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

Dosing and Administration

Adempas has been prescribed to more than 33,000 patients[1]*

*Prescriptions written do not equate to prescriptions fulfilled.

Personalized dosing for your patients

Recommended starting dose

Start with 1 mg taken 3x a day

- For patients who may not tolerate the hypotensive effects of Adempas, consider a starting dose of 0.5 mg taken 3x a day

Titration through maintenance

Individualized dose adjustments

- ▲ If systolic blood pressure remains >95 mm Hg and the patient has no signs or symptoms of hypotension, up-titrate the dose by 0.5 mg. Dose increases should be no sooner than 2 weeks apart. The dose can be increased to the highest tolerated dosage, up to a maximum of 2.5 mg taken 3x a day
- ▼ If at any time the patient has symptoms of hypotension, decrease the dosage by 0.5 mg

INDICATION

- Adempas (riociguat) is indicated for the treatment of adults with persistent/recurrent chronic thromboembolic pulmonary hypertension (CTEPH (WHO Group 4) after surgical treatment or inoperable CTEPH to improve exercise capacity and WHO functional class.
- Adempas is indicated for the treatment of adults with pulmonary arterial hypertension (PAH) (WHO Group 1) to improve exercise capacity, improve WHO functional class, and to delay clinical worsening.*

Efficacy was shown in patients on Adempas monotherapy or in combination with endothelin receptor antagonists or prostanoids. Studies establishing effectiveness included predominantly patients with WHO functional class II–III and etiologies of idiopathic or heritable PAH (61%) or PAH associated with connective tissue diseases (25%).

*Time to clinical worsening was a combined endpoint defined as death (all-cause mortality), heart/lung transplantation, atrial septostomy, hospitalization due to persistent worsening of pulmonary hypertension, start of new PAH-specific treatment, persistent decrease in 6MWD, and persistent worsening of WHO functional class.

Are your patients unable to swallow whole tablets?

Adempas may be crushed and mixed with water or soft foods (such as applesauce) immediately before administration.

Crushed and mixed with water

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Transitioning your patients from or to Adempas

To Adempas from sildenafil or tadalafil

Before administering Adempas:

- Discontinue sildenafil for at least 24 hours
- Discontinue tadalafil for at least 48 hours. Consider initiating Adempas at a starting dose of 0.5 mg in patients at risk of hypotension. Monitor for signs and symptoms of hypotension on initiation

To a PDE-5 inhibitor from Adempas

Before administering Adempas:

- Discontinue Adempas for at least 24 hours. Monitor for signs and symptoms of hypotension on initiation

IMPORTANT SAFETY INFORMATION

WARNING: EMBRYO-FETAL TOXICITY

Do not administer Adempas (riociguat) tablets to a pregnant female because it may cause fetal harm.

Females of reproductive potential: Exclude pregnancy before the start of treatment, monthly during treatment, and one month after stopping treatment. To prevent pregnancy, females of reproductive potential must use effective forms of contraception during treatment and for one month after stopping treatment.

For all female patients, Adempas is available only through a restricted program called the Adempas Risk Evaluation and Mitigation Strategy (REMS) Program.

Dosage considerations:

Dosage interruption

- If a dose is missed, advise patients to continue with the next regularly scheduled dose
- In case Adempas is interrupted for 3 days or more, re-titrate Adempas

Pregnancy testing in females of reproductive potential

- Obtain pregnancy tests prior to start of treatment and monthly during treatment

Use in patients who smoke

- Consider titrating to dosages higher than 2.5 mg 3x a day, if tolerated, in patients who smoke. A dose decrease may be required in patients who stop smoking

Strong CYP and P-gp/BCRP inhibitors

- Consider a starting dose of 0.5 mg, 3x a day when initiating Adempas in patients receiving strong cytochrome P450 (CYP) and P-glycoprotein/breast cancer resistance protein (P-gp/BCRP) inhibitors such as azole antimycotics (for example, ketoconazole, itraconazole) or HIV protease inhibitors (for example, ritonavir). Monitor for signs and symptoms of hypotension on initiation and on treatment with strong CYP and P-gp/BCRP inhibitors

FROM INITIATION TO TITRATION,

Bayer is committed to providing resources like the AIM Support Program to help adult patients get the treatment they prefer

Nursing services for your patients are available every step of the way.

Click here to learn more about the patient support program.

Please see additional Important Safety Information, including Boxed Warning, on second page. The full Prescribing Information and Medication Guide can be accessed at: https://labeling.bayerhealthcare.com/html/products/pi/Adempas_PI.pdf.

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For all female patients, Adempas is available only through a restricted program called the Adempas Risk Evaluation and Mitigation Strategy (REMS) Program.

CONTRAINDICATIONS

Adempas is contraindicated in:

- Pregnancy. Based on data from animal reproduction studies, Adempas may cause fetal harm when administered to a pregnant woman and is contraindicated in females who are pregnant. Adempas was consistently shown to have teratogenic effects when administered to animals. If this drug is used during pregnancy, or if the patient becomes pregnant while taking this drug, the patient should be apprised of the potential hazard to the fetus.
- Co-administration with nitrates or nitric oxide donors (such as amyl nitrite) in any form.
- Concomitant administration with specific phosphodiesterase (PDE)-5 inhibitors (such as sildenafil, tadalafil, or vardenafil) or nonspecific PDE inhibitors (such as dipyridamole or theophylline) is contraindicated. Do not administer within 24 hours of sildenafil. Do not administer 24 hours before or within 48 hours after tadalafil.
- Patients with concomitant use of other soluble guanylate cyclase (sGC) stimulators.
- Patients with Pulmonary Hypertension associated with Idiopathic Interstitial Pneumonias (PH-IIP).

WARNINGS AND PRECAUTIONS

Embryo-Fetal Toxicity. Based on data from animal reproduction studies, Adempas may cause embryo-fetal toxicity when administered to a pregnant female and is contraindicated in females who are pregnant. Advise females of reproductive potential of the potential risk to a fetus. Obtain a pregnancy test before the start of treatment, monthly during treatment, and for one month after stopping treatment. Advise females of reproductive potential to use effective contraception during treatment with Adempas and for at least one month after the last dose.

For females, Adempas is only available through a restricted program under the Adempas REMS Program.

Adempas REMS Program. Females can only receive Adempas through the Adempas REMS Program, a restricted distribution program.

Important requirements of the Adempas REMS Program include the following:

- Prescribers must be certified with the program by enrolling and completing training.
- All females, regardless of reproductive potential, must enroll in the Adempas REMS Program prior to initiating Adempas. Male patients are not enrolled in the Adempas REMS Program.
- Female patients of reproductive potential must comply with the pregnancy testing and contraception requirements.
- Pharmacies must be certified with the program and must only dispense to patients who are authorized to receive Adempas.

Further information, including a list of certified pharmacies, is available at www.AdempasREMS.com or 1-855-4ADEMPAS.

Hypotension. Adempas reduces blood pressure. Consider the potential for symptomatic hypotension or ischemia in patients with hypovolemia, severe left ventricular outflow obstruction, resting hypotension, autonomic dysfunction, or concomitant treatment with antihypertensives or strong CYP and P-gp/BCRP inhibitors. Consider a dose reduction if patient develops signs or symptoms of hypotension.

Bleeding. In the placebo-controlled clinical trials, serious bleeding occurred in 2.4% of patients taking Adempas compared to 0% of placebo patients. Serious hemoptysis occurred in 5 (1%) patients taking Adempas compared to 0 placebo patients, including one event with fatal outcome. Serious hemorrhagic events also included 2 patients with vaginal hemorrhage, 2 with catheter-site hemorrhage, and 1 each with subdural hematoma, hematemesis, and intra-abdominal hemorrhage.

Pulmonary Veno-Occlusive Disease. Pulmonary vasodilators may significantly worsen the cardiovascular status of patients with pulmonary veno-occlusive disease (PVOD). Therefore, administration of Adempas to such patients is not recommended. Should signs of pulmonary edema occur, the possibility of associated PVOD should be considered and if confirmed, discontinue treatment with Adempas.

MOST COMMON ADVERSE REACTIONS

The most common adverse reactions occurring more frequently (≥3%) on Adempas than placebo were headache (27% vs 18%), dyspepsia/gastritis (21% vs 8%), dizziness (20% vs 13%), nausea (14% vs 11%), diarrhea (12% vs 8%), hypotension (10% vs 4%), vomiting (10% vs 7%), anemia (7% vs 2%), gastroesophageal reflux disease (5% vs 2%), and constipation (5% vs 1%).

Other events that were seen more frequently in Adempas compared to placebo and potentially related to treatment were palpitations, nasal congestion, epistaxis, dysphagia, abdominal distension, and peripheral edema.

Please see additional Important Safety Information, including Boxed Warning. The full Prescribing Information and Medication Guide can be accessed at: https://labeling.bayerhealthcare.com/html/products/pi/Adempas_PI.pdf.

References: 1. Daily Metric Report Data on file. United Biosource Corporation. Accessed January 30, 2026. **2.** Adempas Prescribing Information. Whippany, NJ. Bayer Pharmaceuticals Inc., 2023.

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