Prescriber Enrollment and Agreement Form

In order to prescribe Adempas, prescribers must enroll in the Adempas REMS by completing this form. In order to receive samples of Adempas, prescribers must be enrolled in the Adempas REMS and agree to comply with the requirements for a Sample Dispensing Prescriber, detailed in the agreement below.

Access this form online at www.adempasREMS.com, fax this form to 1-855-662-5200 or call the Adempas REMS at 1-855-4ADEMPAS (1-855-423-3672).

Prescriber Information (* indicates required field)

First Name*:	Middle Initial:	Last Name*:	NPI*:

Specialty*: ☐ Cardiology ☐ Pulmonology ☐ Other

Credentials*: ☐ MD ☐ DO ☐ NP ☐ PA ☐ Other with prescriptive authority

Practice/Facility Name:

Address Line 1*: Address Line 2:

City*: State*: Zip code*:

Phone*: Fax*: Email*: Preferred Method of Contact: ☐ Phone ☐ Email ☐ Fax

Office Contact

First Name:	Last Name:	Email* (required if Office Contact is provided):
First Name:	Last Name:	Email* (required if Office Contact is provided):

Prescriber REMS Agreement

By signing below, you signify your understanding of the risks of Adempas treatment and your obligation as an Adempas prescriber to educate your female patients about the Adempas REMS, monitor them appropriately, and report any pregnancies to the Adempas REMS. Specifically, you attest to the following:

- I have reviewed the Adempas Prescribing Information and the *Prescriber and Pharmacy Guide*.
- For all Females, I will:
  - o determine the reproductive potential status of all female patients using the definitions provided in the *Prescriber and Pharmacy Guide*.
  - o advise all females that Adempas is only available through a restricted distribution program called the Adempas REMS.
  - o enroll all female patients into the Adempas REMS by completing the *Patient Enrollment Form* and submitting it to the REMS.
- For Females of Reproductive Potential, I will:
  - o counsel Females of Reproductive Potential (FRP) on Adempas risks, including serious birth defects; and review the *Guide for Female Patients* with the patient.
  - o counsel each FRP to immediately contact her prescr ber if she misses a menstrual period or suspects pregnancy.
  - o order and review pregnancy tests for FRPs before the start of treatment, monthly during treatment, and for one month after stopping treatment.
  - o 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*.
  - o 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:
  - o counsel the Pre-Pubertal Female (PPF) patient on the Adempas risks, including serious birth defects; and to immediately contact her prescr ber if she beings to menstruate.
  - o review the *Guide for Female Patients* with the patient
  - o for PPF, regularly assess the reproductive status of each pre-pubertal female during their treatment with Adempas
  - o at least annually document the reproductive potential status for Pre-Pubertal Females who are at least 8 years of age and older by submitting a *Change in Reproductive Potential Status and Pre-pubertal Annual Verification Form*.
- At all times, I will:
  - o report any change or misclassification in reproductive status by submitting a *Change in Reproductive Potential Status and Pre-pubertal Annual Verification Form* within 10 business days of becoming aware of the change.
  - o provide documentation of compliance with program requirements
  - o notify Bayer of any pregnancies at 1-888-842-2937 or send the information to DrugSafety.GPV.US@bayer.com.

REQUIRED | Prescriber Signature*: | Date* (MM/DD/YYYY):

Prescriber REMS Agreement for Those Who Dispense Samples

I will:

- follow the requirements of a prescriber as I have attested to on the *Prescriber Enrollment and Agreement Form* above
- dispense Adempas to female patients only if the *Patient Enrollment and Consent Form* has been signed and submitted
- report dispensing Adempas to the REMS using the *Patient Enrollment and Consent Form*
- order and review a pregnancy test for FRP prior to dispensing Adempas
- not distribute, transfer, loan, or sell Adempas
- maintain records of all processes and procedures including compliance with those processes and procedures
- comply with audits

REQUIRED | Prescriber Signature*: | Date* (MM/DD/YYYY):

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