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 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, using the ***Patient Guide*** and ***Wallet Card***
- 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*:	Middle Initial:	Last Name*:
National Provider Identifier # (NPI)*:		
Credentials*: ☐ MD ☐ DO ☐ NP ☐ PA ☐ Other (please specify)		
Specialty*: ☐ Neurology ☐ Hematology ☐ 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		

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 please contact the TEGSEDI REMS Coordinating Center at 1-844-4TEGREMS (1-844-483-4736).

Prescriber Signature*: X _____	Date*:

Report serious side effects of TEGSEDI to the REMS at 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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