

Risk Evaluation and Mitigation Strategy (REMS) Document

GATTEX (teduglutide) REMS Program

I. Administrative Information

Application Number: NDA 203441

Application Holder: Shire-NPS Pharmaceuticals, Inc.

Initial REMS Approval: 12/2012

Most Recent REMS Update: 07/2020

II. REMS Goals

The goals of the GATTEX REMS are to mitigate the risks of possible acceleration of neoplastic growth and enhancement of colon polyp growth, gastrointestinal obstruction, and biliary and pancreatic disorders associated with GATTEX by:

1. Informing patients about the risks listed above associated with the use of GATTEX
2. Informing healthcare providers about the risks listed above associated with GATTEX

III. REMS Requirements

Shire-NPS Pharmaceuticals, Inc. must provide training to healthcare providers who prescribe Gattex.

The training includes the following educational materials: Prescribing Information, Medication Guide, [Dear Healthcare Professional Letter](#), [Prescriber Education Slide Deck](#), [Post-Training Knowledge Assessment Questions](#), and [Patient and Caregiver Counseling Guide](#). The training must be available online via the REMS website www.GATTEXREMS.com, by calling the REMS Program Call Center, during prescriber visits by Shire representatives, at professional society meetings, and at medical educational venues where Shire has a presence. In addition, the [Prescriber Education Slide Deck](#) must be part of training/educational programs provided by medical science liaisons.

Target Audience	Communication Materials-& Dissemination Plans
Healthcare providers who are likely to prescribe GATTEX	REMS Letter: Dear Healthcare Professional Letter with attachment: Prescriber Education Slide Deck <ol style="list-style-type: none">1. Mail or email to prescribers within 60 calendar days of their initial prescription who are identified as untrained, and again 12 and 24 months later.2. Mail or email to healthcare providers who inquire about how to become trained and request hard copies of the training materials.3. Mail or email to healthcare providers who have not written a prescription for GATTEX within 12 months of completing the REMS training.

To support REMS Program operations, Shire-NPS Pharmaceuticals, Inc. must:

1. Establish and maintain a REMS Program website, www.GATTEXREMS.com. The REMS Program website must include the capability to complete prescriber training online, and the option to print the Prescribing Information, Medication Guide, and REMS materials. All product websites for consumers and healthcare providers must include prominent REMS-specific links to the REMS Program website. The REMS Program website must not link back to the promotional product website(s).
2. Make the REMS Program website fully operational and all REMS materials available through the REMS website and REMS call center within 60 calendar days of REMS modification.
3. Establish and maintain a REMS Program call center for REMS participants at 1-855-5GATTEX (1-855-542-8839).
4. Establish and maintain a validated, secure database of all healthcare providers who have completed training for the GATTEX REMS Program.
5. Ensure healthcare providers are able to report completion of training by fax at 1-855-359-3393 and online.

IV. REMS Assessment Timetable

Shire-NPS Pharmaceuticals, Inc. must submit REMS Assessments at 12 months from the date of the initial REMS (12/21/2012) and annually thereafter. To facilitate inclusion of as much information as possible while allowing reasonable time to prepare the submission, the reporting interval covered by each assessment should conclude no earlier than 60 calendar days before the submission date for that assessment. Shire-NPS Pharmaceuticals, Inc. must submit each assessment so that it will be received by the FDA on or before the due date.

V. REMS Materials

The following materials are part of the GATTEX REMS:

Training and Educational Materials

Prescriber:

1. [Prescriber Education Slide Deck](#)
2. [Dear Healthcare Professional Letter](#)
3. [Post-Training Knowledge Assessment Questions](#)

Patient:

4. [Patient and Caregiver Counseling Guide](#)

Other Materials

5. [REMS website](#)