



HEPCLUDEX (bulevirtide-gmod)

What are the possible side effects of HEPCLUDEX?

This information is provided in response to your question. It is not treatment advice on how to use **HEPCLUDEX**. Please discuss this question and others you have about your medical condition or treatment with your healthcare provider.

Download the **HEPCLUDEX Patient Information** for more details, including approved use(s) and important warnings:

www.gilead.com/-/media/files/pdfs/medicines/hdv/hepcludex/hepcludex_pi

The short answer¹

If you stop taking **HEPCLUDEX**, your hepatitis B virus (HBV) or hepatitis D virus (HDV) might **flare up**. A "flare-up" is when your HDV or HBV infection suddenly returns in a worse way than before. This means your virus could return, and with worse symptoms. **Do not stop taking HEPCLUDEX** without first talking to your healthcare provider.

Some patients have had **serious allergic reactions** to **HEPCLUDEX**. These reactions can interfere with breathing and might cause death. Stop taking **HEPCLUDEX** and **tell your healthcare provider or get emergency medical help** right away if you develop any signs or symptoms of a severe allergic reaction.

The **most common side effect** of **HEPCLUDEX** seen in clinical trials was a **skin reaction where the shot was given**. Headache was the next most common side effect. These side effects happened in 20% or more patients.

The common side effects that happened in less than 20% of patients were:

- Stomach pain
- Itching
- Feeling tired

What is the most important information I should know about HEPCLUDEX?¹

Some medications have important warnings that are designed to alert you of serious or life-threatening risks that come with taking the medication.

HEPCLUDEX has an important warning for: Worsening of HBV and HDV infection. Your HBV or HDV infection may get worse (flare-up) if you take HEPCLUDEX and then stop taking it, especially if you have cirrhosis. A “flare-up” is when your HDV or HBV infection suddenly returns in a worse way than before.



Do not stop taking HEPCLUDEX without first talking to your healthcare provider.

- Do not run out of HEPCLUDEX. Refill your prescription or talk to your healthcare provider before your HEPCLUDEX is all gone.
- If you stop taking HEPCLUDEX, your healthcare provider will need to check your health often and do blood tests regularly for at least 6 months to check your liver, and may give you medicine to treat your virus infection.
- Tell your healthcare provider about any new or unusual symptoms after you stop HEPCLUDEX.
- If your HBV or HDV flares up, it may need to be treated again.

Who is HEPCLUDEX for?¹

HEPCLUDEX is a prescription medicine used to treat chronic (long-lasting) hepatitis delta virus (HDV) infection in adults without cirrhosis or with compensated cirrhosis.

It is not known if HEPCLUDEX is safe and effective in children less than 18 years of age.

What are the common side effects?¹

Most common side effects



The most common side effect in a clinical trial of HEPCLUDEX was a skin reaction at the needle site where the injection was given. This side effect happened in 30% of patients, which means in 30 of 100 people.



The reactions varied. For some people, injection site reactions included infection, redness, itching, swelling, bruising, rash, and pain at the injection site



Another common side effect was headache. Headaches bothered 20% of patients. That means 20 of 100 people said they got a headache.

Other common side effects

There were other side effects that happened in more than 10% of patients but less than 20%.

- **Stomach area pain**
- **Itching**
- **Feeling tired**

These are not all of the possible side effects of HEPCLUDEX.

What are the serious side effects of HEPCLUDEX?¹

HEPCLUDEX may cause **serious side effects** such as:



- **Worsening of HBV and HDV infection.** Your HDV or HBV infection may get worse (flare-up) if you stop taking HEPCLUDEX, especially if you have cirrhosis. A "flare-up" is when your HDV or HBV infection suddenly returns in a worse way than before. Do not stop taking HEPCLUDEX without first talking to your healthcare provider.



- **Allergic reactions, including severe allergic reactions (anaphylaxis).** Stop taking HEPCLUDEX and tell your healthcare provider or get emergency medical help right away if you develop any signs or symptoms of a severe allergic reaction, including: trouble swallowing or breathing, throat tightness, severe rash, hives, or itching, swelling of the mouth, lips, tongue, or face, dizziness or fainting, stomach area pain, nausea, diarrhea, or vomiting.

What should I tell my healthcare provider before taking HEPCLUDEX?¹

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

Before taking HEPCLUDEX, tell your healthcare provider about all your medical conditions, including if you:



- **Are breastfeeding or plan to breastfeed.** It is not known if HEPCLUDEX passes into your breast milk. Talk with your healthcare provider about the best way to feed your baby.



- **Are pregnant or plan to become pregnant.** It is not known if HEPCLUDEX will harm your unborn baby. Tell your healthcare provider right away if you become pregnant while taking HEPCLUDEX.

Glossary

Clinical trial: a study in people. They may help to find out how well a medicine works or how safe it is.

Compensated cirrhosis: When some liver damage has occurred, but the non-damaged part of the liver is still healthy enough to work.

HBV (hepatitis B virus) infection: a type of virus (HBV) that can cause serious liver infection.

HDV (hepatitis D virus) infection: a type of virus (HDV) that can cause serious liver infection. HDV only develops in patients with HBV.

Rash: an area of irritated or swollen skin.

Reference

1. Enclosed. Gilead Sciences Inc. HEPCLUDEX® (bulevirtide-gmod) injection, for subcutaneous use. US Prescribing Information. Foster City, CA.

More information about HEPCLUDEX

If you would like more detailed information about HEPCLUDEX, please visit:

www.gilead.com/-/media/files/pdfs/medicines/hdv/hepcludex/hepcludex_pi

This is the US FDA-approved Prescribing Information, including the Patient Labeling, for HEPCLUDEX. It will tell you about the uses, warnings, and other important safety information about HEPCLUDEX.

Important note

Gilead Sciences, Inc. is providing this letter in response to your unsolicited request for medical information. Some of the information included in this letter may not be covered in the US FDA-approved Prescribing Information for HEPCLUDEX. Gilead Sciences, Inc. does not intend this letter to be used as medical advice and does not promote use of HEPCLUDEX in a way that has not been approved by the FDA. Please discuss this question and others you may have about your medical condition or treatment with your healthcare provider.

Follow-Up

For any additional questions, please contact Gilead Medical Information at:

☎ 1-866-MEDI-GSI (1-866-633-4474) or 🌐 <https://www.patient.askgileadmedical.com/>

Reporting side effects

Please report all adverse events to:

Gilead Global Patient Safety ☎ 1-800-445-3235, option 3 or

🌐 www.gilead.com/utility/contact/report-an-adverse-event

FDA MedWatch Program by ☎ 1-800-FDA-1088 or ✉ MedWatch, FDA, 5600 Fishers Ln, Rockville, MD 20852 or 🌐 www.accessdata.fda.gov/scripts/medwatch

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