TEGSEDI REMS (Risk Evaluation and Mitigation Strategy) Program

What is the TEGSEDI REMS?

A REMS (Risk Evaluation and Mitigation Strategy) 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 the benefits of the drug outweigh its risks.

Because of the risk of serious bleeding due to severe thrombocytopenia and the risk of glomerulonephritis, TEGSEDI is available only under a restricted program called the TEGSEDI REMS.

Prescribers
Prescribers must be certified in TEGSEDI REMS to prescribe TEGSEDI for adult patients with polyneuropathy of Hereditary Transferrin-mediated Amyloidosis (HATTR) and patients with polyneuropathy of Hereditary Transferrin-mediated Amyloidosis (HATTR).

Pharmacies
Pharmacies must be certified in TEGSEDI REMS to dispense TEGSEDI for adult patients with polyneuropathy of Hereditary Transferrin-mediated Amyloidosis (HATTR). Learn about Pharmacy Certification

Patients
Patients who are prescribed TEGSEDI for the treatment of polyneuropathy of Hereditary Transferrin-mediated Amyloidosis (HATTR) must be enrolled in the TEGSEDI REMS Program. Learn about Patient Enrollment

TEGSEDI is not available to all pharmacies. If you have questions about TEGSEDI REMS or need help with certification or enrollment, call 1-844-683-4796. Monday-Friday, 8:00am – 8:00pm ET

You are encouraged to report serious side effects of TEGSEDI to the REMS at 1-833-442-6262, and the FDA at www.fda.gov/medwatch or call 1-800-FDA-1088.

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TEGSEDI REMS Prescriber Enrollment

Prescribers must be certified in the TEGSEDI REMS Program to be able to prescribe TEGSEDI for adult patients with polyneuropathy of Hereditary Transthyretin-mediated Amyloidosis (HATTR). Because of the safety profile of TEGSEDI, patients treated with TEGSEDI should have lab monitoring prior to initiating therapy and ongoing monitoring during treatment as described in the Prescribing Information.

To become certified in the program, prescribers must complete the following steps:

**STEP 1** REVIEW the TEGSEDI Prescribing Information

**STEP 2** REVIEW the Prescriber Training and REMS Program Overview

**STEP 3A** COMPLETE AND SUBMIT the following online:
- Prescriber Knowledge Assessment
- Prescriber Enrollment Form

OR

**STEP 3B** VIA FAX at 855-483-4736

**STEP 4** RECEIVE notification of successful enrollment and username and password to log in to the TEGSEDI REMS Program and view your enrolled patients

Materials for Prescribers

- Prescriber Training [PDF]
- REMS Program Overview [PDF]
- Prescriber Knowledge Assessment [PDF]
- Prescriber Enrollment Form [PDF]
- Patient Information Form [PDF]
- Patient Guide [PDF]
- Patient Status Form [PDF]
- Patient Wallet Card [PDF]

Adobe® Reader® is required to view PDFs. If you do not have it installed, download it free here.

If you have questions about TEGSEDI REMS or need help with certification, call 1-844-483-4736, Monday-Friday, 8:00am – 8:00pm ET

You are encouraged to report serious side effects of TEGSEDI to the REMS at 1-833-642-0202 and/or the FDA at www.fda.gov/medwatch or call 1-800-FDA-1088.
TEGSEDI REMS Pharmacy Enrollment

Pharmacies must be certified in the TEGSEDI REMS Program to be able to dispense TEGSEDI for adult patients with polyneuropathy of Hereditary Transthyretin-mediated Amyloidosis (ATTR).

To become authorized to dispense TEGSEDI complete the following steps:

**STEP 1** DESIGNATE an authorized representative for the pharmacy

**STEP 2** The Authorized Representative Must Review the REMS Program Overview

**STEP 3** After Reviewing the Material Complete the Pharmacy Enrollment Form and fax to the TEGSEDI REMS Program at 1-844-483-4736

**STEP 4** Implement the necessary staff and training processes to comply with the TEGSEDI REMS Program requirements

Materials for Pharmacies

- REMS Program Overview [PDF]
- Pharmacy Enrollment Form [PDF]

Adobe Reader® is required to view PDFs. If you do not have it installed, download it free here.

Contact the REMS coordinator at 1-844-483-4736 to obtain contact information for certified outpatient pharmacies and for distributors who are authorized to ship to certified inpatient pharmacies.

You are encouraged to report serious side effects of TEGSEDI to the REMS at 1-833-642-6262 and/or the FDA at www.FDA.gov/medwatch or call 1-800-FDA-1088.

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TEGSEDI REMS Patient Information

Below are materials that help inform patients about treatment with TEGSEDI.

Materials for Patients

- Patient Guide (PDF)
- Patient Wallet Card (PDF)

Adobe® Reader® is required to view PDFs. If you do not have it installed, download it free here.

If you have questions about TEGSEDI REMS or need help enrolling, call 1-844-483-4736. Monday-Friday, 8:00am – 8:00pm ET.

You are encouraged to report serious side effects of TEGSEDI to the REMS at 1-833-642-0232 and/or the FDA at www.fda.gov/medwatch or call 1-800-FDA-1088.

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TEGSEDI REMS Enrollment Forms & Resources

Below are downloadable forms needed to support the TEGSEDI REMS Program.

Adobe® Reader® is required to view PDFs. If you do not have it installed, download it here.

Materials for Prescribers
- Prescriber Training [PDF]
- REMS Program Overview [PDF]
- Prescriber Knowledge Assessment [PDF]
- Prescriber Enrollment Form [PDF]
- Patient Enrollment Form [PDF]
- Patient Guide [PDF]
- Patient Status Form [PDF]
- Patient Wallet Card [PDF]

Materials for Pharmacies
- REMS Program Overview [PDF]
- Pharmacy Enrollment Form [PDF]

Materials for Patients
- Patient Guide [PDF]
- Patient Wallet Card [PDF]

If you have questions about TEGSEDI REMS or need help with certification or enrollment, call 1-844-483-4736. Monday-Friday, 8:00am – 8:00pm ET

You are encouraged to report serious side effects of TEGSEDI to the REMS at 1-833-642-6232, and/or the FDA at www.fda.gov/medwatch or call 1-800-FDA-1088.
TEGSEDI REMS Enrollment Forms & Resources

Below are downloadable forms:

Materials for Prescribers
- Prescriber Training [PDF]
- REMS Program Overview [PDF]
- Prescriber Knowledge Assessment [PDF]
- Prescriber Enrollment Form [PDF]
- Patient Enrollment Form [PDF]
- Patient Guide [PDF]
- Patient Status Form [PDF]
- Patient Wallet Card [PDF]

Materials for Pharmacies
- REMS Program Overview [PDF]
- Pharmacy Enrollment Form [PDF]

Materials for Patients
- Patient Guide [PDF]
- Patient Wallet Card [PDF]

If you have questions about TEGSEDI REMS or need help with certification or enrollment, call 1-844-483-4736, Monday-Friday, 8:00am – 8:00pm ET

You are encouraged to report side effects of TEGSEDI to the REMS at 1-833-642-6222, and/or the FDA at www.fda.gov/medwatch or call 1-800-FDA-1088.