TEGSEDI® REMS
Prescriber Enrollment Form

TEGSEDI is available only through the TEGSEDI REMS, a restricted distribution program. Only prescribers, pharmacies, and patients enrolled in the program can prescribe, dispense, and receive TEGSEDI.

Instructions:

1) Review the TEGSEDI Prescribing Information (PI), the ***Program Overview***, and the ***Prescriber Training***.

2) Complete the ***Prescriber Knowledge Assessment*** and this ***Prescriber Enrollment Form***.

3) Submit the completed ***Prescriber Knowledge Assessment*** and this enrollment form:
- Online at www.TEGSEDIrems.com
- Or Fax: 1-855-4TEGREMS (1-855-483-4736)

Please complete all mandatory fields on this form to avoid a delay in the enrollment process. Upon completion of these steps, the REMS will notify you of successful certification.

PRESCRIBER AGREEMENT

By signing below, I agree TEGSEDI is only available through the REMS and I must comply with the following REMS requirements:

I have:

- Reviewed the Prescribing Information, ***REMS Program Overview*** and the ***Prescriber Training***
- Successfully completed the ***Prescriber Knowledge Assessment*** and submitted it to the REMS

Before treatment initiation (first dose) I must:

- Counsel the patient, using the ***Patient Guide*** and ***Wallet Card***, on how to recognize and respond to signs and symptoms of serious bleeding and glomerulonephritis and the need to have their platelets and renal function monitored
- Provide the patient with the ***Patient Guide*** and ***Wallet Card***
- Assess the patient's platelet count, estimated glomerular filtration rate (eGFR), urinalysis, and urine protein to creatinine ratio (UPCR) and the appropriateness of initiating treatment
- Enroll the patient by completing and submitting the ***Patient Enrollment Form*** to the REMS. Provide a completed copy of the form to the patient

During treatment weekly or more frequently as described in the Prescribing Information I must:

- Assess the patient's platelet count and appropriateness of continuing treatment

During treatment every 2 weeks I must:

- Assess the patient's eGFR, urinalysis, and UPCR and appropriateness of continuing treatment

During treatment every 90 days I must:

- Assess the patient's platelet count, signs and symptoms of thrombocytopenia, and appropriateness of continuing treatment. Document and submit to the REMS using the ***Patient Status Form***
- Assess the patient's eGFR, urinalysis, UPCR, signs and symptoms of renal toxicity, and appropriateness of continuing treatment. Document and submit to the REMS using the ***Patient Status Form***

For eight weeks after treatment is discontinued, I must:

- Assess the patient's platelet count weekly, or more frequently as described in the Prescribing Information
- Assess the patient's eGFR, urinalysis, and UPCR every 2 weeks

Eight weeks after treatment is discontinued, I must:

- Assess the patient's platelet count and signs and symptoms of thrombocytopenia. Document and submit to the REMS using the ***Patient Status Form***
- Assess the patient's eGFR, urinalysis, UPCR, and signs and symptoms of renal toxicity. Document and submit to the REMS using the ***Patient Status Form***

At all times, I must:

- Report events of severe thrombocytopenia, serious bleeding with severe thrombocytopenia, and glomerulonephritis by contacting the REMS by phone, online, and fax or by using the ***Patient Status Form*** online and by fax
- Report treatment discontinuation or transfer of care to the REMS using the ***Patient Status Form***

I understand and acknowledge that:

- I will only be able to prescribe TEGSEDI if certified in the REMS
- I am responsible for safeguarding my credentials for the REMS website. I will not share my credentials for the REMS website or allow others to sign into the website using my credentials
- I will allow Akcea Therapeutics and its agents to contact me via phone, mail, fax, or email to support administration of the REMS
- I understand that if I fail to maintain compliance with the requirements of the TEGSEDI REMS, I may no longer be able to prescribe TEGSEDI

Tegsedi® (inotersen) injection 284 mg/1.5 mL

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PRESCRIBER INFORMATION (Fields marked * are required)		
First Name*:	Last Name*:	
National Provider Identifier # (NPI)*:		
Credentials*: ☐ MD ☐ DO ☐ NP ☐ PA ☐ Other (please specify)		
Specialty*: ☐ Neurology ☐ Hematology ☐ Cardiology ☐ Other (please specify):		
Practice type*: ☐ Solo Private Practice ☐ Group Private Practice ☐ Academic/Hospital-Affiliated Practice ☐ Government Institution ☐ Other (please specify):		
Practice/Facility Name:		
Address Line 1*:		
Address Line 2:		
City*:	State*:	ZIP Code*:
Phone*:	Fax*:	Email*:
Preferred method of contact*: ☐ Phone ☐ Fax ☐ Email		

PRESCRIBER DELEGATE (Prescriber delegate may submit the Patient Status Form on behalf of the certified prescriber of record)	
Delegate #1 First Name:	Delegate #1 Last Name:
Phone:	Email:
Delegate #2 First Name:	Delegate #2 Last Name:
Phone:	Email:

OFFICE CONTACT		
First Name:	Last Name:	
Phone: ☐ Same as above	Fax: ☐ Same as above	Email (required if Office Contact is provided):

To provide additional Office Contacts or Delegates, please contact the TEGSEDI REMS Coordinating Center at 1-844-4TEGREMS (1-844-483-4736).

Prescriber Signature*: X _____	Date*:

Report all adverse events to 1-833-MI AKCEA (1-833-642-5232) and/or the FDA at www.fda.gov/medwatch or call 1-800-FDA-1088.

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