

# Adempas REMS (Risk Evaluation and Mitigation Strategy)

## Prescriber Enrollment and Agreement Form

In order to prescribe Adempas, prescribers must enroll in the Adempas REMS Program by completing this form.

<b>Access this form online at <a href="http://www.adempasREMS.com">www.adempasREMS.com</a>, fax this form to 1-855-662-5200 or call the Adempas REMS Program at 1-855-4ADEMPAS (1-855-423-3672).</b>			
<b>Prescriber Information (* indicates required field)</b>			
First Name*:	Middle Initial:	Last Name*:	NPI*:
Specialty*: <input type="checkbox"/> Cardiology <input type="checkbox"/> Pulmonology <input type="checkbox"/> Other		Credentials*: <input type="checkbox"/> MD <input type="checkbox"/> DO <input type="checkbox"/> NP <input type="checkbox"/> PA <input type="checkbox"/> Other with prescriptive authority	
Practice/Facility Name:			
Address Line 1*:		Address Line 2:	
City*:		State*:	Zip code*:
Phone*:	Fax*:	Email*:	Preferred Method of Contact: <input type="checkbox"/> Phone <input type="checkbox"/> Email <input type="checkbox"/> Fax
<b>Office Contact</b>			
First Name:		Last Name:	Email* (required if Office Contact is provided):
<b>Prescriber REMS Agreement</b>			
<p>By signing below, you signify your understanding of the risks of Adempas treatment and your obligation as an Adempas prescriber to educate your female patients about the Adempas REMS Program, monitor them appropriately, and report any pregnancies to the Adempas REMS Program. Specifically, you attest to the following:</p> <ul style="list-style-type: none"><li>• I have read the <i>Adempas Full Prescribing Information</i>, <i>Adempas Medication Guide</i> and the <i>Prescriber and Pharmacy Guide for the Adempas REMS Program</i>.</li><li>• I agree to enroll all female patients into the Adempas REMS Program.</li><li>• I will:<ul style="list-style-type: none"><li>o determine the reproductive potential status of all female patients using the definitions provided in the <i>Prescriber and Pharmacy Guide for the Adempas REMS Program</i>.</li><li>o advise all females that Adempas is only available through a restricted distribution program called the Adempas REMS Program.</li><li>o counsel Females of Reproductive Potential (FRP) on Adempas risks, including serious birth defects; and review the <i>Adempas Medication Guide</i> and the <i>Adempas REMS Guide for Females Who Can Get Pregnant</i> with the patient.</li><li>o counsel each FRP to immediately contact her healthcare provider if she misses a menstrual period or suspects pregnancy.</li><li>o counsel the Pre-Pubertal Female (PPF) patient and/or a parent/guardian on the Adempas risks, including serious birth defects; and review the <i>Adempas Medication Guide</i> with the patient and/or a parent/guardian.</li><li>o verify the reproductive potential status annually for Pre-Pubertal Females who are at least 8 years of age and older by submitting an <i>Adempas REMS Change in Reproductive Potential Status and Pre-pubertal Annual Verification Form</i>.</li><li>o counsel the PPF patient and/or a parent/guardian to contact her healthcare provider if she begins her menstrual period.</li><li>o order and review pregnancy tests for FRPs prior to initiating Adempas treatment, monthly during treatment, and for one month after stopping treatment.</li><li>o counsel each FRP to use reliable contraception during Adempas treatment, and for one month after stopping treatment, and discuss her medical options in the event of unprotected sexual intercourse or known or suspected contraceptive failure.</li><li>o report any change or misclassification in reproductive status by submitting an <i>Adempas REMS Change in Reproductive Potential Status and Pre-pubertal Annual Verification Form</i> within 10 business days of becoming aware of the change.</li><li>o counsel female patients who fail to comply with the Adempas REMS Program requirements.</li><li>o notify Bayer of any pregnancies at 1-888-842-2937 or send the information to <a href="mailto:DrugSafety.GPV.US@bayer.com">DrugSafety.GPV.US@bayer.com</a>.</li></ul></li></ul>			
<b>REQUIRED</b>	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](mailto:DrugSafety.GPV.US@bayer.com).

