

# Adempas Prescription and Patient Support Program Enrollment Form For V.A. Patients

Complete this form which is available at [www.adempas-us.com](http://www.adempas-us.com). Prescribers and all female patients must be enrolled in the Adempas REMS Program prior to initiating treatment. Please visit [www.AdempasREMS.com](http://www.AdempasREMS.com) to access the Adempas REMS materials including the Adempas REMS Patient Enrollment and Consent Form, and fax to the Adempas Program at 1-855-662-5200 or send electronically by visiting [www.adempasREMS.com](http://www.adempasREMS.com).

## A. Contact Information (\* indicates required field)

Patient First Name*:		Patient Middle Initial:	Patient Last Name*:		Birthdate* (MM/DD/YYYY):	Gender*: <input type="checkbox"/> Male <input type="checkbox"/> Female
Address*:	City*:	State*:	Zip Code*:	Preferred Phone*:	Email:	
Prescriber First Name*:			Prescriber Last Name*:			NPI*:
Address Line 1*:			Address Line 2*:		City:	State: Zip Code:
Office Contact:			Phone:		Fax:	

## B. Patient Information (\* indicates required field)

### Please check one ICD-10 Code\*:

<b>Pulmonary arterial hypertension</b> <input type="checkbox"/> I27.0 <input type="checkbox"/> I27.21	<b>Chronic thromboembolic pulmonary hypertension</b> <input type="checkbox"/> I27.24 <input type="checkbox"/> Inoperable <input type="checkbox"/> Persistent/Recurrent	<input type="checkbox"/> <b>OTHER (please specify)</b> _____
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### Therapy Status:

- Initial therapy (monotherapy or in combination)  
 Add-on therapy  
 Transition from other therapy

## C. Prescription (\* indicates required field)

Note: NY Prescribers please submit prescription on an original NY State prescriptions blank. For all other States, send on a State-specific prescription blank if applicable for your State.

I certify that the above information provided is accurate to the best of my knowledge. I appoint the Adempas AIM Program, on my behalf, to convey this prescription to the dispensing pharmacy. I understand that I may not delegate signature authority.

<input type="checkbox"/> Adempas 1 mg tablet by mouth three times a day <input type="checkbox"/> Adempas 0.5 mg tablet by mouth three times a day Quantity: <input type="checkbox"/> 30 day supply <input type="checkbox"/> Other: _____ Refills: _____ Deliver to: <input type="checkbox"/> Patient Home <input type="checkbox"/> V.A. Pharmacy (address listed below) V.A. Pharmacy Name: _____ Department: _____ Attention: _____ Address Line 1: _____ Address Line 2: _____ City: _____ State: _____ Zip code: _____ Phone: _____ Fax Number: _____	<p><b>Please check box for all dosages to be incorporated:</b></p> <input type="checkbox"/> Based on patient's response per clinical evaluation of the physician or the nurse in consultation with the physician, the pharmacy is to provide the Adempas strength to accommodate titration needs of therapy. Adempas Tablets: 0.5 mg, 1 mg, 1.5 mg, 2 mg, 2.5 mg Directions: If systolic blood pressure is >95 mmHg and there are no signs/symptoms of hypotension, up titrate by 0.5 mg 3 times per day at intervals no sooner than 2 weeks to the highest tolerated dosage up to a maximum of 2.5 mg 3 times per day. If at any time, the patient has symptoms of hypotension, decrease the dosage by 0.5 mg 3 times daily. The established individual dose should be maintained. <b>Other special instructions:</b> _____ _____ _____ Quantity: <input type="checkbox"/> 30 day supply <input type="checkbox"/> Other: _____ Refills: _____	<p><b>Patient please select an option below*:</b></p> <input type="checkbox"/> <b>Healthcare nurse interactions (During the interaction, the healthcare nurse will assess the general well-being of the patient. This includes but is not limited to blood pressure, other vital signs, and tolerance to drug.)</b> <input type="checkbox"/> Patient will be seen in this physician's office for assessment and titration Include other special instructions: _____ _____ _____
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**PRESCRIBER SIGNATURE REQUIRED**

Dispense as Written\*:

Substitutions Permitted\*:

Date\*:

Date\*:

## D. Patient Support Program Enrollment

Bayer offers patient support services for Adempas patients that include: (A) nurses to support you in starting therapy and achieving your optimal dose and (B) education about CTEPH and/or PAH as well as helpful tips for managing your Adempas therapy ("myAIM"). These Programs are entirely optional and you may enroll in one or all of these Programs. To enroll in myAIM, you will need to sign a HIPAA authorization in order for your healthcare provider and/or pharmacy to share your protected healthcare information with Bayer and the myAIM Program administrator.

You will remain enrolled in each Program that you select unless you opt-out either by contacting myAIM via telephone at 1-855-423-3672 or by written notification sent to: 200 Pinecrest Plaza, Morgantown WV 26505, or until your HIPAA Authorization expires. These services are not a part of endorsed by or administered by the U.S. Department of Veterans Affairs.

Enroll me in:  A: Nursing  B: Educational Information

Patient - please initial here to confirm your optional elections: \_\_\_\_\_

## E. Written Permission to Share Protected Health Information

I authorize my healthcare providers, pharmacies, and health plan insurers to share my name, address and phone number; along with my prescription, treatment and insurance information with Bayer and its agents to 1) communicate with my healthcare providers, insurers and myself, 2) to provide education materials ("myAIM") support services, including providing Adempas to me, and 3) to allow Bayer to learn how well the Adempas Patient Support Program is working. I understand that Bayer will pay certain providers, such as my pharmacy to receive this information about me.

This authorization will expire in ten (10) years after the date I sign unless a shorter period is mandated by state law or I revoke or cancel my authorization before then. I may cancel at any time by writing to 200 Pinecrest Plaza, Morgantown, WV 26505. Cancellation does not apply to information already received. Once my information is disclosed to Bayer it will no longer be protected by federal privacy laws or as dictated by applicable state law and may be given out (re-disclosed) by Bayer. **I may refuse to sign this written permission to share information and refusal will not affect my treatment, medication coverage, or eligibility for benefits.** I will not, however, be able to receive educational materials and coordination support of the Adempas Patient Support Program. I am entitled to receive a copy of this authorization.

Patient or Parent/Guardian Signature:

Date:

F. Please provide this form, and for female patients also provide the Adempas REMS Patient Enrollment and Consent Form to the VA pharmacy.

The VA pharmacy should submit the documents to the Adempas Program via fax 1-855-662-5200 or send electronically by visiting [www.adempasREMS.com](http://www.adempasREMS.com).

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](mailto:DrugSafety.GPV.US@bayer.com).

Please see next page for Indications and Important Safety Information, including Boxed Warning



# INDICATIONS AND IMPORTANT SAFETY INFORMATION

## 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 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](http://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 ( $\geq 3\%$ ) 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 see the full Prescribing Information, including Boxed Warning.**