Synergen Rx LLC
3990 Flowers Road Suite 530
Doraville GA 30360

Phone: 404-585-7517 Fax 404-900-9209

Please Include the following chart notes and/or labs where applicable and fax the referral form with documents to 404-900-9209.

- Right Heart Catheterization Results
- Echocardiogram Results
- 6-minute Walk Test Results
- WHO Group Classification
- NYHA Class
- Previous tried and failed Medications

Adempas Prescription and Patient Support Program Enrollment Form

Complete this form which is available at 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 to access the Adempas REMS materials including the *Adempas REMS Patient Enrollment and Consent Form*, and fax them along with patient insurance information to the Adempas Program at 1-855-662-5200 or send electronically by visiting www.adempasREMS.com.

A. Contact Information (* indicates required field)

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

Is Patient starting Adempas in a hospital setting? ☐ **Yes** ☐ **No** Other Special Instructions: _____

Does the patient have prescription coverage*? ☐ Yes ☐ No

***PROVIDE ALL PATIENT INSURANCE INFORMATION, INCLUDING DRUG BENEFITS (FRONT AND BACK OF CARD) WITH THIS FORM.**

Please check one ICD-10 Code*:

PAH
- ☐ I27.0
- ☐ I27.21
  - ☐ Newly Diagnosed
  - ☐ Previously Diagnosed

CTEPH
- ☐ I27.24
  - ☐ Inoperable
  - ☐ Persistent/Recurrent

☐ **OTHER (please specify)** _____

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.

Starting 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:_____

Deliver to:
- ☐ Patient Home
- ☐ Prescriber Office

Titration schedule:

Please check box for all dosages to be incorporated:

☐ 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.

Other special instructions:_____

Quantity: ☐ 30 day supply ☐ Other: _____ Refills:_____

☐ Adempas Sample Dispensed*

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

Home Healthcare Visits:

Physician and patient please select an option below*:

☐ **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

Include other special nursing instructions:

_____

_____

_____

_____

I certify that the above therapy is medically necessary and that the 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.

PRESCRIBER SIGNATURE REQUIRED	**Dispense as Written*:**	**Date*:**
	Substitutions Permitted*:	**Date*:**

D. Patient Support Program Enrollment

Bayer provides patient support services for Adempas patients that include (A) nurses who are sent to your home to help you begin therapy and achieve your appropriate dose, (B) financial assistance and (C) information about disease and helpful tips for you ("myAIM"). You may enroll in one or all of these programs. You and your healthcare provider may choose to enroll you in (A) the nursing support portion. To enroll in (C) and receive educational materials, you will also need to provide permission to share your protected healthcare information with Bayer ("HIPAA Authorization" below). If you experience an adverse event, it will be forwarded to Bayer Drug Safety who may contact you or your treating physician. 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. You may opt out of this program at any time by writing to 200 Pinecrest Plaza, Morgantown WV 26505. You do not have to provide HIPAA Authorization to enroll in Option A or B.

Enroll me in: ☐ A: Nursing ☐ B: Financial ☐ C: Educational Information

Patient initial here to confirm your 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. Return this form and the Adempas REMS Patient Enrollment and Consent Form, along with patient insurance information to the Adempas Program via fax to 1-855-662-5200 or send electronically by visiting 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.

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

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):	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:		

☐ Adempas Sample Dispensed* *Adempas Sample should only be dispensed in a 30-day supply

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 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 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, 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

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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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