

# TEGSEDI<sup>®</sup> REMS Program Overview (Risk Evaluation and Mitigation Strategy)

This overview describes the requirements of the TEGSEDI (inotersen) REMS and the responsibilities of prescribers, pharmacies and patients.

If you have any questions regarding the TEGSEDI REMS, please visit [www.TEGSEDIrems.com](http://www.TEGSEDIrems.com) or call 1-844-4TEGREMS (1-844-483-4736).



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## What is the TEGSEDI REMS?

- A Risk Evaluation and Mitigation Strategy (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 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.**

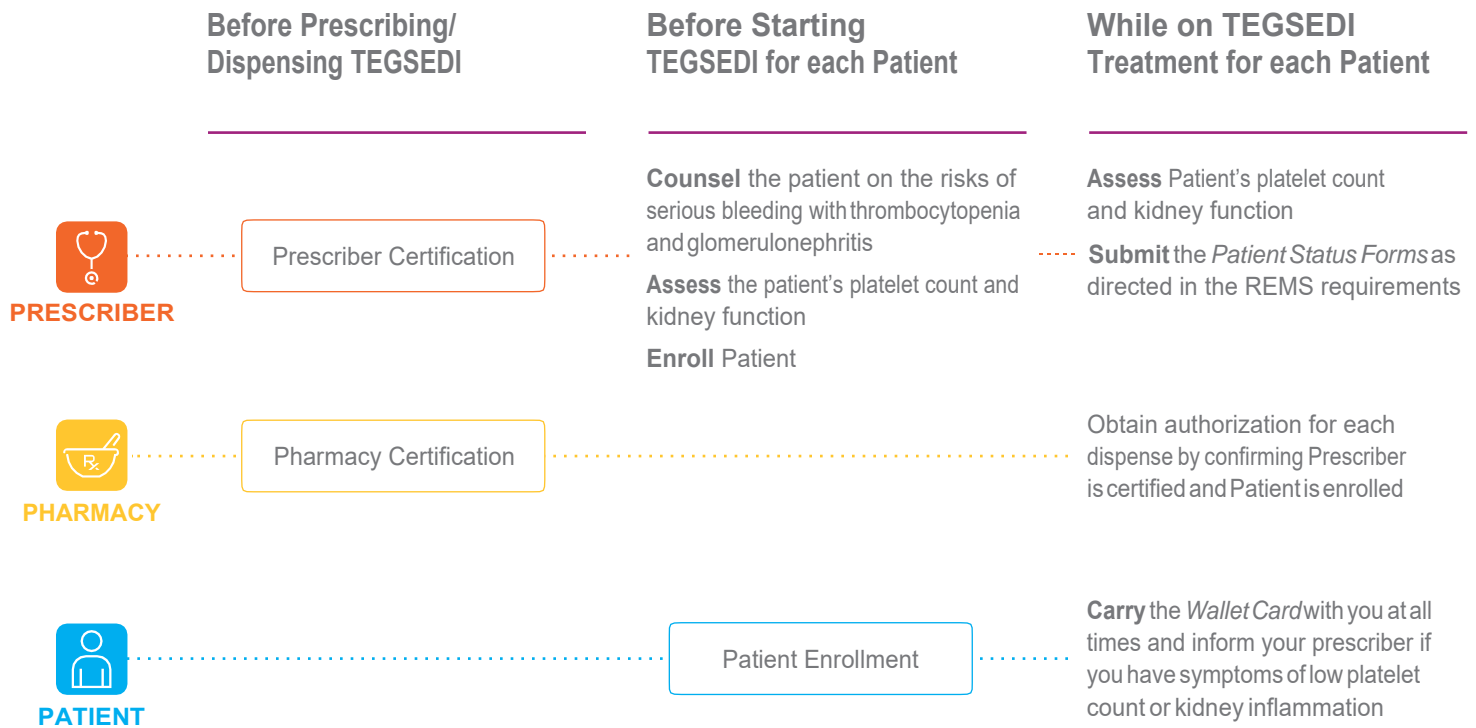
TEGSEDI may cause serious bleeding due to severe thrombocytopenia. The signs and symptoms of thrombocytopenia may include:

- Unusual bruising or a rash of tiny reddish-purple spots, often on the lower legs
- Bleeding from skin cuts that does not stop or oozes
- Bleeding from the gums or nose
- Blood in urine or stools
- Bleeding into the whites of eyes
- Sudden severe headaches or neck stiffness
- Vomiting blood or coughing up blood
- Abnormal or heavy menstrual periods

TEGSEDI may cause glomerulonephritis. The signs and symptoms of glomerulonephritis include:

- Puffiness or swelling in face, feet or hands
- New onset or worsening shortness of breath and coughing
- Blood in urine or brown urine
- Foamy urine (proteinuria)
- Passing less urine than usual

## How does the TEGSEDI REMS work?



## What are the Requirements of the TEGSEDI REMS?

- In order for patients to receive TEGSEDI, prescribers, pharmacies, and patients must comply with the requirements of the TEGSEDI REMS

### To prescribe TEGSEDI:



- Become certified** by completing a one-time certification process
- Assess** the patient's platelet count and kidney function
- As you start patients on TEGSEDI, **counsel** and **enroll** them into the TEGSEDI REMS
- Perform** ongoing assessments of platelet counts and kidney function
- Document and Submit** a *Patient Status Form* during treatment at the time of treatment discontinuation and 8 weeks after treatment discontinuation

### To dispense TEGSEDI\*:



- Designate an authorized representative, become certified, and recertify** if there is a change in the authorized representative
- Train** staff and **comply** with REMS requirements
- Before dispensing TEGSEDI, **verify** prescriber is certified and patient is authorized to receive TEGSEDI

### To receive TEGSEDI:



- Understand** the risks associated with TEGSEDI
- Enroll** in the REMS by completing the *Patient Enrollment Form* with your healthcare provider
- Get** a blood test and a urine test prior to treatment, during treatment and after treatment discontinuation

\*TEGSEDI is not available to all pharmacies. If you have any questions about the REMS or how to obtain TEGSEDI, call 1-844-483-4736.





## Prescriber Requirements

### Become Certified (One-time)

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#### Before prescribing TEGSEDI:

1. **Review** the following educational materials on TEGSEDI to understand the risks of serious bleeding with severe thrombocytopenia and glomerulonephritis, and the TEGSEDI REMS:
  - Prescribing Information
  - Prescriber Training
  - REMS Program Overview (*this document*)
2. **Complete** and **submit** the following to become certified:
  - Prescriber Knowledge Assessment
  - Prescriber Enrollment Form
3. Once completed, the TEGSEDI REMS will notify you that you are certified to prescribe TEGSEDI

### Enroll Patients

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#### Before starting each patient on TEGSEDI:

1. **Counsel** your patient about the risks associated with TEGSEDI, including serious bleeding with severe thrombocytopenia and glomerulonephritis and share the resources below:
  - *Patient Guide*
  - *Wallet Card*
2. **Assess** the patient's platelet count and kidney function for appropriateness of initiating treatment
3. **Submit** a completed *Patient Enrollment Form* to the TEGSEDI REMS. Provide a copy of the form to the patient

### At All Times

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#### Once your patient is on TEGSEDI:

1. **Report** any events of severe thrombocytopenia, serious bleeding with thrombocytopenia, and glomerulonephritis to the REMS Program
2. **Assess** the patient's appropriateness for continuing treatment by monitoring their platelet count and kidney function
3. **Submit** the *Patient Status Form*\* during treatment, at the time of treatment discontinuation and at 8 weeks after treatment discontinuation
4. **Inform** the TEGSEDI REMS if a patient is no longer under your care or has discontinued TEGSEDI

\*The REMS will send a reminder to the certified prescriber of record when the *Patient Status Form* is due.

Completed forms should be submitted to the TEGSEDI REMS online at [www.TEGSEDIrems.com](http://www.TEGSEDIrems.com) or via fax to 1-855-483-4736.



## Pharmacy Requirements

### Become Certified

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#### Before Dispensing TEGSEDI:

1. **Designate** an authorized representative for the pharmacy to carry out the certification process. He or she will need to review the *REMS Program Overview* and will oversee implementation and ensure compliance with the TEGSEDI REMS requirements
2. Have the authorized representative **complete and submit** the *Pharmacy Enrollment Form* by fax
  - Once this step is completed, the TEGSEDI REMS will notify you that you are certified to dispense TEGSEDI
3. Have the authorized representative ensure that all relevant staff involved in dispensing of TEGSEDI are trained on the TEGSEDI REMS requirements using the *Program Overview*, and that a record of the training is maintained by the pharmacy
4. Establish processes and procedures to dispense no more than a 30-day supply
5. Establish processes and procedures to report severe thrombocytopenia, serious bleeding with severe thrombocytopenia, and glomerulonephritis events to the REMS

### Ensure Compliance with REMS Requirements

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#### When Dispensing TEGSEDI:

1. Before dispensing TEGSEDI, **verify** that the prescriber is certified and the patient is authorized to receive TEGSEDI by accessing the TEGSEDI REMS Portal or by calling the TEGSEDI REMS
2. **Report** severe thrombocytopenia, serious bleeding with severe thrombocytopenia, and glomerulonephritis events to the REMS
3. **Maintain** records that all REMS processes and procedures are in place and are being followed
4. **Recertify** in the TEGSEDI REMS if a new authorized representative is designated by completing and submitting the *Pharmacy Enrollment Form*

TEGSEDI is not available to all pharmacies. If you have questions about the REMS or how to obtain TEGSEDI, call 1-844-483-4736.



## Patient Requirements

### Enroll and Get Blood and Urine Testing

#### Before starting TEGSEDI:

1. Discuss with your doctor and understand:
  - The risks associated with TEGSEDI, including serious bleeding and kidney inflammation
  - The need to complete the appropriate lab testing
2. **Receive and read** the:
  - *Patient Guide*
  - *Wallet Card*
3. **Complete** the *Patient Enrollment Form* with your doctor

### Complete Ongoing Testing as Directed by Prescriber

#### After starting TEGSEDI:

1. **Carry** the *Wallet Card* with you at all times and Inform your healthcare provider about this treatment
2. **Inform** your healthcare provider if you have any signs and symptoms of low platelet count or kidney inflammation
3. **Get** the appropriate lab testing during treatment and after discontinuation

## TEGSEDI REMS Resources



PRESCRIBER



PHARMACY



PATIENT

#### Before Prescribing/ Dispensing TEGSEDI

- Prescribing Information
- *Prescriber Training*
- *Program Overview*
- *Prescriber Knowledge Assessment*
- *Prescriber Enrollment Form*
- *Patient Enrollment Form*

- *Program Overview*
- *Pharmacy Enrollment Form*

#### Before Starting TEGSEDI for each Patient

- *Patient Enrollment Form*
- *Wallet Card*
- *Patient Guide*

#### While on TEGSEDI Treatment, at treatment discontinuation and at 8-weeks post TEGSEDI Discontinuation

- *Patient Status Form*

TEGSEDI is indicated for the treatment of the polyneuropathy of hereditary transthyretin-mediated amyloidosis in adults. Please see the Prescribing Information for more information.





Visit [www.TEGSEDIrems.com](http://www.TEGSEDIrems.com) or call the TEGSEDI REMS at 1-844-483-4736 for any questions about the TEGSEDI REMS.

Please see the Prescribing Information for more information.

Website: [www.TEGSEDIrems.com](http://www.TEGSEDIrems.com)

Phone: 1-844-483-4736

Fax: 1-855-483-4736

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