HEPCLUDEX®

bulevirtide-gmod 8.5mg for injection

FREQUENTLY ASKED QUESTIONS

Find answers to common questions about storage, preparation, and administration of HEPCLUDEX.

Discuss any questions you have with your doctor or healthcare provider.

Please review the patient leaflet and Instructions for Use provided with your HEPCLUDEX, or watch a step-by-step video at www.HEPCLUDEX.com.

Please see Patient Prescribing Information for HEPCLUDEX, including Important Warnings and Instructions for Use.

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ABOUT HEPCLUDEX

What is HEPCLUDEX?

HEPCLUDEX (bulevirtide-gmod) 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 under 18 years of age.

1 What will I receive as part of my HEPCLUDEX prescription?

As part of your HEPCLUDEX prescription, you will receive a box containing a 30-day supply of HEPCLUDEX Vials.

Your specialty pharmacy will also include supplies in your shipment for mixing and injecting HEPCLUDEX:

- 2 Sterile Transfer Needles
- 1 Sterile Water for Injection Vial
- 1 Sterile Syringe
- 1 Sterile Injection Needle with Safety Shield

Additional supplies needed that your specialty pharmacy may also provide to you include:

- 1 sharps disposal container
- 1 adhesive bandage
- 1 cotton ball or gauze
- 3 alcohol swabs

2 How will I know that HEPCLUDEX is helping me?

Getting tested regularly is key to knowing how you are responding to treatment. Your doctor will discuss with you how often you will be tested to monitor your treatment response.

3 How long do I need to take HEPCLUDEX?

Your doctor will tell you how long to take HEPCLUDEX. Do not change your dose or stop taking HEPCLUDEX without talking to your doctor, as it may make your infection worse.

Please see additional Important Safety Information throughout and the Patient Prescribing Information for HEPCLUDEX, including Important Warnings and Instructions for Use.

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STORING HEPCLUDEX

IMPORTANT SAFETY INFORMATION

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

HEPCLUDEX may cause serious side effects, including:

Worsening of hepatitis delta virus (HDV) and hepatitis B virus (HBV) 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, as they will need to monitor health regularly to check your liver.

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

1 How should I store HEPCLUDEX?

You should store HEPCLUDEX Vials at room temperature of 68 °F to 77 °F (20 °C to 25 °C). Mixed HEPCLUDEX must be used immediately, and all unused portions should be discarded. Always keep HEPCLUDEX away from children.

2 Can I travel with HEPCLUDEX?

It is possible to travel with HEPCLUDEX and the materials you need for injection. Before you travel, check with your doctor to ensure that you are healthy enough to travel, and discuss traveling with medication with your specialty pharmacy. You may also want to check with your airline or the airport security in your countries of travel regarding restrictions on travel with medication.

3 What should I do if my HEPCLUDEX Vials have not been stored properly?

Improper storage of HEPCLUDEX could disrupt the way the medication works. Do not use improperly stored medication. Tell your doctor or specialty pharmacy, and they will explain what you should do next.

Please see additional Important Safety Information throughout and the Patient Prescribing Information for HEPCLUDEX, including Important Warnings and Instructions for Use.

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MIXING
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IMPORTANT SAFETY INFORMATION (CONT.)

What are the other possible side effects of HEPCLUDEX?

The most common side effects of HEPCLUDEX are injection site reactions (including infection, redness, itching, swelling, bruising, rash, and pain at the injection site), headache, stomach area pain, feeling tired, and itchy skin. These are not all the possible side effects of HEPCLUDEX. Tell your healthcare provider if you have any side effects that bother you or don't go away.

What should I tell my healthcare provider before taking HEPCLUDEX?

All your medical conditions, including:
If you are pregnant or plan to become pregnant. It is not known if HEPCLUDEX can harm your unborn baby. Tell your healthcare provider if you become pregnant during treatment with HEPCLUDEX.

1 Why is it important to clean the rubber stopper of both vials with an alcohol swab before mixing the sterile water with the HEPCLUDEX powder or cake?

Cleaning helps remove germs from the rubber stopper of the vial that could cause infection or interfere with the way HEPCLUDEX works. Only use the sterile water provided by the specialty pharmacy for mixing.

2 Why are there three different needles?

The two longer needles are Sterile Transfer Needles used to transfer Sterile Water for Injection to the HEPCLUDEX Vial and to withdraw mixed HEPCLUDEX into the Sterile Syringe in preparation for injection.

The shorter needle, called the Sterile Injection Needle with Safety Shield, is used for the injection of mixed HEPCLUDEX.

3 How should I attach and remove the Transfer Needle to and from the Syringe?

To attach the Transfer Needle to the Syringe, push the capped needle down slightly into the Syringe while twisting it to the right (clockwise). To remove the capped Transfer Needle, twist to the left (counterclockwise).

4 What should I do if I damage the Transfer Needle?

If the Sterile Transfer Needle gets damaged, you should remove it from the Syringe and place it in a sharps disposal container. Attach a new Transfer Needle onto the Syringe. Call your specialty pharmacy if you need more supplies.

5 How do I mix the sterile water and HEPCLUDEX powder or cake?

Please review the patient leaflet and Instructions for Use provided with your HEPCLUDEX, or watch a step-by-step video at www.HEPCLUDEX.com.

6 What if I notice leftover powder in the vial?

If powder is still visible in the vial, continue to swirl the vial slowly until it is removed. If any particles are visible in the solution after the powder has completely dissolved, do not use that vial, and contact your doctor or specialty pharmacy. Please review the patient leaflet and Instructions for Use for more information about how to mix HEPCLUDEX.

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MIXING
HEPCLUDEX
(CONT.)

IMPORTANT SAFETY INFORMATION (CONT.)

What should I tell my healthcare provider before taking HEPCLUDEX? (cont.)

If you are breastfeeding or plan to breastfeed. It is not known if HEPCLUDEX can pass into your breast milk. Talk to your healthcare provider about the best way to feed your baby during treatment with HEPCLUDEX.

All the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. **Do not start a new medicine without telling your healthcare provider.**

7 How long does it take for the medication to dissolve?

HEPCLUDEX powder can take up to 3 minutes to dissolve once the powder and sterile water are mixed. Do not shake the vial.

8 Should I shake the vial to help HEPCLUDEX dissolve?

Do not shake the vial to help dissolve HEPCLUDEX. You can slowly swirl the vial until the medicine is completely dissolved.

9 What happens if the HEPCLUDEX Vial has bubbles in it after mixing?

Small air bubbles in the medicine are normal after mixing.

10 What should I do if the HEPCLUDEX/ sterile water mixture looks foamy?

The medicine should look clear without any clumps or particles. It is normal to see foam in the medicine.

Do not use the medicine if you see particles or clumps that have not completely dissolved, including powder stuck to the vial wall or rubber stopper.

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INJECTING HEPCLUDEX

IMPORTANT SAFETY INFORMATION (CONT.)

How should I take HEPCLUDEX?

See the detailed Instructions for Use that is provided with HEPCLUDEX for information on how to prepare and inject HEPCLUDEX.

- HEPCLUDEX is given as an injection under your skin (subcutaneous) by you or a caregiver.
- Make sure you or your caregiver are trained by your healthcare provider on how to prepare and inject HEPCLUDEX before you take it for the first time.

1 Can I self-inject HEPCLUDEX at home?

Yes, HEPCLUDEX can be self-injected at home. HEPCLUDEX is injected under the skin once per day. **Do not use HEPCLUDEX unless you have been trained by your healthcare provider.** Your healthcare provider should show you or your caregiver how to prepare and inject HEPCLUDEX before you use it for the first time. You can also follow the patient leaflet and Instructions for Use that came with your medicine, or watch a step-by-step video at www.HEPCLUDEX.com.

2 Where should I inject HEPCLUDEX?

To inject, choose one of the following sites:

- Lower abdomen (stomach)
- Upper thigh
- Back of upper arm (if someone else is injecting the medicine for you)

You will need to pinch and hold a fold of skin at the selected injection site. Do not inject HEPCLUDEX into the same site on consecutive days, into the 1-inch (2.5 cm) area around the belly button (navel), or into moles, scars, bruises, tattoos, or areas where the skin is red, hard, tender, or injured.

3 Should I inject HEPCLUDEX in the same location every day?

It is important to rotate injection sites every day. Do not use the same injection site on consecutive days.

4 How often should I inject HEPCLUDEX?

HEPCLUDEX is injected under the skin once per day.

5 Do I need to inject HEPCLUDEX at the same time every day?

It is important to take HEPCLUDEX on a regular dosing schedule.

6 What should I do if I forget to take HEPCLUDEX?

If you miss a dose, take that dose as soon as possible on that day. However, if it is almost time for your next dose, skip the missed dose and go back to the regular dosing schedule. Do not inject a double dose.

7 What should I do if I take too much HEPCLUDEX?

Tell your doctor or go to the nearest emergency room right away.

8 Are there any specific instructions for disposing of used needles or syringes?

Dispose of all used needles and syringes in a sharps disposal container. Immediately discard the used Syringe with Injection Needle attached and the used Transfer Needles. Keep the container out of reach of children. Dispose of the Sterile Water for Injection Vial and HEPCLUDEX Vial in household trash. Contact your doctor or pharmacist if you have any further questions.

9 What precautions should I take while injecting HEPCLUDEX?

Gather all materials needed for mixing and injecting a dose before you begin.

When selecting an injection site, use a different injection site from the last injection. Dispose of the needle in the sharps container, and keep the sharps disposal container out of the reach of children.

All components provided with HEPCLUDEX such as the HEPCLUDEX Vials, Sterile Water for Injection Vials, needles and other ancillary supplies are for single use only. Reusing may lead to infection.

For more information, please review the patient leaflet and Instructions for Use provided with your HEPCLUDEX or by your doctor.

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ADDITIONAL QUESTIONS

IMPORTANT SAFETY INFORMATION (CONT.)

How should I take HEPCLUDEX? (cont.)

- Do not reuse the vials, syringe, needles, or any remaining Sterile Water for Injection.
- Take HEPCLUDEX exactly as your healthcare provider tells you to take it.
- Take HEPCLUDEX 1 time each day.

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.

1 Are there any side effects associated with the administration of HEPCLUDEX?

The most common side effects of HEPCLUDEX are injection site reactions, headache, stomach area pain, feeling tired, and itchy skin. Tell your healthcare provider if you have any side effect that bothers you or that does not go away.

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

It is important that you tell your doctor or specialty pharmacy immediately about any side effects you experience, including any side effects not listed here. You may report side effects to the FDA at 1-800-FDA-1088.

2 What should I do if I experience an allergic reaction to HEPCLUDEX?

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.

3 Is it normal to feel soreness at the injection site?

Some people may experience infection, redness, itching, swelling, bruising, rash, and pain at the injection site.

4 Is it normal to feel nervous before injecting HEPCLUDEX?

It is normal for some people to feel nervous before injecting HEPCLUDEX. Referring to Important Information You Need to Know Before Injecting HEPCLUDEX within the Instructions for Use and the patient leaflet provided or asking your doctor for more injection training may help. You can also receive in-person help by enrolling in the Hepatitis Delta Nurse Educator Program by calling 1-855-769-7284, option 5.

5 Can I take other medications while taking HEPCLUDEX?

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Also ask them for a full list of medications that should not be taken with HEPCLUDEX.

6 Can I take HEPCLUDEX during pregnancy or while breastfeeding?

Currently, there are insufficient data available on the use of HEPCLUDEX during pregnancy and breastfeeding. Discuss with your doctor if you are or plan to become pregnant or breastfeed.

7 What are some tips for adjusting to HEPCLUDEX?

It is important to keep track of your daily injection by recording the date, time, and injection location of every injection so you don't inject into the same site on consecutive days.

Talk to your doctor about any side effects or administration concerns.

Try to create a routine for your injections. Over time, many people become more comfortable with the injection process.

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Contact your doctor or specialty pharmacy
if you have any further questions.

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