

HEPCLUDEX®

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

▼ This medicine is new or being used differently. Please report side effects. See the [full CMI](#) for further details.

1. Why am I using HEPCLUDEX?

HEPCLUDEX contains the active ingredient bulevirtide. HEPCLUDEX is used to treat long-term (chronic) hepatitis delta virus (HDV) infection in adults with compensated liver disease (when the liver is still working well enough). Infection with HDV causes inflammation of the liver.

For more information, see Section [1. Why am I using HEPCLUDEX?](#) in the full CMI.

2. What should I know before I use HEPCLUDEX?

Do not use if you have ever had an allergic reaction to HEPCLUDEX or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use HEPCLUDEX?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with HEPCLUDEX and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use HEPCLUDEX?

- The recommended dose is 2 mg once daily by subcutaneous injection (just under the skin). Your doctor will say how long you need to take the medicine for.
- Your doctor or nurse will show you how to prepare and inject HEPCLUDEX. This package leaflet contains an instructions for use guide to help you inject the medicine correctly.

More instructions can be found in Section [4. How do I use HEPCLUDEX?](#) in the full CMI.

5. What should I know while using HEPCLUDEX?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using HEPCLUDEX.
Things you should not do	<ul style="list-style-type: none">• Do not stop your treatment with HEPCLUDEX unless your doctor advises you to do so. Stopping the treatment can reactivate the infection and worsen your disease.
Driving or using machines	<ul style="list-style-type: none">• Dizziness and tiredness are side effects which may impair your ability to drive and use machines. If you have any concerns consult your doctor.
Looking after your medicine	<ul style="list-style-type: none">• Store in a refrigerator (2°C – 8°C).• In order to protect from light, keep the vials in the outer carton.• Use reconstituted product immediately. Do not refrigerate.

For more information, see Section [5. What should I know while using HEPCLUDEX?](#) in the full CMI.

6. Are there any side effects?

The most common side effects of HEPCLUDEX are headache, itching and injection site reactions.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.



This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. You can report side effects to your doctor, or directly at www.tga.gov.au/reporting-problems.

HEPCLUDEX

Active ingredient(s): *bulevirtide*

Consumer Medicine Information (CMI)

This leaflet provides important information about using HEPCLUDEX. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using HEPCLUDEX.**

Where to find information in this leaflet:

- [1. Why am I using HEPCLUDEX?](#)
- [2. What should I know before I use HEPCLUDEX?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use HEPCLUDEX?](#)
- [5. What should I know while using HEPCLUDEX?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using HEPCLUDEX?

HEPCLUDEX contains the active ingredient *bulevirtide*.

HEPCLUDEX is used to treat long-term (chronic) hepatitis delta virus (HDV) infection in adults with compensated liver disease (when the liver is still working well enough).

2. What should I know before I use HEPCLUDEX?

Warnings

Do not use HEPCLUDEX if:

- you are allergic to *bulevirtide*, or any of the ingredients listed at the end of this leaflet.
- always check the ingredients to make sure you can use this medicine.

Check with your doctor if you:

- have any other medical conditions.
- take any medicines for any other condition.
- have liver problems other than hepatitis D and hepatitis B infection.
- have kidney problems.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and

how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant. Ask your doctor for advice before taking this medicine. You should not use this medicine unless specifically told to by your doctor.

Talk to your doctor if you are breastfeeding or intend to breastfeed. It is not known whether HEPCLUDEX can pass into breast milk. Therefore, a decision must be made whether to discontinue HEPCLUDEX.

Use in Children and Adolescents

Children and adolescents under 18 years of age should not be treated with HEPCLUDEX.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect HEPCLUDEX.

4. How do I use HEPCLUDEX?

How much to take / use

- The recommended dose is 2 mg once daily by subcutaneous injection (just under the skin). Your doctor will say how long you need to take the medicine for.
- Your doctor and nurse will show you how to prepare and inject HEPCLUDEX. This package leaflet contains an instructions for use guide to help you inject the medicine. See instructions under Section 8.

If you forget to use HEPCLUDEX

- Do not** miss a dose of 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 double doses.

Do not take a double dose to make up for the missed dose. Tell your doctor if you have missed a dose of HEPCLUDEX.

If you stop taking HEPCLUDEX

If you do not want to take HEPCLUDEX anymore, talk to your doctor before stopping the treatment. Stopping the treatment can reactivate the infection and worsen your disease. If this happens, you may need to restart treatment with HEPCLUDEX again. Tell your doctor immediately about any changes in symptoms after stopping treatment.

If you have any further questions on the use of HEPCLUDEX, ask your doctor or nurse.

If you use too much HEPCLUDEX

If you think that you have used too much HEPCLUDEX, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using HEPCLUDEX?

Things you should do

- Remind any doctor, dentist or pharmacist you visit that you are using HEPCLUDEX.
- Always take this medicine exactly as your doctor has told you.
- Check with your doctor if you are not sure.

Things you should not do

- Do not stop using HEPCLUDEX without talking to your doctor. Stopping the treatment can reactivate the infection and worsen your disease. Tell your doctor immediately about any changes in symptoms should you stop treatment.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how HEPCLUDEX affects you.

Dizziness and tiredness are side effect which may impair your ability to drive and use machines. If you have any concerns consult your doctor.

Looking after your medicine

- Store in a refrigerator (2°C – 8°C).
- In order to protect from light, keep the vials in the outer carton.
- Use reconstituted product immediately. Do not refrigerate.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

Do not reuse the vials, syringe, needles, or any remaining Sterile Water for Injection. HEPCLUDEX and auxiliary supplies are for **Single Use Only**. Throw away (dispose of) all components after use, including unused Sterile Water For Injection.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
<p>Very common</p> <ul style="list-style-type: none"> • headache • itching • reactions at the injection site that may include swelling, redness, irritation, bruising, itchiness, rash, hardening, infection or local pain <p><i>Blood tests may also show:</i></p> <ul style="list-style-type: none"> • an increase in the level of bile acids in the blood <p>Common</p> <ul style="list-style-type: none"> • dizziness • nausea • tiredness <p><i>Blood tests may also show:</i></p> <ul style="list-style-type: none"> • an increase in white blood cells (eosinophils) 	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

Serious side effects

Serious side effects	What to do
<p>Uncommon</p> <ul style="list-style-type: none">allergic reactions, including anaphylactic reaction (sudden life-threatening allergic reaction) <p>Signs of allergic reactions can include:</p> <ul style="list-style-type: none">shortness of breath or wheezingswelling of the face, lips, tongue or throat (angioedema)skin rasheschanges to blood pressure or heart rate <p>Symptoms of anaphylactic reaction are like those of allergic reaction, but more severe and require immediate medical care.</p>	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What HEPCLUDEX contains

Active ingredient (main ingredient)	bulevirtide
Other ingredients (inactive ingredients)	Sodium carbonate anhydrous Sodium hydrogen carbonate Mannitol Hydrochloric acid Sodium hydroxide
Potential allergens	N/A

Do not use this medicine if you are allergic to any of these ingredients.

What HEPCLUDEX looks like

Bulevirtide is a powder for solution for injection and comes as a white to off-white powder. Each carton contains 30 single doses.

AUST R 407179

Who distributes HEPCLUDEX

Gilead Sciences Pty Ltd
Level 28, 385 Bourke Street
Melbourne, Victoria 3000
Australia

This leaflet was prepared in August 2025.

8. Instructions for Use

Before using HEPCLUDEX, you must first read and understand sections 1 – 7 of this CMI.

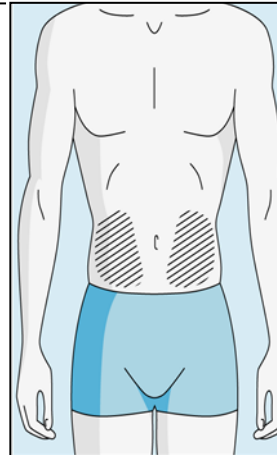
Before you begin treatment with this medicine at home, your doctor or nurse will show you how to prepare and inject HEPCLUDEX. This guide shows how to prepare and inject the medicine yourself. Speak with your doctor or nurse if you are unclear about anything, have questions or need more information or help. Take your time to carefully prepare and inject HEPCLUDEX.

Injection sites

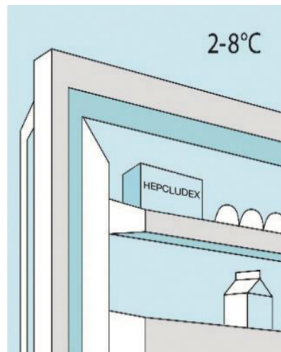
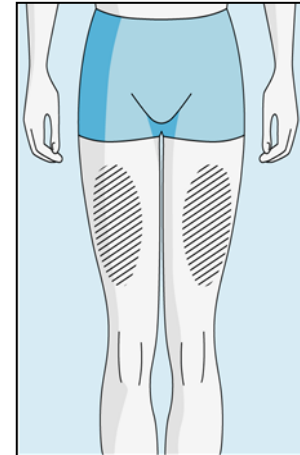
In order to reduce injection site reactions, change the site of HEPCLUDEX injection with each injection.

Do not inject HEPCLUDEX into the following areas: knee, groin, the lower or inner buttocks, directly over a blood vessel, around the navel (belly button), on scar tissue, a bruise, a mole, a surgical scar, tattoo or burn site, or where there is an injection site reaction.

Abdomen

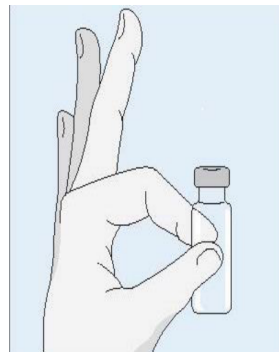


Upper thighs



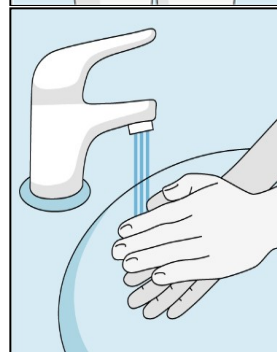
1A Storage

HEPCLUDEX vials must be stored in the original packaging in the refrigerator (2–8°C) in order to protect HEPCLUDEX from light.



1B Preparing doses

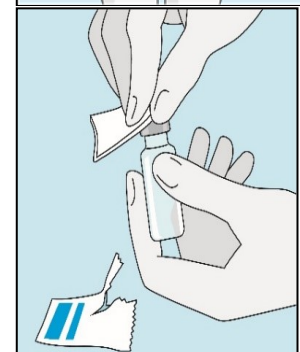
The following instructions are for dissolving a single dose.



1C Wash hands

Wash your hands well using soap and warm water and dry them with a clean towel.

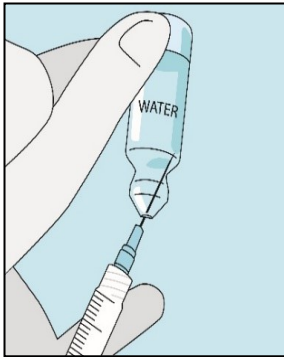
Once your hands are clean, **do not** touch anything else other than the medicine, supplies and the area around the injection site.



1D Clean vial

Wipe the vial top with a new alcohol pad and let the top air-dry.

If you touch the rubber top after cleaning it, clean it again with a new alcohol pad.



2A
Draw up sterile water

Pick up the syringe. Put the longer needle on.

Important! Be sure the capped needle is tight by pushing it down slightly while twisting it clockwise.

Pull off the plastic cap.

Open the sterile water for injection. Insert the needle in the vial and gently turn the water vial upside down. Make sure the tip of the needle is always below the surface of the water to help keep air bubbles from entering the syringe.

Slowly pull the plunger back to get 1 mL of sterile water for injection into the syringe. Carefully remove the needle and syringe from the vial.

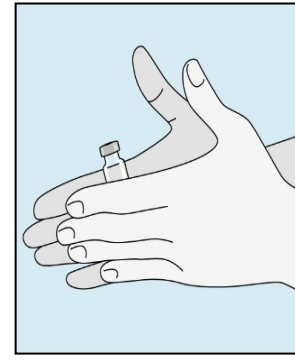


2B
Inject sterile water into the powder

Gently tap the HEPCLUDEX vial to loosen the powder.

Insert the needle with sterile water for injection into the HEPCLUDEX vial at an angle.

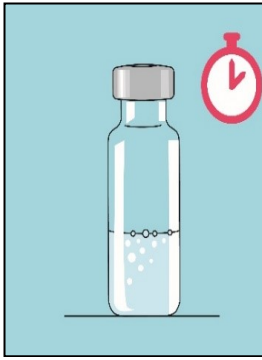
Inject the sterile water for injection slowly, so it can drip down the side of the vial into the HEPCLUDEX powder.



2C
Gently mix bulevirtide

Gently tap the HEPCLUDEX vial with your fingertip for 10 seconds to start dissolving the powder. Then gently roll the HEPCLUDEX vial between your hands to ensure thorough mixing. Make sure no HEPCLUDEX powder is stuck to the vial wall.

Important! Do not shake the HEPCLUDEX vial. Shaking will make the medicine foam and it will take much longer to dissolve.



2D
Inspect
HEPCLUDEX

Once the powder starts to dissolve, just set it aside and it will completely dissolve.

After tapping, it could take up to 3 min to dissolve.



2E
HEPCLUDEX ready for injection

When mixed completely, the HEPCLUDEX solution should be clear.

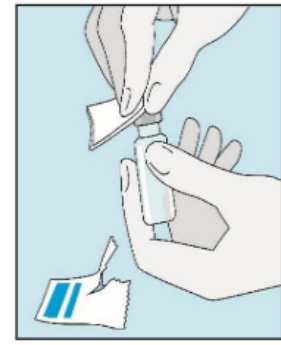
Important! Completely dissolved HEPCLUDEX should be clear and without foam.

If the HEPCLUDEX solution appears foamy, allow more time for it to dissolve.

If you see bubbles, gently tap the vial until they disappear.

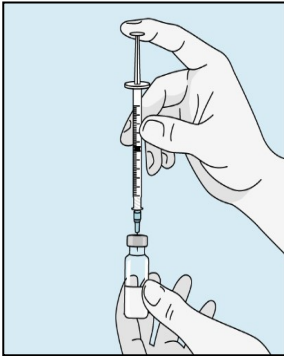
If you see any particles in the HEPCLUDEX solution once it is (completely) dissolved, do not use that vial. Contact your doctor or pharmacist that provided it.

Reconstituted HEPCLUDEX must be used immediately.



2F
Clean Vial

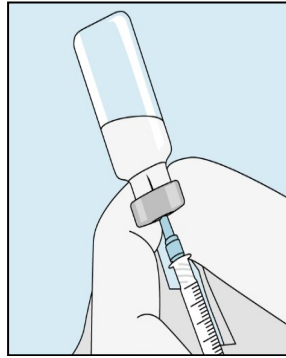
Clean the HEPCLUDEX vial top again, using a new alcohol pad. Allow it to air dry.



3A
Insert needle into vial

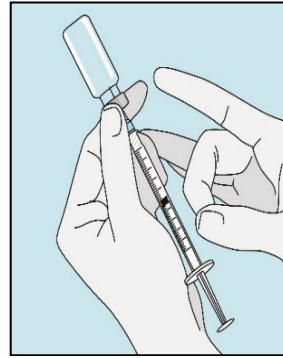
Pick up the syringe.

Insert the needle into the vial of liquid HEPCLUDEX.



3B
Draw up HEPCLUDEX

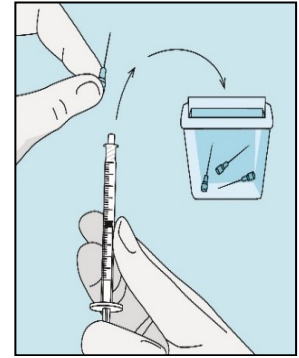
Gently turn the vial upside down. Make sure the tip of the needle is always below the surface of the HEPCLUDEX solution to help keep air bubbles from entering the syringe. Slowly pull the plunger to get 1 mL of HEPCLUDEX.



3C
Finishing preparation

Gently tap or flick the syringe and push/pull the plunger to remove extra air and bubbles. To be sure you end up with 1 mL of HEPCLUDEX in the syringe, you may need to pull the plunger past the 1 mL mark.

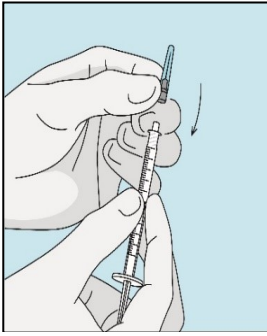
Carefully remove the needle and syringe from the vial.



3D
Change and discard the needle

Remove the longer needle from the syringe and dispose of it properly so that nobody can be injured.

Important! Do not put the plastic cap back on the needle.



3E
Attach needle for injection

Place the shorter needle on the syringe.

Important! Be sure the capped needle is tight by pushing it down slightly while twisting it clockwise.

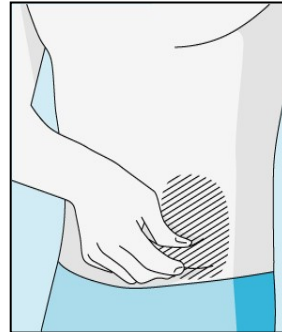
Pull off the plastic cap.



3F
Choose the injection site

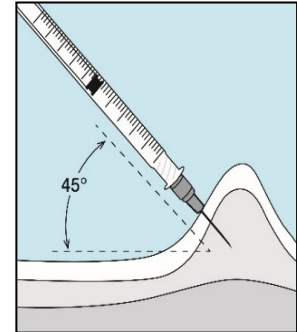
Choose a site different from the one you used for your last injection. Clean the injection site with a new alcohol pad. Start in the centre, apply pressure and clean in a circular motion, working outward.

Important! Allow site to air-dry.



3G
Prepare injection site

Pinch and hold a fold of skin around the injection site.



3H
Inject HEPCLUDEX

Pierce the skin at a 45-degree angle. The needle should be inserted most of the way in.

Slowly push the plunger all the way to inject HEPCLUDEX.

Remove the needle from skin.

Remove the needle from the syringe and dispose of both properly so that nobody can be injured (see 3D).

Important! Do not reuse the HEPCLUDEX vial, syringe, needles, or any remaining Sterile Water for Injection.

Discard the vial after use, including any unused excess liquid.

HEPCLUDEX vials and other supplies are for **Single Use Only**. Throw away (dispose of) all components after use, including unused Sterile Water for Injection.