

Package leaflet: Information for the patient

Hepcludex 2 mg powder for solution for injection bulevirtide

▼ 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. See the end of section 4 for how to report side effects.

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Hepcludex is and what it is used for
2. What you need to know before you use Hepcludex
3. How to use Hepcludex
4. Possible side effects
5. How to store Hepcludex
6. Contents of the pack and other information
7. Step-by-step injection guide

If Hepcludex has been prescribed for your child, please note that all the information in this leaflet is addressed to your child (in this case please read “your child” instead of “you”).

1. What Hepcludex is and what it is used for

What Hepcludex is

Hepcludex contains the active substance bulevirtide, which is an antiviral medicine.

What Hepcludex is used for

Hepcludex is used to treat long-term (chronic) hepatitis delta virus (HDV) infection in adults and children 3 years of age and older weighing at least 10 kg with compensated liver disease (when the liver is still working well enough).

Infection with hepatitis delta virus causes inflammation of the liver.

How Hepcludex works

HDV uses a particular protein in liver cells to enter the cells. Bulevirtide, the active substance in this medicine blocks the protein and so prevents the HDV from getting into liver cells. This reduces the spread of HDV in the liver and reduces inflammation.

2. What you need to know before you use Hepcludex

Do not use Hepcludex:

1. if you are allergic to bulevirtide or any of the other ingredients of this medicine (listed in section 6).

If you are not sure, speak to your doctor before using this medicine.

Warnings and precautions

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. If this happens, you may need to restart treatment with Hepcludex again.

Talk to your doctor or pharmacist before using Hepcludex:

1. if your liver is not working well enough – it is not known how well Hepcludex works in these circumstances; if your liver is not functioning well, using Hepcludex is not recommended.
2. if you have had kidney disease or if tests have shown problems with your kidneys. Before and during treatment, your doctor may order blood tests to check how well your kidneys are working;
3. if you have HIV infection or hepatitis C - it is not known how well Hepcludex works in these circumstances; your doctor may order blood tests to check the status of your HIV or hepatitis C infection

Children and adolescents

Children under 3 years of age or weighing less than 10 kg should not be treated with Hepcludex.

Other medicines and Hepcludex

Please tell your doctor if you are using, have recently used, or might use any other medicines.

Some medicines can increase side effects of Hepcludex and you should not use them at the same time. This is why you should tell your doctor if you are using any of these medicines:

1. ciclosporin, a medicine that suppresses the immune system;
2. ezetimibe, used for treating high blood cholesterol;
3. irbesartan, used for treating high blood pressure and heart disease;
4. ritonavir, used to treat HIV infection;
5. sulfasalazine, (used for treating rheumatoid arthritis, ulcerative colitis, and Crohn's disease).

Some medicines can increase or decrease the effects of Hepcludex when used together. In some cases, you may need to have certain tests or your doctor may change the dose or monitor you regularly:

1. cancer treatments (e.g. dasatinib, docetaxel, ibrutinib, paclitaxel);
2. antihistamine medicines used for allergies (e.g. ebastine, fexofenadine);
3. immune system medicines (e.g. everolimus, sirolimus, tacrolimus);
4. medicines for hepatitis C and HIV treatment (e.g. darunavir, glecaprevir, grazoprevir, indinavir, maraviroc, paritaprevir, saquinavir, simeprevir, tipranavir, voxilaprevir);
5. medicines for diabetes (e.g. glibenclamide, nateglinide, repaglinide);
6. medicines for erectile dysfunction (e.g., avanafil, sildenafil, vardenafil);
7. medicines for treating high blood pressure and heart disease (e.g. olmesartan, telmisartan, valsartan);
8. statin, medicines used for high blood cholesterol (e.g. atorvastatin, fluvastatin, lovastatin, pitavastatin, pravastatin, rosuvastatin, simvastatin);
9. thyroid hormones used to treat thyroid problems;
10. alfentanil, an opioid medicine used to treat severe pain;
11. bosentan, used for pulmonary arterial hypertension;

12. buspirone, an anxiety medicine;
13. budesonide, used for asthma and chronic obstructive pulmonary disease;
14. conivaptan and tolvaptan, used to treat hyponatraemia (low sodium levels);
15. darifenacin, used to treat urinary incontinence;
16. dronedarone, heart medicine for cardiac arrhythmias;
17. eletriptan, used for migraine headaches;
18. eplerenone, used for high blood pressure;
19. estrone-3-sulfate a menopausal hormone medicine;
20. felodipine and nisoldipine (heart medicines);
21. lomitapide, used for high blood cholesterol;
22. lurasidone and quetiapine, antipsychotic medicines for psychiatric disorders;
23. midazolam and triazolam, medicines to treat insomnia (inability to sleep) and for anaesthesia (to avoid pain during surgery);
24. naloxegol, used to treat dependence on opioid medicines for severe pain;
25. ticagrelor, anticoagulant to prevent blood clotting.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before using this medicine. You should not use this medicine unless specifically told to by your doctor.

If you are a woman of childbearing potential, you should not use this medicine without using an effective method of contraception.

Talk to your doctor to decide whether you should breastfeed while using Hepcludex.

It is not known whether Hepcludex can pass into breast milk. Therefore, a decision must be made whether to discontinue breast-feeding or to discontinue Hepcludex.

Driving and using machines

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

Hepcludex contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per ml, that is to say essentially "sodium-free".

3. How to use Hepcludex

Always use this medicine exactly as your doctor has told you. Check with your doctor if you are not sure.

Dosage

Hepcludex is to be given once a day, as an injection just under the skin (subcutaneous injection).

Your doctor and nurse will show you how to prepare and inject Hepcludex. This package leaflet contains a step-by-step injection guide to help you inject the medicine (see section 7).

Recommended dose

The recommended dose of Hepcludex in adults is 2 mg once daily.

The recommended dose of Hepcludex in patients aged 3 to less than 18 years depends on weight, as outlined in the table below.

Age/ weight	Dose	Amount to inject
Children aged 3 years or more who weigh 35 kg or more	2 mg, once a day	1.0 ml

Age/ weight	Dose	Amount to inject
Children aged 3 and over, who weigh at least 25 kg but less than 35 kg	1.5 mg, once a day	0.75 ml
Children aged 3 and over, who weigh at least 10 kg but less than 25 kg	1 mg, once a day	0.5 ml

Your doctor will say how long you need to use the medicine for.

If you use more Hepcludex than you should

If you think you may have used more than you should, tell your doctor immediately.

If you forget to use Hepcludex

If less than 4 hours have passed since your missed dose of Hepcludex, take the missing dose as soon as possible and take your next scheduled dose at the usual time.

If more than 4 hours have passed since your missed dose of Hepcludex, **do not** take the missed dose. Take the next dose the following day at the usual time. 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 using Hepcludex

If you do not want to use Hepcludex anymore, talk to your doctor before stopping the treatment. Stopping the treatment can reactivate the infection and worsen your disease. 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.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Please tell your doctor if any of the side effects occur, or if you notice any side effects not listed in this leaflet.

The following side effect is **very common** (this may affect more than 1 in 10 people):

- headache
- itching
- reactions at the injection site that may include swelling, redness, irritation, bruising, itchiness, rash, hardening, infection or local pain

The following side effects are **common** (these may affect up to 1 in 10 people):

- dizziness
- nausea
- tiredness
- flu-like illness
- joint pain

The following side effects are **uncommon** (these may affect up to 1 in 100 people):

- allergic reactions, including anaphylactic reaction (sudden life-threatening allergic reaction).

Symptoms of allergic reactions can include:

- shortness of breath or wheezing
- swelling of the face, lips, tongue or throat (angioedema)

- skin rashes
- changes to blood pressure or heart rate.

Symptoms of anaphylactic reaction are like those of allergic reaction, but more severe and require immediate medical care.

Blood tests may also show:

- an increase in the level of bile acids in the blood (very common)
- an increase in white blood cells (eosinophils) (common).

Reporting of side effects

If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system:

Italian Medicines Agency

Website:

<https://www.aifa.gov.it/content/segnalazioni-reazioni-avverse>

By reporting side effects, you can help to provide more information on the safety of this medicine.

5. How to store Hepcludex

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and vial after EXP. The expiry date refers to the last day of that month.

Store in a refrigerator (2°C -8°C). In order to protect from light, keep the vials in the outer carton.

The reconstituted solution should be used immediately. However, if this is not possible it can be stored for up to 2 hours at a temperature of up to 25°C.

Important: Do not reuse the vials, syringe, needles or any remaining sterile water for injection. Hepcludex and ancillary supplies are for single use only. Throw away all components after use, including unused sterile water for injection.

Do not throw away any medicines or used needles via wastewater or household waste. Ask your pharmacist how to safely dispose medicines and used needles.

6. Contents of the pack and other information

What Hepcludex contains

The active substance is bulevirtide 2 mg. Each vial contains bulevirtide acetate equivalent to 2 mg bulevirtide.

The other ingredients are: sodium carbonate anhydrous, sodium hydrogen carbonate, mannitol, hydrochloric acid, sodium hydroxide.

What Hepcludex looks like and contents of the pack

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

Marketing Authorisation Holder

Gilead Sciences Ireland UC
Carrigtohill
County Cork, T45 DP77
Ireland

Manufacturer

Gilead Sciences Ireland UC
IDA Business and Technology Park
Carrigtohill
Co. Cork
Ireland

For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder:

België/Belgique/Belgien

Gilead Sciences Belgium SRL-BV
Tél/Tel: + 32 (0) 24 01 35 50

България

Gilead Sciences Ireland UC
Тел.: + 353 (0) 1 686 1888

Česká republika

Gilead Sciences s.r.o.
Tel: + 420 (0) 910 871 986

Danmark

Gilead Sciences Sweden AB
Tlf.: + 46 (0) 8 5057 1849

Deutschland

Gilead Sciences GmbH
Tel: + 49 (0) 89 899890-0

Eesti

Gilead Sciences Ireland UC
Tel.: + 353 (0) 1 686 1888

Ελλάδα

Gilead Sciences Ελλάς Μ.ΕΠΕ.
Τηλ: + 30 (0) 210 8930 100

España

Gilead Sciences, S.L.
Tel: + 34 (0) 91 378 98 30

France

Gilead Sciences
Tél: + 33 (0) 1 46 09 41 00

Hrvatska

Gilead Sciences Ireland UC
Tel: + 353 (0) 1 686 1888

Ireland**Lietuva**

Gilead Sciences Ireland UC
Tel.: + 353 (0) 1 686 1888

Luxembourg/Luxemburg

Gilead Sciences Belgium SRL-BV
Tél/Tel: + 32 (0) 24 01 35 50

Magyarország

Gilead Sciences Ireland UC
Tel.: + 353 (0) 1 686 1888

Malta

Gilead Sciences Ireland UC
Tel: + 353 (0) 1 686 1888

Nederland

Gilead Sciences Netherlands B.V.
Tel: + 31 (0) 20 718 36 98

Norge

Gilead Sciences Sweden AB
Tlf: + 46 (0) 8 5057 1849

Österreich

Gilead Sciences GesmbH
Tel: + 43 (0) 1 260 830

Polska

Gilead Sciences Poland Sp. z o.o.
Tel.: + 48 (0) 22 262 8702

Portugal

Gilead Sciences, Lda.
Tel: + 351 (0) 21 7928790

România

Gilead Sciences (GSR) S.R.L.
Tel: +40 31 631 18 00

Slovenija

Gilead Sciences Ireland UC
Tel: + 353 (0) 214 825 999

Ísland

Gilead Sciences Sweden AB
Sími: + 46 (0) 8 5057 1849

Italia

Gilead Sciences S.r.l.
Tel: + 39 02 439201

Κύπρος

Gilead Sciences Ελλάς Μ.ΕΠΕ.
Τηλ: + 30 (0) 210 8930 100

Latvija

Gilead Sciences Ireland UC
Tel.: + 353 (0) 1 686 1888

Gilead Sciences Ireland UC
Tel: + 353 (0) 1 686 1888

Slovenská republika

Gilead Sciences Slovakia s.r.o.
Tel: + 421 (0) 232 121 210

Suomi/Finland

Gilead Sciences Sweden AB
Puh/Tel: + 46 (0) 8 5057 1849

Sverige

Gilead Sciences Sweden AB
Tel: + 46 (0) 8 5057 1849

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7. Step-by-step injection guide for patients/caregivers

Before using Hepcludex, you must first read sections 1 – 6 of this package leaflet.

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 Hepcludex. Speak with your doctor or nurse if you are unclear about anything or you have questions or need more information or help. Take your time to carefully prepare and inject Hepcludex.

If your child has been prescribed Hepcludex, but is unable to administer it themselves, please note that all the information in this step-by-step injection guide for administration of Hepcludex is addressed to you, as the child's caregiver.

Children or adolescents should only inject themselves following training from a healthcare professional and under supervision of an adult caregiver.

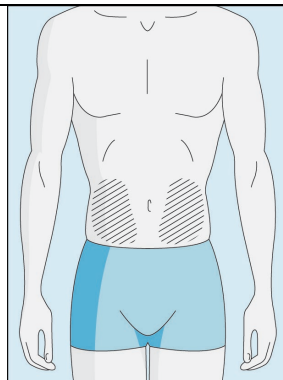
Note: The supplies (needles, syringes, sterile water for injection) not included in the Hepcludex carton may slightly differ in size, shape and color from the figures shown in this step-by-step injection guide. These instructions provide the steps to mix and inject Hepcludex using an example set of supplies. If you have any questions, contact your healthcare provider or pharmacist.

Injection sites

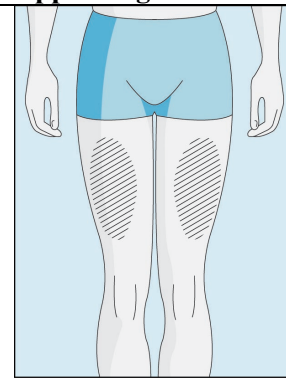
The best places to inject are the abdomen and upper thighs, shown in the pictures. In order to reduce injection site reactions, you may change the site of Hepcludex injection regularly.

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.

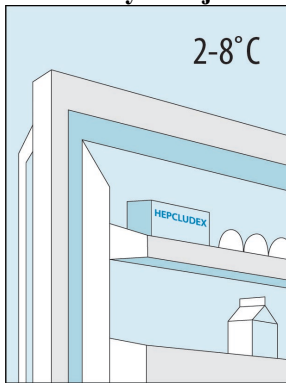
Abdomen



Upper thighs

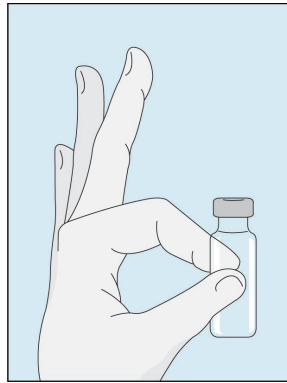


1. Before you inject



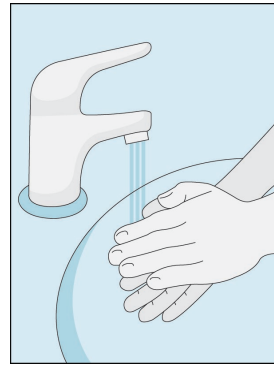
1A
Storage

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

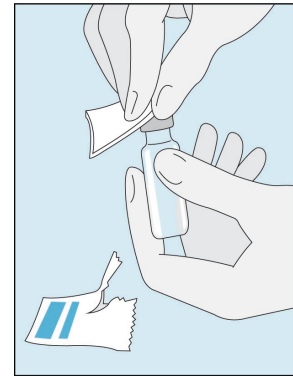
The following instructions are for dissolving a single dose.



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.

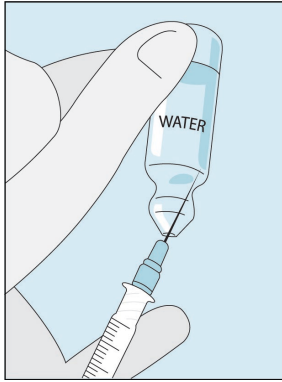


1D
Clean vial

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.

2. Mix the injection



2A
Draw up sterile water

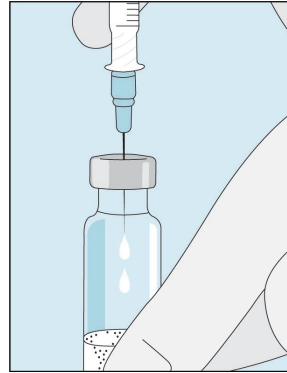
Pick up the syringe. Put the longer needle on.

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

Pull off the plastic cap.

Open the vial of 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 1.0 ml of sterile water into the syringe. Carefully remove the needle and syringe from the vial.



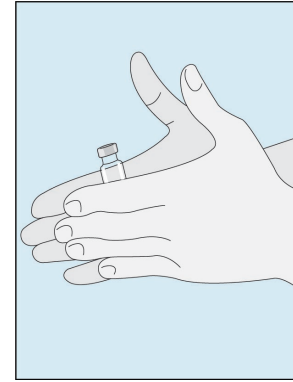
2B
Inject sterile water into the powder

Gently tap the Hepcludex vial to loosen the powder.

Insert the needle with sterile water all the way into the Hepcludex vial by pushing it straight through the centre of the rubber stopper at a 90° angle.

Inject all the sterile water slowly.

Remove the needle from the vial and put the syringe and needle somewhere safe.

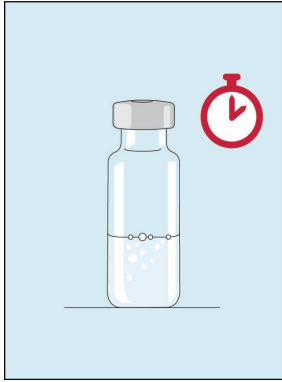


2C
Gently mix Hepcludex

Gently tap the Hepcludex vial with your fingertip for 10 seconds to start dissolving the powder.

Then gently roll the vial between your hands to ensure thorough mixing. Make sure no powder is stuck to the vial wall.

Important! Do not shake the 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 completely will dissolve.

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



2E
Hepcludex ready for injection

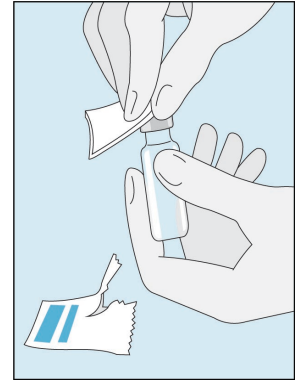
When mixed completely, the Hepcludex solution should be clear.

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

If the solution appears foamy or yellowish, 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 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.

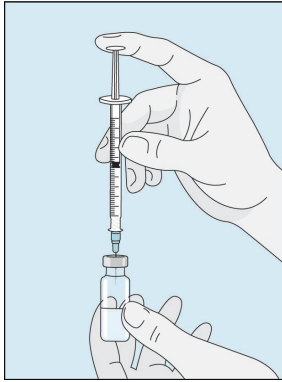


2F
Clean vial

Clean the Hepcludex vial top again, using a new alcohol pad.

Allow it to air dry.

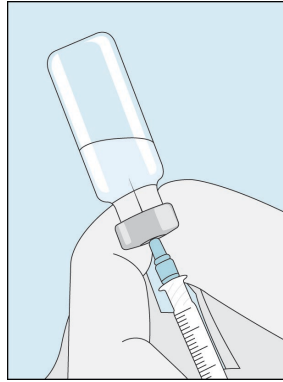
3. Inject a dose



3A
Insert needle into vial

Pick up the syringe.

Re-insert the needle all the way into the Hepcludex vial by pushing it straight through the centre of the rubber stopper at a 90° angle.



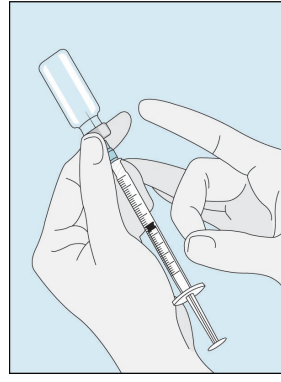
3B
Draw up Hepcludex

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.

Double check the amount to inject, using the table called *Recommended dose* in section 3 of the package leaflet.

Slowly pull the plunger to get the amount of liquid you need.

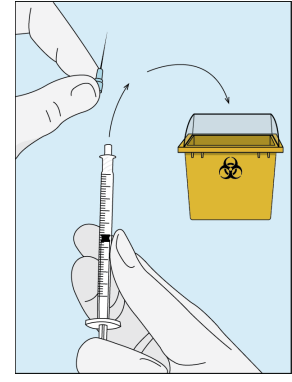


3C
Finishing preparation

Gently tap or flick the syringe and push/pull the plunger to remove extra air and bubbles.

To be sure you end up with the right amount of Hepcludex in the syringe, you may need to pull the plunger past the mark on the syringe.

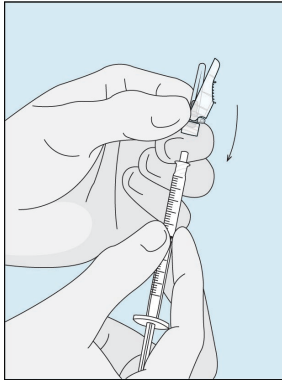
Carefully remove the needle and syringe from the vial.



3D Change and discard the needle

Remove the longer needle from the syringe and dispose of it properly into a sharps disposal container so that nobody can be injured.

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

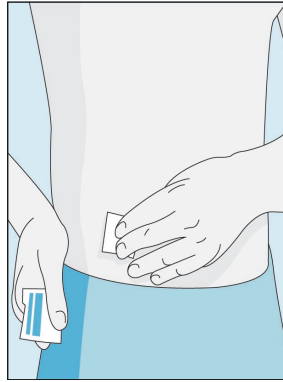


3E
Attach needle for injection

Place the shorter needle on the syringe.

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

Note: The shorter needle may or may not have a safety shield on the side.



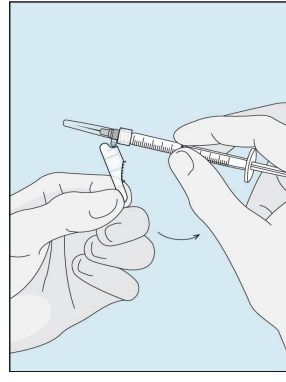
3F
Choose the injection site

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.

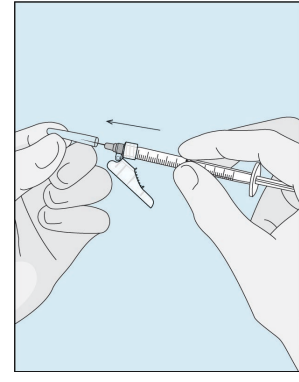


3G
Fold back safety shield (if applicable)

Note: If there is no safety shield on the injection needle, go directly to Step **3H**.

Hold the syringe with one hand and fold the safety shield back towards the syringe.

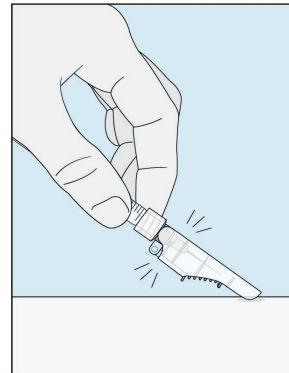
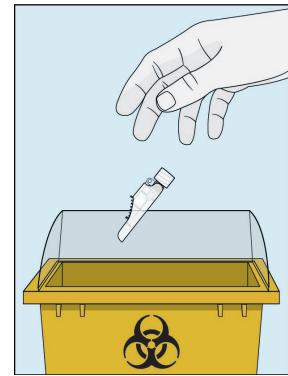
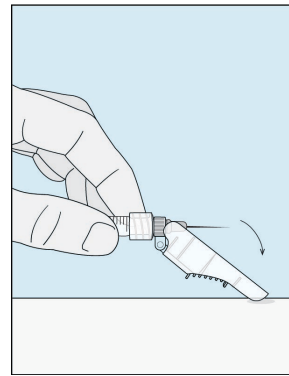
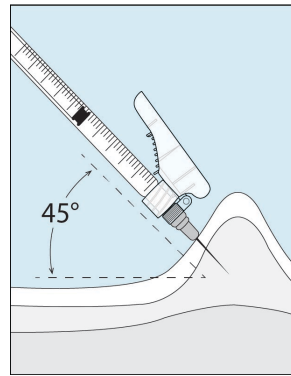
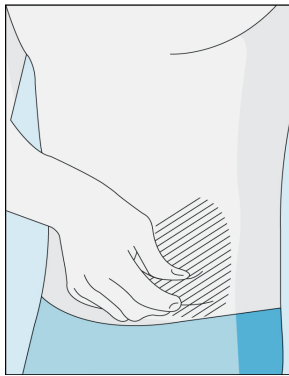
Do not remove the needle safety shield from the injection needle.



3H
Remove needle cap

Carefully pull off the injection needle plastic cap.

Do not touch the needle or allow it to touch any other surface.



3I
Prepare injection site

3J
Inject Hepcludex

3K
After injecting, cover needle with safety shield (if applicable)

3L
Dispose of the needle properly

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

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

Note: If there is no safety shield on the injection needle, go directly to Step **3L**.

Remove the needle from the syringe and throw away (dispose of) into the sharps disposal container so that nobody can be injured.

Slowly push the plunger all the way to inject Hepcludex .

Place the injection needle safety shield on the work surface.

Dispose of the syringe (without needle) separately and according to local guidelines.

Remove the needle from skin.

Press the needle toward the safety shield to cover the needle and lock the safety shield.

Important! Do not reuse the Hepcludex vial, syringe, needles or any remaining sterile water for injection.

Do not touch the needle.

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.