RIOCIGUAT

0.5 mg, 1 mg, 1.5 mg, 2 mg, and 2.5 mg tablets

DOSE TRACKER

INDICATIONS AND IMPORTANT SAFETY INFORMATION INCLUDING BOXED WARNING

WARNING: EMBRYO-FETAL TOXICITY

Riociguat is contraindicated for use during pregnancy because it may cause fetal harm based on animal data.

Exclude pregnancy prior to the start of treatment with Riociguat. Advise use of effective contraception prior to initiation of treatment, during treatment, and for one month after treatment with Riociguat.

If pregnancy is detected, discontinue Riociguat as soon as possible.

Please turn the page for important risk and use information, or scan the QR code above for our full Prescribing Information, including Boxed Warning and Medication Guide.

To help you stay compliant with your Riociguat tablet dosing, you can use this dose tracker to check off when you take your medication.

While Riociguat tablets are generally taken three times a day, you should always take your medication as prescribed by your healthcare provider. If you miss a dose, take your next dose at the next regularly scheduled time.

Riociguat can cause serious birth defects if taken during pregnancy. Females must not be pregnant when they start taking Riociguat or become pregnant during treatment with Riociguat. See Boxed Warning and Important Safety Information through the QR code at the top of this dose tracker and consult with your care team to discuss appropriate steps to take to avoid pregnancy while taking Riociguat.

Call your doctor for medical advice about side effects. **SUSPECTED ADVERSE REACTIONS**, contact Zydus Pharmaceuticals (USA) Inc. at **1-877-993-8779** or FDA at **1-800-FDA-1088** or **www.fda.gov/medwatch**.

Please see accompanying full Prescribing Information, including Boxed Warning, and Medication Guide, also available at the QR Code:

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zydus Pharmaceuticals USA

INDICATIONS

Riociguat 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
- pulmonary arterial hypertension (PAH) (WHO Group 1)

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

IMPORTANT SAFETY INFORMATION

Riociguat can cause serious birth defects if taken during pregnancy.

- **Females must not be pregnant when they start taking Riociguat tablets or become pregnant during treatment with Riociguat.**
- **Females who are able to get pregnant must have a negative pregnancy test before beginning treatment with Riociguat, each month during treatment, and 1 month after you stop treatment with Riociguat. Talk to your doctor about your menstrual cycle. Your doctor will decide when to do the test.**
- Females who are able 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 are not able 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 Riociguat treatment and for one month after stopping Riociguat.

- If you have had a tubal sterilization, hysterectomy, 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 Riociguat.
  - **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 Riociguat 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.**

Do not take Riociguat if:

- **you are pregnant, plan to become pregnant, or become pregnant during treatment with Riociguat. Riociguat 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 Riociguat, 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. Riociguat and other medicines may affect each other causing side effects. Do not start any new medicine until you check with your doctor.

What should I avoid while taking Riociguat?

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

Riociguat 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 Riociguat.
- **Worsening of symptoms in people with Pulmonary Veno-Occlusive Disease (PVOD).** If you have PVOD, treatment with Riociguat 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 Riociguat and switch you to a different medicine.

The most common side effects of Riociguat are:

- Headache; indigestion; inflammation of the stomach; dizziness; nausea; diarrhea; low blood pressure; anemia; 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 Riociguat.

Call your doctor for medical advice about side effects. You are encouraged to report side effects of prescription drugs to the FDA. Visit
www.fda.gov/medwatch or call 1-800-FDA-1088.

For important risk and use information please see the full Prescribing Information, including Boxed Warning and Medication Guide at (riociguat website).