Adempas® REMS (Risk Evaluation and Mitigation Strategy)
Guide for Females Who Can Get Pregnant
Table of Contents

I. What is Adempas? .......................................................................................................................................................... 3
II. What are the serious risks of Adempas? ...................................................................................................................... 3
III. What is the Adempas REMS Program? ..................................................................................................................... 3
IV. Who is a female who is able to get pregnant? ............................................................................................................. 4
V. How do I enroll in the Adempas REMS Program? ........................................................................................................ 4
VI. What are my birth control options? .......................................................................................................................... 5
VII. How will I get my Adempas medicine? ..................................................................................................................... 6
VIII. What do I need to do while taking Adempas? ........................................................................................................... 6
IX. Where can I look for more information about Adempas or the Adempas REMS Program? ................................. 6
I. What is Adempas (riociguat)?

Adempas® is a prescription medicine used 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. 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.

II. What are the serious risks of Adempas?

Adempas may cause serious birth defects if taken while you are pregnant. You must not be pregnant when you start to take Adempas, become pregnant while taking Adempas, or become pregnant for one month after stopping Adempas.

III. What is 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.

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 and
    - The Adempas REMS Guide for Females Who Can Get Pregnant (this guide)

- 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
  - Your healthcare provider will order the pregnancy tests for you
  - Your pharmacy will call you every month to:
    - ask if you have taken a pregnancy test in the last month
    - remind you to use reliable birth control
  - Be sure you take your monthly pregnancy tests as ordered by your healthcare provider. You may not receive your Adempas refill on time if you do not take your monthly pregnancy tests
• Use reliable forms of birth control during Adempas treatment and for one month after stopping treatment with Adempas.
  - Do not have unprotected sex.
  - Use the birth control options described on page 5 of this guide during your Adempas treatment and for one month after stopping your Adempas treatment.
  - Talk to your healthcare provider or pharmacist right away if you have unprotected sex, if you think your birth control has failed, or if you think you may be 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 may be pregnant.
• Immediately notify your healthcare provider if you miss a menstrual period or suspect you are pregnant!

IV. Who is a female who is able to get pregnant?

You are considered a female who is able to get pregnant if you have had a menstrual period or any menstrual bleeding in the past 12 months or have not gone through menopause. Menopause means that you have not had any menstrual bleeding for 12 months.

Your healthcare provider gave you this guide and the Adempas Medication Guide to read because you are taking Adempas and may be able to get pregnant. Talk to your healthcare provider if you have any questions about being a female who is able to get pregnant or about taking Adempas.

V. How do I enroll in the Adempas REMS Program?

• Talk with your healthcare provider to make sure that Adempas is right for you
• Read the Adempas Medication Guide (comes with your medicine) and the Adempas REMS Guide for Females Who Can Get Pregnant (this guide)
• Ask your healthcare provider any questions that you have about Adempas and the Adempas REMS Program
• Agree to all the requirements of the Adempas REMS Program
• Complete and sign the Adempas Patient Enrollment and Consent Form with your healthcare provider

To enroll you in the Adempas REMS Program, your healthcare provider will send in your Adempas Patient Enrollment and Consent Form. The Adempas REMS Program will keep your information in a secure and validated database.
VI. What are my birth control options?

Your healthcare provider will talk to you about your options for reliable birth control. Use the tables below to help decide what birth control option is best for you.

**Option 1**

One method from this list:

- Intrauterine system
- LNg-20 IUS-progestosterone IUD
- LNG-13.5 progestosterone IUD
- Standard intrauterine device
- Copper T 380 A IUD
- Tubal sterilization (tie, clip, band, burn)
- Progesterone implant

**Option 2**

One method from this list:

- Estrogen and progesterone oral contraceptives ("the pill")
- Estrogen and progesterone transdermal patch
- Vaginal ring
- Progesterone injection

**Option 3**

One method from this list:

- Diaphragm with spermicide
- Cervical cap with spermicide

**Option 4**

This method:

- Partner's vasectomy

If you can get pregnant, do not have unprotected sex. Talk to your healthcare provider or pharmacist right away if you have unprotected sex or if you think your birth control has failed. If so, your healthcare provider may discuss medical options with you (e.g. emergency contraception). Tell your healthcare provider right away if you miss a menstrual period or if you think you may be pregnant.
VII. How will I get my Adempas medicine?

Adempas is not available at your local pharmacy. You can only get it through a certified pharmacy, sometimes called a “specialty” pharmacy. After you enroll, your prescription will be sent to a certified pharmacy.

Before the pharmacy sends your prescription, they will call to confirm that you had a pregnancy test taken in the last month.

The pharmacy will send Adempas directly to your home or where you tell them to send it.

- If you did not complete your pregnancy test for that month, your Adempas prescription or refill will be delayed.
- The pharmacy will remind you to use reliable birth control during treatment with Adempas and for one month after stopping treatment with Adempas.

The pharmacy will also:

- Handle your insurance claims
- Answer questions that you have about Adempas

VIII. What do I need to do while taking Adempas?

- Use reliable birth control during treatment with Adempas and for one month after stopping Adempas.
- Have a pregnancy test taken every month.
- Tell your healthcare provider right away if you:
  - have unprotected sex
  - think that your birth control failed
  - miss a menstrual period
  - think you may be pregnant

IX. Where can I find more information about Adempas and the Adempas REMS Program?

- Get the Adempas Medication Guide from your healthcare provider or nurse. It will also come with your medicine.
- Talk with your healthcare provider, nurse, or pharmacist about Adempas.
- For questions about getting your Adempas prescription filled or being in the Adempas REMS Program, please call the Adempas REMS Program Coordinating Center at 1-855-4ADEMPAS (1-855-423-3672).