



HEPCLUDEX (bulevirtide-gmod)

Have people treated with HEPCLUDEX had reactions where the injection was given?

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



In the main clinical trial, skin reactions where the injection was given happened in 15 of the 50 patients, or 30%.



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

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 or 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.

Have people treated with HEPCLUDEX had reactions where the injection was given?¹

Study MYR301

MYR301 was a study in patients who had chronic (long-lasting) HDV infection. In the first 48 weeks of the study, 50 patients received daily injections of HEPCLUDEX 8.5 mg under the skin.

The most common side effect in those patients was a reaction where the injection was given.



Reactions where the injection was given happened in 15 of the 50 patients, or 30%.



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

What should I do if I have a reaction where the injection was given?¹

If you have a reaction where the injection was given or other bothersome side effect, call your doctor for medical advice about side effects.

Glossary

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.

Reference

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

Gilead Sciences, Inc. is providing this letter in response to your unsolicited request for medical information. It is not promotional. It is intended for a US audience 18 years or older.

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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