

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 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 REMS 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*:	Birthdate*(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):
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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.



Phone: 1-855-4ADEMPAS (1-855-423-3672)

www.adempasREMS.com

Fax: 1-855-662-5200