# Adempas Patient Enrollment and Consent Form

**Enroll patient in Lab Coordination Program:** ☐ Yes ☐ No

**Access this form online at www.adempasREMS.com, or fax this form to the Adempas Program at 1-855-662-5200**

## 1 Patient Information (* indicates required field)

First Name*: | Middle Initial: | Last Name*: | Birthdate*(MM/DD/YYYY): | Gender*: ☐ Male ☐ Female

Address Line 1*: | Address Line 2:

City*: | State*: | Zip code*:

Preferred Phone*: | Can we leave a message on this phone? ☐ Yes ☐ No | Preferred Time to Contact: Day Evening

Alternate Phone: | Email:

Alternate Contact Name: | Phone: | Relationship:

Does the patient have medical insurance*? ☐ Yes ☐ No Does the patient have prescription coverage*? ☐ Yes ☐ No
***Provide all patient insurance information, including drug benefits (front and back) with this form.**

## 2 Female Patient Agreement

**For all Females:** I acknowledge that I understand that Adempas is only available through a restricted distribution program under an FDA-required Risk Evaluation and Mitigation Strategy (REMS).

**For Females Who Can Get Pregnant:** I acknowledge that I have been counseled on the risks of Adempas, including the risk of serious birth defects. I have read the *Adempas Medication Guide* and the *Adempas REMS Guide for Females Who Can Get Pregnant*. I understand that I will be contacted by Bayer and/or its agents and contractors to receive counseling on the risk of serious birth defects, the need to use reliable contraception during Adempas treatment and for one month after stopping Adempas treatment, and the importance of not becoming pregnant; and to ensure that I have completed pregnancy testing before I started Adempas, monthly before each refill, and for one month after stopping Adempas. I agree to be counseled each month by the pharmacy on the need to use reliable contraception during Adempas treatment and for one month after stopping Adempas. I understand that I must immediately contact my healthcare provider if I miss a menstrual period or suspect that I am pregnant and that I may be contacted by Bayer and/or its agents and contractors to obtain information about my pregnancy.

**For Pre-Pubertal Females:** I acknowledge that I have been counseled on the risks of Adempas, including the risk of serious birth defects, and that I have read the *Adempas Medication Guide*. I understand that I must immediately contact my healthcare provider if I get my menstrual period.

**For Post-Menopausal Females:** I acknowledge that I have received and read the *Adempas Medication Guide*.

**REQUIRED FOR ALL FEMALE PATIENTS** | Patient or Parent/Guardian Signature: | Date:

## 3 Prescriber Information (* indicates required field)

First Name*: | Last Name*: | NPI*:

Practice/Facility Name (where you see this patient):

Address Line 1*: | Address Line 2:

City: | State: | Zip code: | Phone*: | State License #:

## 4 PRESCRIPTION (* indicates required field)

**Prescription is only valid if faxed. Note: NY Prescribers please submit prescription on an original NY State prescription blank, for all other States, if not faxed, must be on State-specific blank if applicable for your State.**

**Initial dose*:**

☐ Adempas 1 mg tablet by mouth three times a day

☐ Adempas 0.5 mg tablet by mouth three times a day

Quantity:

☐ 30 day supply

☐ Other _____

Refills:

**Titration schedule:**

☐ **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.**

Strength: Adempas 0.5 mg Adempas 1 mg Adempas 1.5 mg Adempas 2 mg Adempas 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.

☐ Other special instructions: _____

Quantity: ☐ 30 day supply ☐ Other _____ Refills:

Check which option below is to be followed for this patient during the titration period

**Select either home healthcare nurse visits are authorized or patient will be seen in this physician's office for assessment and titration*:**

☐ Home healthcare nurse visits (During the home visit, the home 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.)

☐ Patient will be seen in this physician's office for assessment and titration

Deliver to: ☐ Patient Home (address listed above) ☐ Prescriber Office (address listed above)

## 5 Prescriber Authorization

**REQUIRED FOR ALL FEMALE PATIENTS**

**For female patients, please indicate the patient's current reproductive status below (please see definitions of these terms on the following page)**

Female of Reproductive Potential

If this patient is a Female of Reproductive Potential, has a pregnancy test been completed prior to prescribing Adempas? ☐ Yes ☐ No

Female of Non-Reproductive Potential (choose one below)

☐ Pre-Pubertal Female ☐ Female of Non-Reproductive Potential

I certify that the above therapy is medically necessary and that the information provided is accurate to the best of my knowledge. I certify that for female patients, I have provided the appropriate counseling and Adempas REMS materials, and I will continue to fulfill my obligations under the Adempas REMS Program. I appoint the Adempas REMS Program, on my behalf, to convey this prescription to the dispensing pharmacy. I understand that I may not delegate signature authority. I authorize the Lab Coordination Program to order laboratory tests on my behalf for patients enrolled in the Adempas REMS Program based on the orders I will provide. I understand that it is not the responsibility of the Lab Coordination Program to review or interpret laboratory test results or to provide patient care or patient counseling.

**REQUIRED** | Prescriber Signature*: | Date*:

First Name*:_____ Last Name*:_____ Birthdate* (MM/DD/YYYY):_____

**5 Prescriber Authorization (continued)**

Definitions:

Females of Reproductive Potential

- Females of reproductive potential include girls who have entered puberty and all females who have a uterus and have not passed through menopause (as defined below).
- For the purposes of this REMS, puberty includes those girls who are at least Tanner Stage 3 and have not yet had a menses (premenarchal).

Females of Non-Reproductive Potential

- Pre-Pubertal Females: Females who are at Tanner Stages 1 and 2 are not considered to be of reproductive potential.
- Post-Menopausal Females: Females who have passed through menopause (as defined below).

Definition of Menopause

- Menopause is defined as 12 months of spontaneous amenorrhea (not amenorrhea induced by a medical condition or medical therapy) or post-surgical from bilateral oophorectomy.

Prescriber Obligations under the Adempas REMS Program

For All Females

- I acknowledge that I have counseled the patient (and parent/guardian when appropriate) that Adempas is only available through a restricted distribution program under an FDA-required REMS.
- I will evaluate the patient and agree to document any change in reproductive status by completing and submitting an *Adempas REMS Reproductive Potential Status Form* within 10 business days of becoming aware of the change.

For Females of Reproductive Potential

- I acknowledge that I have counseled the patient (and parent/guardian when appropriate) on the risks of Adempas, including the risk of serious birth defects, and that I have reviewed the *Adempas Medication Guide* and the *Adempas REMS Guide for Females Who Can Get Pregnant* with the patient (and parent/guardian when appropriate).
- I will order and review pregnancy tests prior to initiation of Adempas treatment, monthly during treatment, and for one month after stopping treatment in accordance with the Adempas REMS Program.

For Pre-Pubertal Females

- I acknowledge that I have counseled the patient and parent/guardian on the risks of Adempas, including the risk of serious birth defects, and that I have reviewed the *Adempas Medication Guide* with the patient and parent/guardian.
- I will evaluate the patient's reproductive status, verify reproductive status annually for Pre-Pubertal Females who are at least 8 years of age and older, and agree to report any change in reproductive status on an *Adempas REMS Reproductive Potential Status Form* within 10 business days of becoming aware of the change.

**6 Statement of Medical Necessity (* indicates required field)**

**The following does not suggest approved uses or indications.**

**Diagnosis*:**

☐ Chronic thromboembolic pulmonary hypertension
- ☐ inoperable
- ☐ after surgical treatment

☐ Pulmonary arterial hypertension

☐ Other

Pulmonary hypertension status*: ☐ Newly diagnosed ☐ Previously diagnosed

**ICD-9 Code*:**

☐ 416.0 (Primary pulmonary hypertension)

☐ 416.8 (Other chronic pulmonary heart diseases, e.g. pulmonary hypertension, secondary)

☐ 416.9 (Chronic pulmonary heart disease, unspecified)

☐ **Other (specify):**_____

**7 Written Permission to Share 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 relating to my use or need for Adempas with Bayer and its agents and contractors (collectively "Bayer"). I understand that certain healthcare providers, such as my pharmacies, will receive payment from Bayer in connection with the disclosure of my information as I allow through this authorization.

I allow my information to be shared with Bayer so that it may: 1) communicate with me, my healthcare providers and health plans about my medical care; 2) provide support services, including providing Adempas to me and planning laboratory testing for me; 3) learn how well Adempas, the Adempas REMS, or Adempas Program is working; and 4) contact me so that I may receive educational materials about Adempas, the Adempas REMS, or the Adempas Program.

This authorization expires at the end of my participation in the Adempas Program or 10 years after the date I sign it if earlier. I can cancel this authorization earlier by writing to 200 Pinecrest Plaza, Morgantown, WV 26505. The cancellation will not apply to information already released by my healthcare providers, pharmacies, and health plans and before they learn about my cancellation. Once my information is disclosed to Bayer it will no longer be protected by federal privacy laws and my information may be given out (re-disclosed) by Bayer. However, I understand that Bayer will make every effort to keep my information confidential and only use and share it for the purposes stated in this authorization. I may refuse to sign this form, and this refusal will not affect my treatment, payment for treatment, enrollment in a health plan, or eligibility for benefits. However, if I refuse, I know that this means I may no longer be able to receive assistance from the Adempas Program. I understand I am entitled to receive a copy of this authorization once signed.

| REQUIRED FOR ALL PATIENTS | Patient or Parent/Guardian Signature*: | Date*: |
|---|---|---|

**8 Submit this form online at www.adempasREMS.com or fax this form to 1-855-662-5200**

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.

Adempas® (riociguat) tablets