inpatient is under the care of a healthcare provider certified in the Adempas REMS Program.
- develop a process to track compliance with the conditions above and provide information about its compliance to Bayer upon request.
- report any pregnancies associated with the use of Adempas to Bayer at 1-888-842-2937, or send the information to DrugsSafety.CPV.US@bayer.com.
- dispense no more than a 15-day temporary supply of Adempas to any patient upon discharge from the healthcare facility.

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

- Agree to follow the REMS requirements by completing and submitting an Adempas REMS Inpatient Pharmacy Enrollment Form to the Adempas REMS Program.
  - Authorized representatives can complete the Adempas REMS Inpatient Pharmacy Enrollment Form:
    - Online
    - By fax at 1-855-662-5200
    - By calling the Adempas REMS Program at 1-855-4ADEMPAS (1-855-423-3672)

- If an inpatient pharmacy needs Adempas and is not certified in the Adempas REMS Program, 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.

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 Full Prescribing Information including Boxed Warning, Spanish Full Prescribing Information, Adempas Medication Guide, Spanish Adempas Medication Guide, and the Prescriber Guide for the Adempas REMS Program.
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.

To learn more about the serious risks associated with Adempas, please refer to the Full Prescribing Information including Boxed Warning, Spanish Full Prescribing Information, Adempas Medication Guide, Spanish Adempas Medication Guide, and the Prescriber Guide for the Adempas REMS Program.