



Our Continued Commitment to the Hemophilia B Community: An Update on HEMGENIX® (etranacogene dezaparvovec-drlb) Supply and Patient Access

Dear Hemophilia B Community,

In March, we shared an update regarding HEMGENIX® (etranacogene dezaparvovec-drlb) availability and our efforts to support people living with hemophilia B while maintaining the highest quality standards for this one-time gene therapy. Since then, we have provided monthly updates to healthcare professionals and patient organizations to enable them to support patient care. Today, we are pleased to share an encouraging update on the progress made over the past several months.

Since reestablishing limited supply in April 2026, HEMGENIX has been delivered to support treatment for 22 people living with hemophilia B in commercial and clinical trial settings. This includes the first commercial HEMGENIX treatment in Canada, and the first-ever adolescent to receive a gene therapy in a global clinical trial for hemophilia B, and continued experience across new and established treatment centers. Together, these achievements reflect our steadfast commitment to supporting the hemophilia B community. More than 100 people with hemophilia B have now received commercial treatment with HEMGENIX globally since approval, underscoring the continued progress being made in expanding access.

Our highest priority remains supporting eligible people living with hemophilia B and healthcare providers to plan and deliver their hemophilia care. We remain committed to actively managing HEMGENIX supply so they have the confidence to continue shared decision-making conversations, complete evaluations, testing and other readiness activities to enable appropriate patient access.

We will continue to keep the community informed as additional updates become available. Thank you for your continued trust and partnership.

Sincerely,
Dr. Deborah Long
SVP, Medical Affairs

IMPORTANT SAFETY INFORMATION AND INDICATION

Before you can receive HEMGENIX®, etranacogene dezaparvovec-drlb, your doctor will perform tests to check for Factor IX inhibitors. If you have inhibitors, or have had them in the past, you are not a candidate for HEMGENIX. Your doctor will also check your **liver health** and screen for **hepatitis B and C**, as active infection may affect how well the treatment works or increase the risk of side effects.

Infusion-related and allergic reactions (including anaphylaxis) can occur. You will be monitored throughout infusion and for at least 3 hours afterward. If a reaction occurs during infusion, the infusion may be slowed or interrupted as symptoms are addressed, then started at a slower rate once symptoms have resolved.

Liver effects including liver injury can occur. Your doctor will monitor your liver with blood tests every week for 3 months and then monthly up to 1 year after treatment. Increased liver enzymes may require corticosteroid treatment. Because HEMGENIX works in the liver, there is a **potential (possible but not proven) risk of liver cancer**, and some patients may be monitored for up to 5 years.

After treatment, your body will develop **antibodies to HEMGENIX**, which may affect how well it works.

Your doctor will **monitor Factor IX levels** and check for inhibitors. You may still need support to help control bleeding, especially in the initial weeks after treatment.

Most common side effects include increased liver enzymes, headache, increased blood creatine kinase, flu-like symptoms, infusion-related reactions, fatigue, nausea, and feeling unwell. These are not the only side effects possible. Tell your healthcare provider about any side effect you may experience.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call [1-800-FDA-1088](tel:1-800-FDA-1088).

You can also report side effects to CSL Behring's Pharmacovigilance Department at [1-866-915-6958](tel:1-866-915-6958).

INDICATION

HEMGENIX is indicated for the treatment of adults with Hemophilia B (congenital Factor IX deficiency) who:

- Currently use Factor IX prophylaxis therapy, or
- Have current or historical life-threatening hemorrhage, or
- Have repeated, serious spontaneous bleeding episodes

Please see full [prescribing information](#) for HEMGENIX.