



HEPCLUDEX (bulevirtide-gmod)

How should I take HEPCLUDEX?

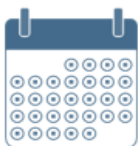
This information is provided in response to your question. It is not treatment advice on how to use **HEPCLUDEX**. Please discuss this question and others you have about your medical condition or treatment with your healthcare provider.

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

Take HEPCLUDEX **1 time each day**.



- **Do not stop taking** HEPCLUDEX without first talking to your healthcare provider.
- Take HEPCLUDEX exactly as your healthcare provider tells you to take it.
- **Do not change your dose** unless your healthcare provider tells you to.

If you take too much HEPCLUDEX, call your healthcare provider or go to the nearest hospital emergency room right away.

Your **healthcare provider should show you or your caregiver how to prepare** and inject HEPCLUDEX before you use it for the first time. If you have questions or do not understand the instructions, talk to your healthcare provider.



- Stay under a healthcare provider's care when taking HEPCLUDEX.

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, 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 you may have 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.

How should I take HEPCLUDEX?¹

Take HEPCLUDEX **1 time each day**.



- **Do not stop taking** HEPCLUDEX unless your healthcare provider tells you to.
- Take HEPCLUDEX exactly as your healthcare provider tells you to take it.
- **Do not change your dose** unless your healthcare provider tells you to.

Do not miss a dose of HEPCLUDEX.



- If you miss a dose, take it as soon as possible **that day**.
- If it is almost time for your next dose, skip the missed dose. Take your next dose as usual. **Do not take a double dose.**
- If you do not give a full dose of medicine, **ask your healthcare provider** what to do.

Do not run out of HEPCLUDEX. Refill your prescription or talk to your healthcare provider before your HEPCLUDEX is all gone. This is very important because your HDV and HBV infection **may get worse (flare-up) if you stop taking HEPCLUDEX.**

How do I get started?

Your **healthcare provider should show you or your caregiver how to prepare and inject HEPCLUDEX** before you use it for the first time.



- **Do not change your dose** unless your healthcare provider tells you to.
- Stay under a healthcare provider's care when taking HEPCLUDEX.
- If you have any problems using HEPCLUDEX, **ask your healthcare provider.**

Read the Instructions for Use before you start using HEPCLUDEX.



- This document explains how to prepare and take HEPCLUDEX.
- If you have questions or do not understand the instructions, **talk to your healthcare provider.**
- Read the Instructions for Use again **each time you get a refill.** There may be **new information.**



Your carton of HEPCLUDEX contains **30 vials.** This is a **30-day supply** of medicine. Your pharmacy will provide you with the following **supplies for mixing and injecting HEPCLUDEX:**

- Transfer needles
- Empty syringes
- Sterile Water for Injection vials
- Injection needles

HEPCLUDEX comes as a **powder or cake in a vial.** It **must be mixed and dissolved** with Sterile Water for Injection before use.



- Use a **fresh vial** of Sterile Water for Injection **from your pharmacy** for every HEPCLUDEX dose.
- **Do not** use tap water, bottled water, or water from any source other than Sterile Water for Injection from your pharmacy.
- Sterile Water for Injection comes in vials that are for **one-time use only.**
- **Throw away** the vial **after the dose** even if there is some water remaining in it.
- Using the wrong water or reusing vials of Sterile Water for Injection may lead **to infection.**



You also need syringes and needles to prepare and inject HEPCLUDEX.

- Get these supplies **from your pharmacy**.
- **Throw away any used** transfer needles and injection needles in a **sharps disposal container**.

All of your supplies for taking HEPCLUDEX are for one time use only. Do not reuse any of the supplies.

Once you have mixed HEPCLUDEX, **it must be used right away**. Do not reuse or save mixed HEPCLUDEX. Throw away (discard) unused portion

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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