Adempas REMS Patient Enrollment and Consent Form

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

1 Patient Information (* indicates required field)

First Name*:	Middle Initial:	Last Name*:	Birthdate* (MM/DD/YYYY):	Sex*: ☐ 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:

☐ 1 mg Adempas Sample Dispensed* / Date: _____ ☐ 0.5 mg Adempas Sample Dispensed* / Date: _____

*Adempas Sample should only be dispensed as a 30-day supply

2 Statement of Medical Necessity (* indicates required field)

The following does not suggest approved uses or indications.

Diagnosis*:

Pulmonary arterial hypertension
- ☐ I27.0
- ☐ I27.21

Chronic thromboembolic pulmonary hypertension
I27.24
- ☐ Inoperable
- ☐ Persistent/Recurrent

☐ **OTHER (please specify)**
_____
_____

Therapy Status:
- ☐ Initial therapy (monotherapy or in combination)
- ☐ Add-on therapy
- ☐ Transition from other therapy

3 Female Patient Agreement

For all Females: 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 have been counseled on the risks of Adempas, including the risk of serious birth defects. I have read the *Guide for Females Patients*. Before treatment initiation, I understand that I will receive counseling from the prescriber on: the risk of serious birth defects, the need to use effective contraception during Adempas treatment and for one month after stopping Adempas treatment, my medical options in the event of unprotected sexual intercourse or known or suspected contraception failure, and to immediately contact my prescriber if I miss a menstrual period or suspect that I am pregnant. Before each prescription, I will receive counseling by the pharmacy or the prescriber who dispenses Adempas on the risk of serious birth defects, the need to use effective contraception during Adempas treatment and for one month after stopping Adempas treatment, to get monthly pregnancy tests, and to report a pregnancy immediately. Ensure that I have completed pregnancy testing before I started Adempas, monthly before each refill, and for one month after stopping Adempas. I understand that I may be contacted by Bayer and/or its agents and contractors to obtain information about my pregnancy. I will communicate with the pharmacy to confirm completion of pregnancy testing.
For Pre-Pubertal Females: I have been counseled on the risks of Adempas, including the risk of serious birth defects, and that I have read the *Guide for Female Patients*. I understand that I must immediately contact my healthcare provider if I get my menstrual period.
For Post-Menopausal Females: I have received and read the *Guide for Female Patients* and that I will inform my prescriber if there is a change in my reproductive status.
For Females with other medical reasons for permanent, irreversible infertility: I have received and read the *Guide for Female Patients* and that I will inform my prescriber if there is a change in my reproductive status.

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

OR

☐ **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

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, I will:
- 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

For All Females, I will:
- determine the reproductive potential status of all female patients using the definitions provided in the *Prescriber and Pharmacy Guide*.
- advise all females that Adempas is only available through a restricted distribution program called the Adempas REMS.
- enroll all female patients into the Adempas REMS by completing the *Patient Enrollment and Consent Form* and submitting it to the REMS

For Females of Reproductive Potential, I will:
- counsel Females of Reproductive Potential (FRP) on Adempas risks, including serious birth defects; and review the *Guide for Female Patients* with the patient.
- counsel each FRP to immediately contact her prescriber if she misses a menstrual period or suspects pregnancy.
- order and review pregnancy tests for FRPs before the start of treatment, monthly during treatment, and for one month after stopping treatment.
- counsel each FRP to use effective contraception during Adempas treatment and for one month after stopping treatment and discuss her medical options in the event of unprotected sexual intercourse or known or suspected contraceptive failure using the *Guide for Female Patients*.
- counsel each FRP during treatment if she is not complying with the required testing or if she is not using effective contraception, and to immediately contact her prescriber if she misses a menstrual period or suspects that she is pregnant.

For Pre-Pubertal Females, I will:
- counsel the Pre-Pubertal Female (PPF) patient on the Adempas risks, including serious birth defects and to immediately contact her prescriber if she begins to menstruate
- Review the *Guide for Female Patients* with the patient.
- for PPF, regularly assess the reproductive status of each pre-pubertal female during their treatment with Adempas.

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.

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

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