

Patient information factsheet

Bulevirtide (Hepcludex[®]) for the treatment of chronic hepatitis D

We have given you this factsheet because you are due to start a course of medication called bulevirtide (also known by its brand name Hepcludex[®]) to treat hepatitis D. It explains what bulevirtide is, how it is given and the possible side effects. We hope it will answer some of your questions. If you have any further questions or concerns, please contact us using the details at the end of the factsheet.

What is hepatitis D?

Hepatitis D is an infection of the liver caused by the hepatitis delta virus (HDV). It only affects people who are already infected with hepatitis B, as it needs the hepatitis B virus to be able to survive in the body.

Chronic (long-term) HDV infection can increase your risk of developing serious problems, such as cirrhosis (scarring of the liver caused by long-term liver damage) and liver cancer.

What is bulevirtide?

Bulevirtide is an antiviral medication used to treat chronic HDV infection in adults with compensated liver disease (when the liver is damaged but is still able to work). Bulevirtide is the only recommended treatment for HDV infection.

How does bulevirtide work?

The HDV enters your liver cells using special entrances called proteins. Bulevirtide works by blocking these proteins, preventing infection.

How is bulevirtide given?

Bulevirtide is given as a daily subcutaneous injection (into the subcutaneous fat under the skin), usually into the upper thigh or abdomen.

We will show you how to safely give yourself the injection. A step-by-step injection guide can also be found in the leaflet supplied with your medication.

What should I do if I miss a dose?

If a dose is **less than four hours** late, give yourself the missed dose as soon as possible. The next dose can be given at the normal time the next day.

If a dose is **more than four hours** late, the missed dose should **not** be given and the next dose should be given at the normal time the next day.

Never take a double dose of bulevirtide.

How long is the course of bulevirtide?

How long your course is will depend on your response to the medication. We will monitor your response to the medication on a regular basis and advise when the treatment can be stopped.

It is important that you continue to give yourself the bulevirtide injections until we tell you to stop. Stopping early can reactivate your HDV infection and make your symptoms worse.

What are the possible side effects?

Like all medications, bulevirtide can cause some side effects. The most common side effects include:

- headaches
- itchy skin (pruritus)
- dizziness (if you experience this, you **must not** drive or use heavy machinery)
- tiredness (if you experience this, you **must not** drive or use heavy machinery)
- nausea (feeling sick)
- flu-like symptoms
- eosinophilia (an unusually high number of eosinophils (a type of immune cell) in your blood)
- injection site reactions (including swelling, redness, irritation, bruising, itchiness, rash, skin hardening, infection and localised pain)

Injection site reactions can be reduced by:

- using a good injection technique (we will show you how to inject yourself correctly)
- changing the injection site regularly

For the full list of possible side effects that may occur with bulevirtide, please read the leaflet supplied with your medication.

If you experience any side effects, please contact us as soon as possible for advice.

How should bulevirtide be stored?

- Store in a refrigerator (between 2°C and 8°C).
- Protect the medication from the light by keeping the vials in the outer carton.
- Once you have prepared the injection, you should give it immediately. If this is not possible, it can be stored for up to two hours at a temperature of up to 25°C.
- Do not use this medication after its expiry date (this can be found on the carton and vial). The expiry date refers to the last day of that month. If the medication has passed its expiry date, contact us as soon as possible for advice.

Will I be monitored while having this treatment?

You will need regular check-up appointments after starting the course of bulevirtide. These appointments will either be face-to-face in our hepatology nurse clinic or by telephone. We will let you know in advance what type of appointment it will be. The appointments will usually be:

- once a week for the first four weeks
- then every two weeks for the next four weeks
- then once a month until you have finished the course of treatment.

We will check your HDV viral count every 12 weeks until you have finished the course of treatment.

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Is bulevirtide suitable for everyone?

Bulevirtide is **not** recommended for people:

- with decompensated liver disease (when the liver is severely damaged and is unable to work properly)
- who are allergic to the active substance or to any of the other substances found in bulevirtide (for example, sodium carbonate anhydrous, sodium hydrogen carbonate, mannitol, hydrochloric acid, and sodium hydroxide)

Can I take bulevirtide if I am pregnant or breastfeeding?

If you are pregnant, could be pregnant, trying to become pregnant or breastfeeding, please speak to your doctor before taking bulevirtide.

Can I take other medications at the same time as bulevirtide?

It is important that you tell your doctor what medications you are taking (including non-prescription medications, herbal therapies and recreational drugs) before starting bulevirtide. This is because some medications may interact with bulevirtide.

Additional advice

For more information about bulevirtide, please read the leaflet supplied with your medication.

When to seek medical help

Contact us immediately if you experience any of the following symptoms while on bulevirtide:

- confusion or disorientation
- swelling of your tummy and/or ankles
- yellowing of the whites of your eyes and/or skin (this is called jaundice)
- coughing up or vomiting blood
- passing any blood in your stools (this can look like black tar)

Contact us

If you have any further questions or concerns, please contact us.

Hepatology nurse specialists

Telephone: **023 8120 4617** (Monday to Friday, 8am to 4pm, excluding bank holidays)

Useful links

www.ema.europa.eu/en/medicines/human/EPAR/hepcludex

www.nice.org.uk/guidance/ta896/informationforpublic

www.nhs.uk/conditions/hepatitis

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For help preparing for your visit, arranging an interpreter or accessing the hospital, please visit **www.uhs.nhs.uk/additionalsupport**