Aim

Adempas®
riociguat tablets
0.5mg | 1mg | 1.5mg | 2mg | 2.5mg

Getting Started On Your Treatment Today

This guide will help you remember important use and safety information about your medication

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Getting to know Adempas

Some facts about your treatment

INDICATION

Adempas is a prescription medicine used to treat adults with:

- chronic thromboembolic pulmonary hypertension (CTEPH) (WHO Group 4) 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 (measured by 6-minute walk distance) and can help to improve some of your symptoms.
- pulmonary arterial hypertension (PAH) (WHO Group 1)
  - PAH is a type of high blood pressure in the arteries of your lungs. Adempas can improve your ability to exercise (measured by 6-minute walk distance), improve some of your symptoms, and help slow down the worsening of your physical condition [this includes death, heart/lung transplant, a surgery to reduce pressure in your lung, hospitalization for worsening of pulmonary hypertension, start of a new PAH-specific treatment, continued decline in your ability to exercise (measured by 6-minute walk distance) and some of your symptoms].

The Adempas clinical studies included mostly patients with WHO functional class II-III symptoms. It is unknown if Adempas is safe and effective in children.

IMPORTANT SAFETY INFORMATION

Adempas can cause serious birth defects if taken during pregnancy.

- **Females must not be pregnant when they start taking Adempas (riociguat) tablets 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 test.
- Females who <u>are able</u> to get pregnant are females who:
  - Have entered puberty, even if they have not started their period, have a uterus, and have not gone through menopause (have not had a period for at least 12 months for natural reasons, or have had their ovaries removed).
- Females who <u>are not able</u> to get pregnant are females who:
  - Have not yet entered puberty, do not have a uterus, or have gone through menopause.

Females who are able to get pregnant must use two acceptable forms of birth control, during Adempas treatment and for one month after stopping Adempas.

- 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 how to prevent pregnancy during treatment with Adempas.
  - **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 tell you to use 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.

Please see additional Important Safety Information, including Boxed Warning, throughout, and full Prescribing Information at http://www.adempas-us.com/PI/

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Getting into your new routine

The basics

- Adempas will be provided to you by a certified pharmacy. Your doctor will give you complete details
- Take Adempas 3 times each day, about 6 to 8 hours apart, with or without food
- If you miss a dose, take your next dose at the regular time
- If you take a heartburn medicine (antacid) that contains aluminum hydroxide or magnesium hydroxide, do not take within **1 hour of taking Adempas**

morning

midday

evening

Dose adjustments

Starting dose
0.5 mg or 1 mg

During the first weeks

Your doctor may increase your dose

When you begin treatment, your blood pressure should be monitored about every 2 weeks to help your doctor decide the correct dose of medicine for you

Available dosage forms and strengths	0.5 mg	1 mg	1.5 mg	2 mg	2.5 mg

Do not take more than a total of 7.5 mg of Adempas in one day unless your doctor tells you to

Do not take Adempas within 24 hours of sildenafil. Do not take Adempas 24 hours before or within 48 hours after tadalafil.

However, always take Adempas exactly as your doctor tells you. Don't stop taking it or change your dose without talking to your doctor.

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.**
- **you take:**
  - another medicine called a soluble guanylate cyclase stimulator (sGC). Ask your healthcare provider if you are not sure if you are taking an sGC medicine
  - 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
- **you have pulmonary hypertension associated with idiopathic interstitial pneumonias (PH-IIP).**

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

Before you take Adempas, tell your doctor if you:

- smoke; have recently had serious bleeding from your lungs, 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.

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Call your doctor if

- You have symptoms of low blood pressure such as dizziness, lightheadedness, or fainting
- You ever experience any side effects
- You take too much Adempas
- You miss 3 or more days of Adempas
- You stop smoking or start smoking
- You are a female patient and miss a menstrual period, think you may be pregnant, or have questions about feeding your baby (it is not known if Adempas passes into your breast milk)

Always take Adempas exactly as your doctor tells you. Don't stop taking it or change your dose without talking to your doctor.

What should I avoid while taking Adempas?

- **Do not get pregnant** while taking 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.

Call toll-free: **1-855-4ADEMPAS** (1-855-423-3672)
Or visit: **Adempas-US.com** for more information

Adempas can cause serious side effects including:

- **Serious birth defects.**
- **Reduced blood pressure.** This may cause symptoms of low blood pressure, such as lightheadedness, chest pain, and dizziness especially in people who are dehydrated, have a severe blockage of blood flow out of the heart, or have certain other medical problems. Your doctor will check you for any of 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) which may result in shortness 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.

For important risk and use information, please see the full Prescribing Information, including Boxed Warning at http://www.adempas-us.com/PI/

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