# Adempas REMS Patient Enrollment and Consent Form

**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 |
|---|---|---|

| Cell/Alternate Phone: | Email: |
|---|---|

| Alternate Contact Name: | Phone: | Relationship: |
|---|---|---|

## 2 Statement of Medical Necessity (* indicates required field)

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

**Diagnosis*:**

☐ Chronic thromboembolic pulmonary hypertension (inoperable)
☐ Chronic thromboembolic pulmonary hypertension (after surgical treatment)
☐ Pulmonary arterial hypertension
☐ Other

Pulmonary hypertension status: ☐ Newly diagnosed ☐ Previously diagnosed

## 3 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*.

**For Females with other medical reasons for permanent, irreversible infertility:** I acknowledge that I have received and read the *Adempas Medication Guide*.

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

## 4 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 #: |
|---|---|---|---|---|

## 5 Prescriber Authorization

REQUIRED FOR ALL FEMALE PATIENTS

**For female patients, please indicate the patient's current reproductive status below.**

**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

OR

**Female of Non-Reproductive Potential**

☐ Pre-Pubertal Female
☐ Post-Menopausal Female
☐ Female with other medical reasons for permanent, irreversible infertility

I certify 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 understand that I may not delegate signature authority.

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

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. 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.
- Females with other medical reasons for permanent, irreversible infertility.

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 or misclassification in reproductive status by completing and submitting an *Adempas REMS Change in Reproductive Potential Status and Pre-pubertal Annual Verification 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 or misclassification in reproductive status on an *Adempas REMS Change in Reproductive Potential Status and Pre-pubertal Annual Verification Form* within 10 business days of becoming aware of the change.

**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 0.5mg | 1mg | 1.5mg | 2mg | 2.5mg

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