

What is TEGSEDI?

TEGSEDI is a medicine used to treat the polyneuropathy of hereditary transthyretin-mediated (hATTR) amyloidosis in adults. It is not known if TEGSEDI is safe and effective in children.

Risks of Serious Bleeding, Kidney Inflammation, and Kidney Failure

TEGSEDI can cause serious side effects such as serious bleeding caused by a low platelet count (thrombocytopenia) and kidney inflammation (called glomerulonephritis) and kidney failure. Please talk about these side effects with your doctor.

You must get blood tests to check your platelet count, as well as blood and urine tests to check your kidneys, to take TEGSEDI.

Low Platelet Counts:

TEGSEDI may cause the number of platelets in your blood to be reduced. This is a common side effect of TEGSEDI. When your platelet count is too low, your body cannot form clots. You could have serious bleeding that could lead to death. You need to call your doctor right away or go to the emergency room.

The signs and symptoms of low platelet count 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 your gums or nose
- Blood in urine or stools
- Bleeding into the whites of your eyes
- Sudden severe headaches or neck stiffness
- Vomiting blood or coughing up blood
- Abnormal or heavy periods (menstrual periods)

Kidney Inflammation (Glomerulonephritis) and Kidney Failure:

Your kidneys may stop working properly. Glomerulonephritis can lead to kidney damage and kidney failure that needs dialysis. You need to call your doctor right away or go to the emergency room.

The signs and symptoms of kidney inflammation include:

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

If you have 1 or more of the symptoms for the serious side effects of low platelet count, kidney inflammation, or kidney failure, call your doctor right away or go to the emergency room. Do not take TEGSEDI unless your doctor confirms that it is safe to continue TEGSEDI treatment.

TEGSEDI® REMS Patient Guide

What is the TEGSEDI REMS?

Because of the risks associated with TEGSEDI, the Food and Drug Administration (FDA) has required a special program called a Risk Evaluation and Mitigation Strategy (REMS). As part of the REMS, your doctor will discuss the risks of TEGSEDI with you and give you materials to review on your own.

Both you and your doctor must sign the Patient Enrollment Form for you to receive TEGSEDI. Your doctor will provide a copy of the signed form to the TEGSEDI REMS.

The TEGSEDI REMS also requires TEGSEDI to be dispensed by a REMS-certified pharmacy. Your doctor will send your prescription to the certified pharmacy, who will contact you if they need more information. The pharmacy will only dispense a 1-month supply of TEGSEDI to you at a time.

What Do I Need To Do?

Before Starting Treatment:

Tell your doctor if you take blood thinners or medicines that affect blood clotting.

Your doctor will test your blood and urine to check your platelet count and kidney function before you start TEGSEDI.

During Treatment:

Your doctor will do blood and urine tests to check your platelet count and kidney function every 1-2 weeks or more frequently if he/she thinks you need it.

Watch for symptoms of low platelet count, kidney inflammation, or kidney failure and call your doctor if you have concerns.

Carry your TEGSEDI Wallet Card with you at all times. The Wallet Card tells other doctors that you are taking TEGSEDI. In the event of an emergency, give the Wallet Card to the emergency room doctor and inform all of your healthcare providers about this treatment.

If You Stop Treatment:

If your doctor has you stop taking TEGSEDI, you will need to continue to get your blood and urine tested for 8 more weeks.

Where can I find more information about the TEGSEDI REMS?

If you have questions about the REMS, you can call the TEGSEDI REMS Coordinating Center at 1-844-483-4736, 8:00 am-8:00 pm EST.

Phone: 1-844-483-4736 | www.TEGSEDIrems.com | Fax: 1-855-483-4736