AVEED® REMS
Healthcare Setting Enrollment Form

AVEED (testosterone undecanoate) injection 750mg/3mL CIII

This form may be used to register a new healthcare setting, change the information for a certified healthcare setting (e.g., name of the Authorized Representative), or for reenrollment (required every two years).

Instructions

AVEED is only available through the AVEED Risk Evaluation and Mitigation Strategy (REMS) Program. In order to dispense and administer AVEED, each healthcare setting must:

1. Designate an Authorized Representative.
2. Review the AVEED REMS Education Program for Healthcare Settings, including the Prescribing Information.
3. Complete and sign the Healthcare Setting Enrollment Form. This Enrollment must be renewed every 2 years.
4. Associate certified Prescribing Healthcare Providers to your account. Your healthcare setting is not eligible to receive AVEED until you have associated at least one certified Prescribing Healthcare Provider.
5. Implement the necessary staff training and processes to comply with the AVEED REMS Program requirements.

For online enrollment, please go to **www.AveedREMS.com.**

For enrollment via fax, please complete all required fields on the next page and fax the page to **1-855-755-0495**. You will receive enrollment confirmation via your preferred method of communication (email or fax) within two business days.

For questions regarding the AVEED REMS Program, please either visit **www.AveedREMS.com** or call the AVEED REMS Program at **1-855-755-0494**.

Authorized Representative Responsibilities

I am the Authorized Representative designated by my healthcare setting to coordinate the activities of the AVEED REMS Program. I agree to comply with the following program requirements:

- I understand that my healthcare setting must be certified with the AVEED REMS Program and have at least one certified prescriber associated with my facility to be able to order, receive or administer AVEED.
- I have completed the AVEED REMS Education Program for Healthcare Settings.
- I understand the risks of serious pulmonary oil microembolism (POME) reactions and anaphylaxis following the administration of AVEED.
- I understand this healthcare setting must verify the current Authorized Representative annually and renew its enrollment in the AVEED REMS Program every two years from the date of initial enrollment.
- This healthcare setting has immediate access on-site to equipment and personnel to manage POME or anaphylaxis.
- This healthcare setting will establish procedures and protocols that are subject to audit, to help ensure compliance with the safe use conditions required in the AVEED REMS Program, including the following:
  - All Healthcare Providers (HCPs) who prescribe AVEED in my healthcare setting are specially certified prior to prescribing AVEED and a record of such training must be maintained.
  - All non-prescribing HCPs who administer AVEED in my healthcare setting are trained and a record regarding such training must be maintained.
  - Prior to initiating treatment and before each injection, review with and provide a copy of "What You Need To Know About AVEED Treatment: A Patient Guide" to each patient to inform them about the risks of serious POME reactions and anaphylaxis.
  - To observe each patient administered AVEED for **30 minutes** at my healthcare setting following each injection in order to provide appropriate medical treatment in the event of serious POME reactions or anaphylaxis following the administration of AVEED.
- Not to loan, sell or transfer AVEED to another pharmacy, healthcare setting, prescriber, institution or distributor, except in the case where the transfer is to another certified healthcare setting (unique ship-to site address) where I am also the Authorized Representative.
- This healthcare setting must not dispense AVEED for home or patient self-administration.
- To make available to Endo Pharmaceuticals Solutions Inc. (Endo), and/or a designated third party or the FDA, documentation to verify understanding of, and adherence to, the requirements of the AVEED REMS Program.
- I understand that this certified healthcare setting must recertify in the AVEED REMS Program if the healthcare setting designates a new Authorized Representative.

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THIS FORM IS BEING USED TO (CHECK ONE):

- ☐ Register a new healthcare setting
- ☐ Change the information for a certified healthcare setting
- ☐ Re-enrollment of a certified healthcare setting
- ☐ For change of information or reenrollment, provide HCS ID: FAC

AUTHORIZED REPRESENTATIVE INFORMATION (*REQUIRED FIELDS)

☐ M.D. ☐ D.O. ☐ Nurse ☐ Physician Assistant ☐ Practice Manager

☐ Other _____

*First Name (please print) MI *Last Name (please print)

Title *Email Address *Phone Number Ext *Fax Number

*Preferred Method of Communication (please select **one**) ☐ Email ☐ Fax

☐ Yes ☐ No **Does this healthcare setting have the necessary on-site equipment and personnel to manage POME or anaphylaxis?**

I understand that this enrollment only applies to me as the designated Authorized Representative of this healthcare setting. I will complete a separate enrollment form for each healthcare setting (unique ship-to site address) for which my designation and responsibilities extend. Failure to enroll a healthcare setting and have certified healthcare providers in the AVEED REMS program will result in the inability to receive shipments of AVEED.

Healthcare Setting Authorized Representative Signature* Date* (MM/DD/YYYY)

HEALTHCARE SETTING INFORMATION (*REQUIRED FIELDS)

*Healthcare Setting Name

*DEA Number (On file with distributor account)

*Address

*City *State *ZIP

Setting Type:

☐ Group practice ☐ Independent practice ☐ Institution ☐ Central Ordering Pharmacy

☐ Infusion Center ☐ Other _____

*Phone Number *Fax Number *Email Address

Fax this page to **1-855-755-0495**.

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CERTIFIED HEALTHCARE PROVIDERS (PLEASE LIST ALL CERTIFIED HEALTHCARE PROVIDERS ASSOCIATED WITH THIS FACILITY)

*First Name (please print)	MI	*Last Name (please print)	DEA/NPI Number
*First Name (please print)	MI	*Last Name (please print)	DEA/NPI Number
*First Name (please print)	MI	*Last Name (please print)	DEA/NPI Number
*First Name (please print)	MI	*Last Name (please print)	DEA/NPI Number

Fax this page to **1-855-755-0495**.

endo Pharmaceuticals

Rx Only

August 2018 www.AveedREMS.com 1-800-462-ENDO (3636)