

MEDICATION GUIDE
Adempas (a dem pahs)
(riociguat)
tablets

Read this Medication Guide before you start taking Adempas and each time you get a refill. There may be new information. This Medication Guide does not take the place of talking to your doctor about your medical condition or your treatment.

What is the most important information I should know about Adempas?

- **Serious birth defects.**

Adempas can cause serious birth defects if taken during pregnancy.

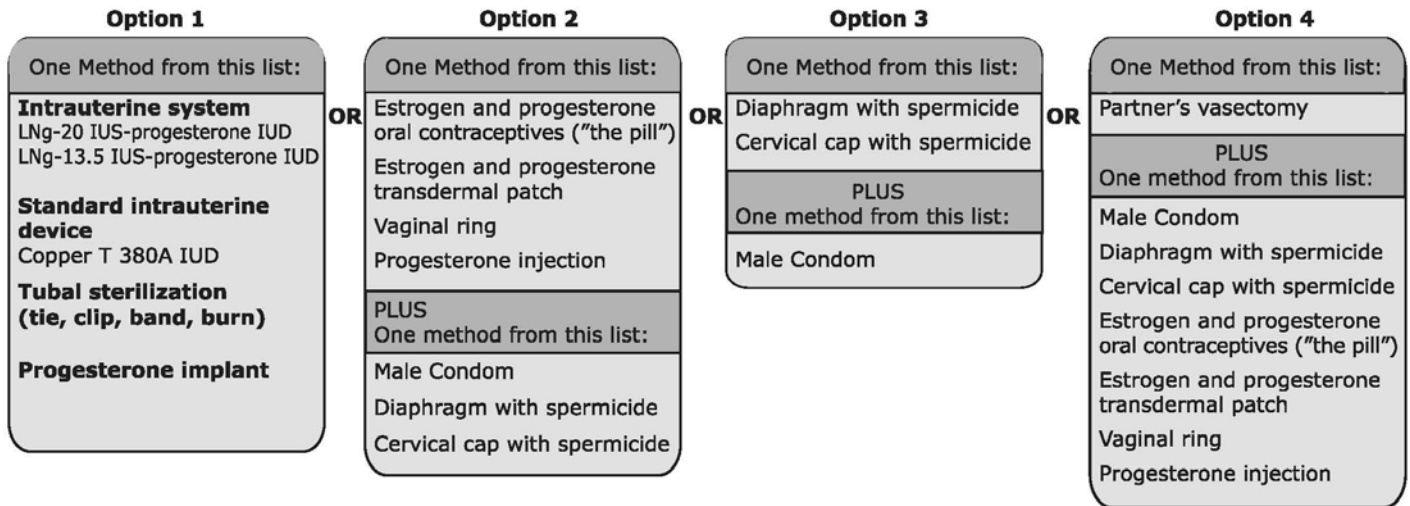
- **Females must not be pregnant when they start taking Adempas or become pregnant during treatment with Adempas.**
- Females who are able to get pregnant must have a negative pregnancy test before beginning treatment with Adempas, each month during treatment, and 1 month after you stop treatment with Adempas. Talk to your doctor about your menstrual cycle. Your doctor will decide when to do the tests, and order the tests for you depending on your menstrual cycle.
 - Females who are able to get pregnant are females who:
 - Have entered puberty, even if they have not started their 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 who have had their ovaries removed)
 - Females who are not able to get pregnant are females who:
 - Have not yet entered puberty, **or**
 - Do not have a uterus, **or**
 - Have gone through menopause (have not had a period for at least 12 months for natural reasons, or who have had their ovaries removed)

Females who are able to get pregnant must use two acceptable forms of birth control, during treatment with Adempas and for one month after stopping Adempas because the medicine may still be in the body.

- If you have had a tubal sterilization, have a progesterone implant, or have an IUD (intrauterine device), these methods can be used alone and no other form of birth control is needed.
- Talk with your doctor or gynecologist (a doctor who specializes in female reproduction) to find out about options for acceptable birth control that you may use to prevent pregnancy during treatment with Adempas.
- If you decide that you want to change the form of birth control that you use, talk with your doctor or gynecologist to be sure that you choose another acceptable form of birth control.

See the chart below for Acceptable Birth Control Options during treatment with Adempas.

Acceptable Birth Control Options



- **Do not have unprotected sex. Talk to your doctor or pharmacist right away if you have unprotected sex or if you think your birth control has failed. Your doctor may talk with you about using emergency birth control.**
- **Tell your doctor right away if you miss a menstrual period or think you may be pregnant for any reason.**

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 any pubic hair. Your doctor should decide if your child has reached puberty. **Your child may reach puberty before having her first menstrual period.**

Females can only receive Adempas through a restricted program called the Adempas Risk Evaluation and Mitigation Strategies (REMS) Program. If you are a female who can become pregnant, you must talk to your doctor, understand the benefits and risks of Adempas, and agree to all of the instructions in the Adempas REMS Program.

Males can receive Adempas without taking part in the Adempas REMS Program.

What is Adempas?

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 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.

Who should not take Adempas?

Do not take Adempas if:

- **you are pregnant, plan to become pregnant, or become pregnant during treatment with Adempas. Adempas can cause serious birth defects.** (See the Medication Guide section above called "What is the most important information I should know about Adempas?")
- **you take:**
 - a nitrate medicine to treat high blood pressure or heart disease, such as nitroglycerin, or a medicine called a nitric oxide donor, such as amyl nitrite
 - certain other medicines that contain sildenafil (Revatio or Viagra), tadalafil (Adcirca or Cialis), vardenafil (Levitra or Staxyn), dipyridamole, or theophylline. Revatio and Adcirca are also used to treat PAH

Ask your doctor or pharmacist if you are not sure if you take any of the medicines listed above.

What should I tell my doctor before taking Adempas?

Before you take Adempas, tell your doctor if you:

- smoke
- have recently had serious bleeding from your lung, or if you have had a medical procedure called bronchial arterial embolization to stop you from coughing up blood
- have problems with your heart or blood circulation
- have low blood pressure
- have liver problems
- have kidney problems or are on dialysis
- have narrowing of the pulmonary veins, a condition called pulmonary veno-occlusive disease or PVOD
- have any other medical conditions

Tell your doctor about all the medicines you take, including prescription and non-prescription medicines, vitamins, and herbal supplements. Adempas and other medicines may affect each other causing side effects. Do not start any new medicine until you check with your doctor.

How should I take Adempas?

Adempas will be provided to you by a certified pharmacy. Your doctor will give you complete details.

- Take Adempas exactly as your doctor tells you. Do not stop taking Adempas or change your dose without talking to your doctor.
- When you begin treatment with Adempas, your blood pressure should be monitored about every 2 weeks to help your doctor decide the correct dose of medicine for you.

- Your doctor may change your dose during treatment, especially when you first start taking Adempas. It is important to tell your doctor if you have any symptoms of low blood pressure during this time, such as dizziness, lightheadedness, or fainting.
- Take Adempas 3 times each day, about 6 to 8 hours apart.
- Take Adempas with or without food.
- **Do not take more than a total of 7.5 mg of Adempas in 1 day unless your doctor tells you to.**
- If you take a heartburn medicine (antacid) that contains aluminum hydroxide or magnesium hydroxide, do not take it within **1 hour of taking Adempas.**
- If you take too much Adempas, call your doctor right away or go to the nearest hospital emergency room.
- If you miss a dose, take your next dose of Adempas at the regular time.
- If you miss 3 or more days of treatment with Adempas, call your doctor for instructions before you restart Adempas.

What should I avoid while taking Adempas?

- **Do not get pregnant** while taking Adempas. (See serious birth defects section of the Medication Guide above called "What is the most important information I should know about Adempas?") If you miss a menstrual period, or think you might be pregnant, call your doctor right away.
- It is not known if Adempas passes into your breast milk. You should not breastfeed if you take Adempas. Talk to your doctor about the best way to feed your baby if you take Adempas.
- Adempas may make you feel dizzy. **Do not drive, operate machinery, or do other activities that require mental alertness or coordination until you know how Adempas affects you.** Talk with your doctor if you are concerned about when it is safe for you to do these activities.
- **Smoking.** Adempas may not work as well if you smoke during treatment. Tell your doctor if you stop smoking **or** start smoking during treatment with Adempas, because your dose of Adempas may need to be changed.

What are the possible side effects of Adempas?

Adempas can cause serious side effects including:

- **Serious birth defects.** (See "What is the most important information I should know about Adempas?")
- **Reduced blood pressure.** Adempas reduces blood pressure. This may cause symptoms of low blood pressure, such as lightheadedness, chest pain, and dizziness especially in people who are dehydrated, or have a severe blockage of blood flow out of the heart, or have certain other medical problems. Your doctor will check you for these problems.
- **Increased risk of bleeding, including bleeding from the respiratory tract.** Tell your doctor right away if you cough up blood during treatment with Adempas.
- **Worsening of symptoms in people with Pulmonary Veno-Occlusive Disease (PVOD).** If you have PVOD, treatment with Adempas may cause a build-up of fluid in your lungs

(pulmonary edema). This may cause you to feel short of breath. Your doctor may tell you to stop taking Adempas and switch you to a different medicine.

The most common side effects of Adempas are:

- headache
- dizziness
- indigestion
- swelling of your hands, legs, feet, and ankles (peripheral edema)
- nausea, diarrhea, and vomiting

Tell your doctor if you have any side effect that bothers you or that does not go away. These are not all the possible side effects of Adempas.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store Adempas?

- Store Adempas at room temperature between 59° F to 86° F (15° C to 30° C)

Keep Adempas and all medicines out of the reach of children.

General Information about Adempas

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use Adempas for a condition for which it is not prescribed. Do not give Adempas to other people, even if they have the same symptoms that you have. It may harm them.

This Medication Guide summarizes the most important information about Adempas. If you would like more information about Adempas, talk with your doctor. You can ask your doctor or pharmacist for information about Adempas that is written for health professionals. For more information go to www.Adempas-us.com or call 1-800-526-4099.

What are the ingredients in Adempas?

Active ingredient: riociguat

Inactive ingredients: cellulose microcrystalline, crospovidone, hypromellose 5cP, lactose monohydrate, magnesium stearate, sodium laurylsulfate, hydroxypropylcellulose, hypromellose 3cP, propylene glycol, titanium dioxide. Adempas 1 mg, 1.5 mg, 2 mg and 2.5 mg tablets also contain ferric oxide yellow. Adempas 2mg and 2.5 mg tablets also contain ferric oxide red.

This Medication Guide has been approved by the U.S. Food and Drug Administration.

Manufactured for:



Bayer HealthCare

Bayer HealthCare Pharmaceuticals Inc.
Whippany, NJ 07981

Manufactured in Germany

Issued Month Year {Applicant, upon approval please add the month and year that the MG is issued. }

