# 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

**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 must complete this form within 10 business days of awareness of the change in reproductive status.**

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

| First Name*: | Middle Initial: | Last Name*: | Bir hdate*(MM/DD/YYYY): |
|---|---|---|---|
| Address Line 1*: | | Address Line 2: | |
| City*: | State*: | Zip code*: | Phone: |

**Prescriber Information (* indicates required field)**

| First Name*: | Last Name*: | NPI*: |
|---|---|---|
| Practice/Facility Name: | | |
| Address Line 1*: | Address Line 2: | |
| City: | State: | Zip code: | Phone*: |

**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)

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.

| 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.