

TRADENAME REMS Program Fact Sheet How to Obtain TRADENAME

What is the TRADENAME REMS (Risk Evaluation and Mitigation Strategy) Program?

A REMS is a strategy to manage known or potential risks associated with a drug, and is required by the Food and Drug Administration (FDA) to ensure that the benefits of the drug outweigh its risks.

TRADENAME is intended for subcutaneous injection only by a healthcare provider.

TRADENAME is available only through a restricted distribution program called the TRADENAME REMS Program because of the risk of **serious harm or death that could result from intravenous administration.**

What are the TRADENAME REMS Program requirements?

Any pharmacy that dispenses TRADENAME as well as any healthcare setting* (including a prescriber office) that purchases TRADENAME from a distributor must be enrolled prior to dispensing / purchasing TRADENAME.

Prescriber offices that only order TRADENAME from an enrolled pharmacy for a specific patient are exempt from enrollment.

How can DATA 2000-waivered prescribers obtain TRADENAME for their patients?

Prescribers who are DATA 2000-waivered can obtain TRADENAME for their patients in two ways.

1. Through an enrolled pharmacy for a specific patient:

In advance of the patient's appointment, send a prescription for your named patient to an enrolled pharmacy. The enrolled pharmacy will send TRADENAME to you to administer it directly to that patient. **TRADENAME should never be dispensed directly to the patient.** It should be administered by a healthcare professional in your office or clinic. Your healthcare setting **does not need to be enrolled** in the TRADENAME REMS Program for you to administer TRADENAME, if obtained through an enrolled pharmacy, to an individual named patient. A current list of enrolled pharmacies may be obtained on the TRADENAME REMS website or from the TRADENAME REMS Program at 1-XXX-XXX-XXXX.

2. By ordering TRADENAME directly through a distributor:

To order TRADENAME through a distributor, the healthcare setting in which you practice must first become enrolled.

How can healthcare settings* obtain TRADENAME for potential patients?

To receive and store a supply of TRADENAME for a healthcare setting, all healthcare settings and pharmacies that dispense TRADENAME* must:

1. Be enrolled in the TRADENAME REMS Program.

***Examples of healthcare settings** include: group practice, independent practice, institution, Department of Defense (DoD) facility, outpatient clinic, hospital, Veterans Administration (VA) facility, opioid treatment program (OTP), closed healthcare system, and other healthcare setting

2. Designate an “authorized representative” to complete the ***TRADENAME REMS Program Healthcare Setting and Pharmacy Enrollment Form*** and submit it to the TRADENAME REMS Program for enrollment.
3. Train relevant staff involved in the dispensing of TRADENAME, to ensure that it is dispensed directly to a healthcare provider.
4. Establish processes and procedures to verify that TRADENAME is dispensed directly to a healthcare provider. **TRADENAME should never be dispensed directly to a patient.**

How should TRADENAME be stored?

Once TRADENAME is delivered for a named patient or is obtained for a healthcare setting’s bulk supply:

- Store BRAND NAME at 20 to 25°C (68 to 77°); excursions permitted at 15 to 30° C (59 to 86° F) [see USP Controlled Room Temperature].

Store BRAND NAME in accordance with Federal and State controlled substance laws and regulations.

Where can I find more information about the TRADENAME REMS Program?

- Visit www.TRADENAMEREMS.com to access the following materials:
 - ***TRADENAME REMS Program Healthcare Setting and Pharmacy Enrollment Form***
 - ***TRADENAME REMS Program Dear Healthcare Provider Letter***
 - ***Prescribing Information***
 - ***Medication Guide*** (educational tool designed specifically for patients)
- Contact the TRADENAME REMS Program at 1-XXX-XXX-XXXX for TRADENAME REMS materials and for additional information about the TRADENAME REMS Program.
- Visit the REMS@FDA website at: <https://www.accessdata.fda.gov/scripts/cder/rems/index.cfm>.
- Call Braeburn’s Information line (1-XXX-XXX-XXXX).