Adempas Hospital Program Checklist

We have received the enrollment request for your Adempas hospital patient. In order to maintain continuity of care and allow your patient who has started on Adempas in-hospital to continue treatment upon discharge, please complete this checklist and fax it to us at 1-855-662-5200.

Please check for patient signatures prior to sending. Fax this completed form to the Aim Coordination Center at 1-855-662-5200.

Hospital contact information

Type of facility: ☐Hospital ☐ Long-term Care Facility ☐ Prison ☐ Other_____		NPI:
Facility name:		
Address line 1:	Address line 2:	
City:	State:	Zip code:
Phone:	Fax:	Email:

In-hospital patient contact information

Please provide the appropriate hospital contact for the patient (this could be the patient's treating physician, nurse, case manager, clinic manager, other).

Healthcare professional name and title:

Patient name:

This information is optional and patient must consent to and provide this information.	Patient cell phone number:
	Alternate family member name and contact number (if available):

When did or when will the patient receive his or her first dose of Adempas? (MM/DD/YYYY):

When is the potential discharge date of the patient? (MM/DD/YYYY):

For all patients, please fax

- The Prescription and Patient Enrollment Form (Sections A, B, C are required; Sections D and E are optional) ☐
- REMS Patient Enrollment Form (females only) ☐
- Hospital Face Sheet (if available) ☐
- Insurance card copy (front and back) ☐

Authorized representative acknowledgment

- ☐ Nurse
- ☐ Physician
- ☐ Physician's Assistant
- ☐ Other _____

REQUIRED	Authorized Representative Signature:	Date (MM/DD/YYYY):

After we receive the checklist, your patient will be triaged to the Specialty Pharmacy in order to set up a shipment. Please note the pharmacy will need to speak to the patient or appointed patient representative to set up shipment to his or her home. You may also be asked to provide a medication list to the Specialty Pharmacy.

To report any adverse events, product technical complaints, medication errors or pregnancies associated with the use of Adempas, contact Bayer at 1-888-842-2937, or send the information to DrugSafety.GPV.US@bayer.com.

Please see Important Safety Information, including Boxed Warning, on the next page, and the full Prescribing Information at http://www.adempas-us.com/PI/.

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

Phone: 1-855-4ADEMPAS (1-855-423-3672) www.adempasREMS.com Fax: 1-855-662-5200

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INDICATIONS

- Adempas (riociguat) tablets 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.

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.

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.

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