



Adempas[®] REMS (Risk Evaluation and Mitigation Strategy) Guide for Female Patients

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I. What is Adempas (riociguat)?

Adempas® is a prescription medicine used to treat adults with:

- **chronic thromboembolic pulmonary hypertension (CTEPH)**
 - o treated with surgery but who continue to have high pulmonary blood pressure (persistent) or it comes back after surgery (recurrent), **or**
 - o 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.

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)?

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.

IV. How do I enroll in the Adempas REMS?

- Talk with your healthcare provider to make sure that Adempas is right for you
- Read the *Guide for Female Patients* (this guide)
- Ask your healthcare provider any questions that you have about Adempas and the Adempas REMS
- Agree to all the requirements of the Adempas REMS
- Complete and sign the *Patient Enrollment and Consent Form* with your healthcare provider

To enroll you in the Adempas REMS, your healthcare provider will send in your *Patient Enrollment and Consent Form*. The Adempas REMS will keep your information in a secure and validated database.

V. What are the Adempas REMS requirements for me?

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:

- Receive counseling from your prescriber on the risk of serious birth defects (Pre-menopausal only)
- Tell your prescriber if your ability to become pregnant changes
- If you are over the age of 8: Be monitored to see if your ability to become pregnant changes and immediately contact your prescriber if you begin to menstruate.

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
- 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)

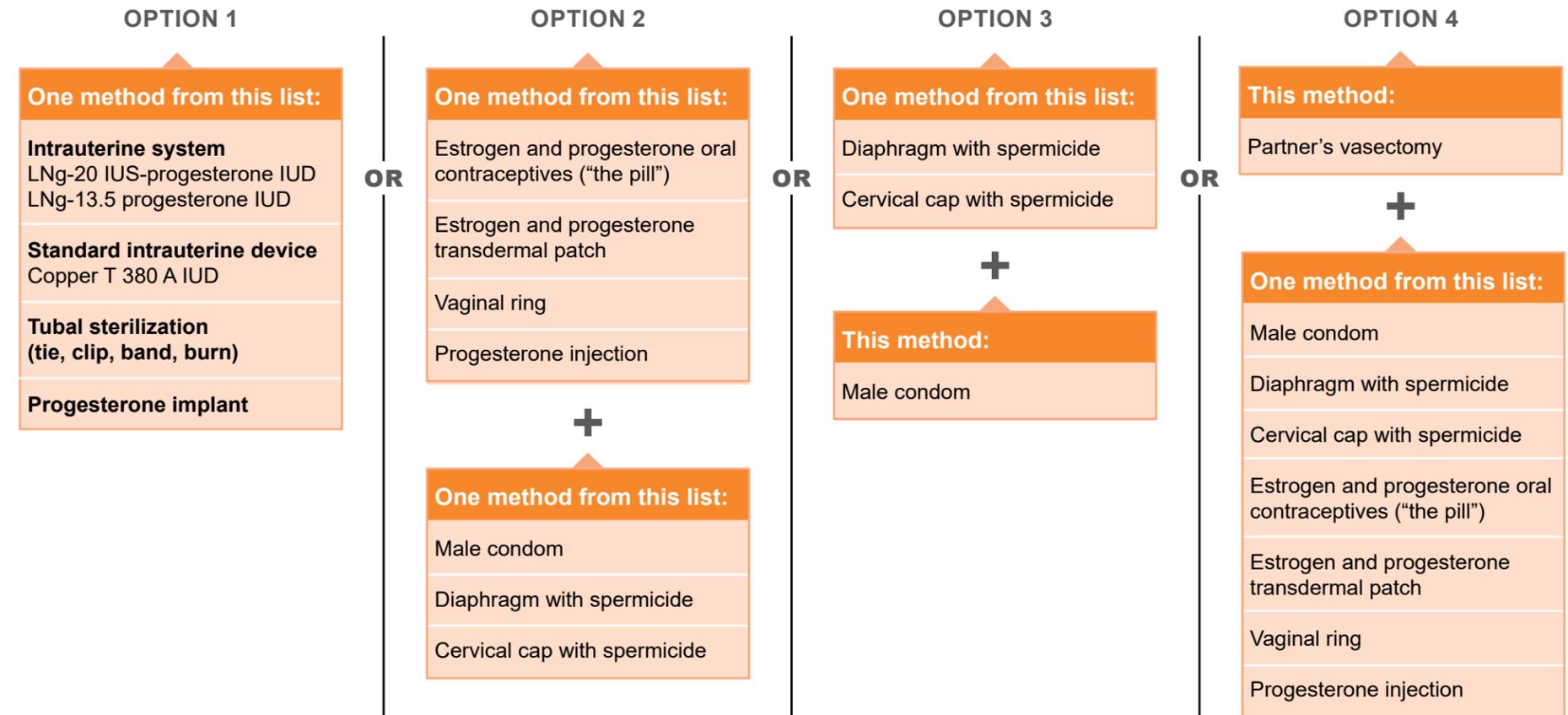
If you are a female who can get pregnant, to receive Adempas you must:

- Receive counseling from your prescriber on the risks and benefits of Adempas
- 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
 - o Your healthcare provider will order the pregnancy tests for you
 - o Your pharmacy will call you every month to:
 - ask if you have taken a pregnancy test in the last month
 - remind you to use effective birth control
 - o 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 effective forms of birth control during Adempas treatment and for one month after stopping treatment with Adempas
 - o Do not have unprotected sex.
 - o Use the birth control options described on page 4 of this guide during your Adempas treatment and for one month after stopping your Adempas treatment.
 - o 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.**
- Talk to your healthcare provider if you have any questions about being a female who is able to get pregnant or about taking Adempas.

VI. What are my birth control options?

If you are a female who can get pregnant, your healthcare provider will talk to you about your options for effective birth control. Use the tables below to help decide what birth control option is best for you.



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 if you are a female who can get pregnant.

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

- Talk with your healthcare provider, nurse, or pharmacist about Adempas.
- For questions about getting your Adempas prescription filled or being in the Adempas REMS, please call the Adempas REMS Coordinating Center at 1-855-4ADEMPAS (1-855-423-3672).

*You may also receive a 30-day supply of Adempas from your doctor when you first start taking Adempas.



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/s/

MARY R SOUTHWORTH
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