

# Adempas Patient Enrollment and Consent Form

For V.A. Use Only

Prescriber complete and forward to VA Pharmacy for review and submission to the Adempas Program

**1 Patient Information (\* indicates required field)**

First Name*:	Middle Initial:	Last Name*:	Birthdate* (MM/DD/YYYY):	Gender*: <input type="checkbox"/> Male <input type="checkbox"/> Female
Address Line 1*:		Address Line 2:		
City*:		State*:	Zip code*:	
Preferred Phone*:		Preferred Time to Contact: <input type="checkbox"/> Day <input type="checkbox"/> Evening		Cell/Alternate Phone:
Is patient starting therapy in a hospital setting?: <input type="checkbox"/> Yes <input type="checkbox"/> No				

**V.A. PATIENT-NO INSURANCE REQUIRED**

**2 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:
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**3 Prescriber Information (\* indicates required field)**

First Name*:	Last Name*:	NPI*:
V.A. Facility Name (where you see this patient)*:		
Address Line 1*:		Address Line 2:
City:	State:	Zip code:
Phone*:		State License #:

**4 Prescription (\* indicates required field)** Prescription is only valid if faxed. Note NY Prescribers please submit prescription on an original NY State prescription blank, for all other States, if not faxed, must be on State-specific blank if applicable for your State.

Initial dose*:	Titration schedule:	
<input type="checkbox"/> Adempas 1 mg tablet by mouth three times a day <input type="checkbox"/> Adempas 0.5 mg tablet by mouth three times a day  Quantity: <input type="checkbox"/> 30 day supply <input type="checkbox"/> Other _____  Refills:	<input type="checkbox"/> 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.  Strength: Adempas 0.5 mg    Adempas 1 mg    Adempas 1.5 mg Adempas 2 mg    Adempas 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.  <input type="checkbox"/> Other special instructions: _____ _____ Quantity: <input type="checkbox"/> 30 day supply <input type="checkbox"/> Other _____    Refills:	Check which option below is to be followed for this patient during the titration period  <b>Select either home healthcare nurse visits are authorized or patient will be seen in this physician's office for assessment and titration*:</b>  <input type="checkbox"/> 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.)  <input type="checkbox"/> Patient will be seen in this physician's office for assessment and titration

Deliver to:  Patient Home (address listed above)     V.A. Pharmacy (address listed below)

V.A. Pharmacy Name:	Department:	Attention:
Address Line 1:		Address Line 2:
City:	State:	Zip code:
Phone:		Fax Number:

**5 Prescriber Authorization**

REQUIRED FOR ALL FEMALE PATIENTS	<p><b>For female patients, please indicate the patient's current reproductive status below (please see definitions of these terms on the following page)</b></p> <p>Female of Reproductive Potential                      If this patient is a Female of Reproductive Potential, has a pregnancy test been completed prior to prescribing Adempas? <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>Female of Non-Reproductive Potential (choose one below)  <input type="checkbox"/> Pre-Pubertal Female    <input type="checkbox"/> Post-Menopausal Female    <input type="checkbox"/> Female with other medical reasons for permanent, irreversible infertility</p> <p>I certify that the above therapy is medically necessary and 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 appoint the Adempas REMS Program, on my behalf, to convey this prescription to the dispensing pharmacy. I understand that I may not delegate signature authority.</p>
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REQUIRED	Prescriber Signature*:	Date*:
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**5 Prescriber Authorization (continued)**

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.

**6 Statement of Medical Necessity (\* indicates required field)**

The following does not suggest approved uses or indications.

**Diagnosis\*:**

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

Pulmonary hypertension status:  Newly diagnosed  Previously diagnosed

**7 Written Permission to Share Information**

I authorize my V.A. healthcare provider, and V.A. pharmacy to share my name, address, and phone number; along with my prescription and treatment information relating to my use or need for Adempas with Bayer and its agents and contractors (collectively "Bayer") for purposes of activities related to the quality, safety, or effectiveness of such FDA-regulated product and my potential pregnancy status at any given point. I understand that certain healthcare providers, such as my pharmacies, may receive payment from Bayer in connection with the disclosure of my information as I allow through this authorization.

I allow my information to be shared with Bayer so that it may: 1) communicate with me and my healthcare providers about my medical care; and 2) learn how well Adempas, the Adempas REMS, or Adempas Program is working.

This authorization expires at the end of my participation in the Adempas Program or 10 years after the date I sign it if earlier. I can cancel this authorization earlier by contacting my VA healthcare provider. The cancellation will not apply to information already released by my healthcare providers, pharmacies, and health plans and before they learn about my cancellation. Once my information is disclosed to Bayer it will no longer be protected by federal privacy laws and my information may be given out (re-disclosed) by Bayer. However, I understand that Bayer will make every effort to keep my information confidential and only use and share it for the purposes stated in this authorization. I may refuse to sign this form, and this refusal will not affect my treatment, payment for treatment, enrollment in a health plan, or eligibility for benefits. I understand I am entitled to receive a copy of this authorization once signed.



Patient or Parent/Guardian Signature: \_\_\_\_\_

Date: \_\_\_\_\_

**8 Please forward this completed document to the VA pharmacy for review. If appropriate, the VA pharmacy will relay to the Adempas Program at 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.

