# Inpatient Pharmacy Enrollment Form

Due to a risk of fetal exposure and adverse fetal outcomes in females of reproductive potential prescribed Adempas, Adempas is available only through the Adempas REMS. The Adempas REMS is a component of a Risk Evaluation and Mitigation Strategy (REMS). In order for inpatients to receive Adempas, females as well as inpatient pharmacies that wish to stock this product, must be enrolled in the Adempas REMS and agree to comply with the requirements of the program.

**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).**

## Inpatient Pharmacy Information (* Indicates required field)

| | | |
|---|---|---|
| Type of facility*: ☐ Hospital ☐ Long-term Care Facility ☐ Prison ☐ Other _____ | | NPI*: |
| Facility Name*: | | |
| Address Line 1*: | Address Line 2: | |
| City*: | State*: | Zip code*: |
| Phone*: | Fax*: | |

## Ship To Information (* Indicates required field)

| | | |
|---|---|---|
| Ship To Address ☐ Same as above | Ship To Contact Name*: | |
| Address Line 1*: | Address Line 2: | |
| City*: | State*: | Zip code*: |
| Phone*: | Fax*: | |

## Authorized Representative Information (* Indicates required field)

| | | |
|---|---|---|
| First Name*: | Middle Initial: | Last Name*: |
| Position/Title: ☐ Hospital Pharmacist ☐ Head of P & T Committee ☐ Other Title | | |
| Phone*: | Fax*: | Email*: |

## Inpatient Pharmacy / Authorized Representative Acknowledgement

This inpatient pharmacy will:

- establish processes and procedures to ensure the REMS requirements are met.
- complete training in the Adempas REMS by reading the *Prescriber and Pharmacy Guide*.
- assume responsibility for the training of all relevant staff in dispensing on the Adempas REMS requirements, procedures and Adempas REMS materials prior to dispensing Adempas, using the *Prescriber and Pharmacy Guide*.
- establish processes and procedures to verify the female patient is enrolled in the REMS or will be enrolled prior to discharge, her reproductive status, and the female patient is under the supervision and care of a certified prescriber.
- for females of reproductive potential: establish processes and procedures to verify pregnancy testing is complete and that the patient is counseled on the risk of embryo-fetal toxicity, the need to use effective contraception, to get monthly pregnancy tests, and to inform the prescriber of a pregnancy immediately.

Before Dispensing:

- verify the female patient is under the supervision and care of a certified prescriber, her reproductive status, and that she is enrolled or will be enrolled in the REMS prior to discharge through the processes and procedures established as a requirement of the REMS.
- for females of reproductive potential: verify pregnancy testing is complete, and that the patient is counseled on the risk of embryo-fetal toxicity, the need to use effective contraception, to get monthly pregnancy tests, and to inform the prescriber of a pregnancy immediately through the processes and procedures established as a requirement of the REMS.

At Discharge:

- verify the female patient is enrolled in the REMS through the processes and procedures established as a requirement of the REMS.
- dispense no more than a 15-day temporary supply of Adempas to any female patient upon discharge from the healthcare facility.

At all times:

- not distribute, transfer, loan, or sell Adempas.
- report any pregnancies associated with the use of Adempas to Bayer at 1-888-842-2937 or send the information to DrugSafety.GPV.US@bayer.com.
- comply with audits by the manufacturer or a third party acting on behalf of the manufacturer to ensure all processes and procedures are in place and being followed.
- maintain records of all processes and procedures including compliance with those processes and procedures.

**Note:** If your inpatient pharmacy needs Adempas and is not certified in the Adempas REMS, contact the Adempas REMS Coordinating Center at 1-855-4ADEMPAS (1-855-423-3672) for assistance in obtaining up to a 15-day supply of Adempas for a specific inpatient while initiating enrollment.

| | | |
|---|---|---|
| REQUIRED | Authorized Representative 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