# Adempas REMS (Risk Evaluation and Mitigation Strategy)

## Change in Reproductive Potential Status and Pre-pubertal Annual Verification Form

All females must be enrolled in the Adempas REMS Program in order to receive Adempas. Complete this form to:
1) Change the reproductive status of any female patient, or
2) Perform the annual verification of reproductive status for Pre-Pubertal Females, 8 years of age or older

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### Access this form online at www.adempasREMS.com or fax this form to the Adempas Program at 1-855-662-5200 and to the patient’s certified pharmacy.

### Prescriber Information (indicates required field)

<table>
<thead>
<tr>
<th>First Name*</th>
<th>Middle Initial</th>
<th>Last Name*</th>
<th>Birth Date (MM/DD/YYYY)</th>
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<tr>
<th>Address Line 1*</th>
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<th>City*</th>
<th>State*</th>
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### Definitions of Reproductive Potential Status

#### 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.

### Please select the most appropriate reason for submitting this form*:

- **Change in Status**
  - Based on definitions of reproductive potential status, patient is (please check one):
    - Female of Reproductive Potential
    - Female of Non-Reproductive Potential – Patient is pre-pubertal
    - Female of Non-Reproductive Potential – Patient is post-menopausal
    - Female of Non-Reproductive Potential – Female with other medical reasons for permanent, irreversible infertility
  - Reason for change in classification (please check one):
    - Physiological transition
    - Medical/surgical (please specify): ____________________________
    - Other (please specify): ____________________________

- **Annual Verification**
  - Patient remains a Pre-Pubertal Female (8 years of age or older)

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By signing, I certify that the patient's reproductive potential status and reason for submitting this form are accurately noted above. I certify that I will follow the REMS requirements while treating this patient.

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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.

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<tr>
<th>REQUIRED</th>
<th>Prescriber Signature*</th>
<th>Date* (MM/DD/YYYY)</th>
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Reference ID: 3994854