

Package leaflet: Information for the patient

Zeffix 100 mg film-coated tablets lamivudine

Read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have further questions, ask your doctor or pharmacist.
- 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 pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Zeffix is and what it is used for
2. What you need to know before you take Zeffix
3. How to take Zeffix
4. Possible side effects
5. How to store Zeffix
6. Contents of the pack and other information

1. What Zeffix is and what it is used for

The active ingredient in Zeffix is lamivudine.

Zeffix is used to treat long term (chronic) hepatitis B infection in adults.

Zeffix is an antiviral medicine that suppresses the hepatitis B virus and belongs to a group of medicines called *nucleoside analogue reverse transcriptase inhibitors (NRTIs)*.

Hepatitis B is a virus which infects the liver, causes long term (chronic) infection, and can lead to liver damage. Zeffix can be used in people whose liver is damaged, but still functions normally (compensated liver disease) and in combination with other medicines in people whose liver is damaged and does not function normally (decompensated liver disease).

Treatment with Zeffix can reduce the amount of hepatitis B virus in your body. This should lead to a reduction in liver damage and an improvement in your liver function. Not everyone responds to treatment with Zeffix in the same way. Your doctor will monitor the effectiveness of your treatment with regular blood tests.

2. What you need to know before you take Zeffix

Do not take Zeffix

- if you're **allergic** to lamivudine or to any of the other ingredients of this medicine (*listed in Section 6*).

→ **Check with your doctor** if you think this applies to you.

Warnings and precautions

Some people taking Zeffix or other similar medicines are more at risk of serious side effects. You need to be aware of the extra risks:

- if you have ever had other types of **liver disease**, such as hepatitis C
- if you're seriously **overweight** (especially if you're a woman).

→ **Talk to your doctor if any of these apply to you.** You may need extra check-ups, including blood tests, while you're taking your medication. **See Section 4** for more information about the risks.

Don't stop taking Zeffix without your doctor's advice, as there is a risk of your hepatitis getting worse. When you stop taking Zeffix your doctor will monitor you for at least four months to check for any problems. This will mean taking blood samples to check for any raised liver enzyme levels, which may indicate liver damage. See section 3 for more information about how to take Zeffix.

Protect other people

Hepatitis B infection is spread by sexual contact with someone who has the infection, or by transfer of infected blood (for example, by sharing injection needles). Zeffix will not stop you passing hepatitis B infection on to other people. To protect other people from becoming infected with hepatitis B:

- **Use a condom** when you have oral or penetrative sex.
- **Don't risk blood transfer** — for example, don't share needles.

Other medicines and Zeffix

Tell your doctor or pharmacist if you're taking, have recently taken or might take any other medicines, including herbal medicines or other medicines you bought without a prescription.

Remember to tell your doctor or pharmacist if you begin taking a new medicine while you're taking Zeffix.

These medicines should not be used with Zeffix:

- medicines (usually liquids) containing sorbitol and other sugar alcohols (such as xylitol, mannitol, lactitol or maltitol), if taken regularly
 - other medicines containing lamivudine, used to treat **HIV infection** (sometimes called the AIDS virus)
 - emtricitabine used to treat **HIV** or **hepatitis B infection**
 - cladribine, used to treat **hairy cell leukaemia**
- **Tell your doctor** if you're being treated with any of these.

Pregnancy

If you are pregnant, think you may be pregnant or are planning to have a baby:

→ **Talk to your doctor** about the risks and benefits of taking Zeffix during your pregnancy.

Do not stop treatment with Zeffix without your doctor's advice.

Breast-feeding

Zeffix can pass into breast-milk. If you are breast-feeding, or thinking about breast-feeding:

→ **Talk to your doctor** before you take Zeffix.

Driving and using machines

Zeffix may make you feel tired, which could affect your ability to drive or use machines.

→ Don't drive or use machines unless you are sure you're not affected.

Zeffix contains sodium

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

3. How to take Zeffix

Always take this medicine exactly as your doctor has told you to. Check with your doctor or pharmacist if you're not sure.

Stay in regular contact with your doctor

Zeffix helps to control your hepatitis B infection. You need to keep taking it every day to control your infection and stop your illness getting worse.

→ **Keep in touch with your doctor, and don't stop taking Zeffix** without your doctor's advice.

How much to take

The usual dose of Zeffix is one tablet (100 mg lamivudine) once a day.

Your doctor may prescribe a lower dose if you have problems with your kidneys. An oral solution of Zeffix is available for people who need a lower than usual dose, or who can't take tablets.

→ **Talk to your doctor** if this applies to you.

If you are already taking another medicine that contains lamivudine for HIV infection, your doctor will continue to treat you with the higher dose, (usually 150 mg twice a day), because the dose of lamivudine in Zeffix (100 mg) is not enough to treat HIV infection. If you are planning to change your HIV treatment, discuss this change with your doctor first.

Swallow the tablet whole, with some water. Zeffix can be taken with or without food.

If you take more Zeffix than you should

If you accidentally take too much Zeffix, tell your doctor or your pharmacist, or contact your nearest hospital emergency department for further advice. If possible, show them the Zeffix pack.

If you forget to take Zeffix

If you forget to take a dose, take it as soon as you remember. Then continue your treatment as before. Don't take a double dose to make up for a missed dose.

Don't stop taking Zeffix

You must not stop taking Zeffix without consulting your doctor. There is a risk of your hepatitis getting worse (*see section 2*). When you stop taking Zeffix your doctor will monitor you for at least four months to check for any problems. This will mean taking blood samples to check for any raised liver enzyme levels, which may indicate liver damage.

4. Possible side effects

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

Side effects that were commonly reported in Zeffix clinical trials were tiredness, respiratory tract infections, throat discomfort, headache, stomach discomfort and pain, nausea, vomiting and diarrhoea, increases in liver enzymes and enzymes produced in the muscles (*see below*).

Allergic reaction

These are rare (may affect up to 1 in 1,000 people). Signs include:

- swelling of eyelids, face or lips
- difficulty swallowing or breathing

→ **Contact a doctor immediately** if you get these symptoms. **Stop taking Zeffix.**

Side effects thought to be caused by Zeffix

A very common side effect (these may affect **more than 1 in 10** people) which may show up in blood tests is:

- an increase in the level of some liver enzymes (*transaminases*), which may be a sign of inflammation or damage in the liver.

A common side effect (these may affect **up to 1 in 10** people) is:

- cramps and muscle pains
- skin rash or ‘hives’ anywhere on the body

A common side effect which may show up in blood tests is:

- an increase in the level of an enzyme produced in the muscles (*creatine phosphokinase*) which may be a sign that body tissue is damaged.

A very rare side effect (these may affect up to 1 in 10,000 people) is:

- lactic acidosis (excess lactic acid in the blood).

Other side effects

Other side effects have occurred in a very small number of people but their exact frequency is unknown

- breakdown of muscle tissue
- a worsening of liver disease after Zeffix is stopped or during treatment if the hepatitis B virus becomes resistant to Zeffix. This can be fatal in some people.

A side effect which may show up in blood tests is:

- a decrease in the number of cells involved in blood clotting (*thrombocytopenia*).

If you get any side effects

➔ **Talk to your doctor or pharmacist.** This includes any possible side effects not listed in this leaflet.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Zeffix

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

Don't take this medicine after the expiry date shown on the carton and blister.

Don't store above 30 °C.

Do not throw away any medicines in your wastewater or household rubbish. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. Contents of the pack and other information

What Zeffix contains

The active substance is lamivudine. Each film-coated tablet contains 100 mg of lamivudine.

The other ingredients are: microcrystalline cellulose, sodium starch glycolate, magnesium stearate, hypromellose, titanium dioxide, macrogol 400, polysorbate 80, synthetic yellow and red iron oxide.

What Zeffix looks like and contents of the pack

Zeffix film-coated tablets are supplied in tamper evident foil blisters containing 28 or 84 tablets. The tablets are butterscotch coloured, capsule shaped, biconvex and engraved “GX CG5” on one side.

Not all pack-sizes may be available in your country.

Manufacturer

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Poland

Marketing Authorisation Holder

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Other formats:

To listen to or request a copy of this leaflet in Braille, large print or audio please call, free of charge:
0800 198 5000 (UK Only)

Please be ready to give the following information:

Product name Zeffix 100 mg film-coated tablets

Reference number 19494/0283

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