

Package leaflet: Information for the user

Epivir 10 mg/ml oral solution *lamivudine*

Read all of this leaflet carefully before you start taking 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 pharmacist.
- This medicine has been prescribed for you or for your child. 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 of the side effects talk to your doctor. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

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

1. What Epivir is and what it is used for

Epivir is used to treat HIV (human immunodeficiency virus) infection in adults and children.

The active ingredient in Epivir is lamivudine. Epivir is a type of medicine known as an anti-retroviral. It belongs to a group of medicines called *nucleoside analogue reverse transcriptase inhibitors (NRTIs)*.

Epivir does not completely cure HIV infection; it reduces the amount of virus in your body and keeps it at a low level. It also increases the CD4 cell count in your blood. CD4 cells are a type of white blood cells that are important in helping your body to fight infection.

Not everyone responds to treatment with Epivir in the same way. Your doctor will monitor the effectiveness of your treatment.

2. What you need to know before you take Epivir

Do not take Epivir:

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

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

Take special care with Epivir

Some people taking Epivir or other combination treatments for HIV are more at risk of serious side effects. You need to be aware of the extra risks:

- if you have ever had **liver disease**, including hepatitis B or C (if you have hepatitis B infection, do not stop Epivir without your doctor's advice, as your hepatitis may come back)
- if you are seriously **overweight** (especially if you are a woman)
- **if you or your child has a kidney problem**, your dose may be altered.

Talk to your doctor if any of these apply to you. You may need extra check-ups, including blood tests, while you are taking your medicine. **See Section 4 for more information.**

Look out for important symptoms

Some people taking medicines for HIV infection develop other conditions, which can be serious. You need to know about important signs and symptoms to look out for while you are taking Epivir.

Read the information ‘Other possible side effects of combination therapy for HIV’ in Section 4 of this leaflet.

Other medicines and Epivir

Tell your doctor or pharmacist if you are taking any other medicines, or if you have taken any recently, 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 are taking Epivir.

These medicines should not be used with Epivir:

- 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** or **hepatitis B infection**)
- emtricitabine (used to treat **HIV infection**)
- high doses of **co-trimoxazole**, an antibiotic
- cladribine (used to treat hairy cell leukaemia).

Tell your doctor if you are being treated with any of these.

Pregnancy

If you are pregnant, if you become pregnant, or are planning to become pregnant, talk to your doctor about the risks and benefits to you and your baby of taking Epivir.

Epivir and similar medicines may cause side effects in unborn babies. If you have taken Epivir during your pregnancy, your doctor may request regular blood tests and other diagnostic tests to monitor the development of your child. In children whose mothers took NRTIs during pregnancy, the benefit from the protection against HIV outweighed the risk of side effects.

Breast-feeding

Breast-feeding is **not recommended** in women living with HIV because HIV infection can be passed on to the baby in breast milk.

A small amount of the ingredients in Epivir can also pass into your breast milk.

If you are breast-feeding, or thinking about breast-feeding, you should **discuss it with your doctor as soon as possible**.

Driving and using machines

Epivir is unlikely to affect your ability to drive or use machines.

Important information about some of the ingredients of Epivir

If you are a diabetic, please note that each dose (150 mg = 15 ml) contains 3 g sugar.

Epivir contains sucrose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking Epivir. Sucrose may be harmful to the teeth.

Epivir also contains preservatives (*parahydroxybenzoates*) which may cause allergic reactions (possibly delayed).

Epivir contains sodium

This medicine contains 39 mg sodium in each 15 ml. This is equivalent to 1.95% of the recommended maximum daily dietary intake of sodium for an adult.

3. How to take Epivir

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

Epivir can be taken with or without food.

Stay in regular contact with your doctor

Epivir helps to control your condition. You need to keep taking it every day to stop your illness getting worse. You may still develop other infections and illnesses linked to HIV infection.

Keep in touch with your doctor, and do not stop taking Epivir without your doctor's advice.

How much to take

Adults, adolescents and children weighing at least 25 kg

The usual dose of Epivir is 30 ml (300 mg) a day. This can be taken either as 15 ml (150 mg) twice a day (leaving approximately 12 hours between each dose), or as 30 ml (300 mg) once a day.

Children from 3 months of age weighing less than 25 kg

The dose depends on the child's body weight. The usual dose of Epivir is 0.5 mL/kg (5 mg/kg) twice daily (leaving approximately 12 hours between each dose), or 1 mL/kg (10 mg/kg) once daily.

Use the oral dosing syringe supplied with the pack to measure your dose accurately.

1. Remove the plastic wrap from the syringe/adapter.
2. Remove the adapter from the syringe.
3. **Remove the bottle cap** and keep it safe.
4. Hold the bottle firmly. **Push the plastic adapter into the neck of the bottle.**
5. **Insert the syringe** firmly into the adapter.
6. Turn the bottle upside down.
7. **Pull out syringe plunger** until the syringe contains the first part of your full dose.
8. Turn the bottle the correct way up. **Remove the syringe** from the adapter.
9. **Put the syringe into your mouth**, placing the tip of the syringe against the inside of your cheek. **Slowly push the plunger in**, allowing time to swallow. **Do not** push too hard and squirt the liquid into the back of your throat or you may choke.
10. **Repeat steps 5 to 9** in the same way until you have taken your whole dose. *For example, if your dose is 15 ml, you need to take one and a half syringe-fulls of medicine.*
11. **Take the syringe out of the bottle** and **wash** it thoroughly in clean water. Let it dry completely before you use it again.
12. **Close the bottle tightly** with the cap, leaving the adapter in place.

Discard oral solution one month after first opening.

If you or your child has a kidney problem, the dose may be altered.

Talk to your doctor if this applies to you or your child.

If you take more Epivir than you should

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

If you forget to take Epivir

If you forget to take a dose, take it as soon as you remember. Then continue your treatment as before. Do not take a double dose to make up for a forgotten dose.

4. Possible side effects

During HIV therapy there may be an increase in weight and in levels of blood lipids and glucose. This is partly linked to restored health and life style, and in the case of blood lipids sometimes to the HIV medicines themselves. Your doctor will test for these changes.

Like all medicines, this medicine can cause side effects, but not everyone gets them.

When you are being treated for HIV, it can be hard to tell whether a symptom is a side effect of Epivir or other medicines you are taking, or an effect of the HIV disease itself. **So it is very important to talk to your doctor about any changes in your health.**

As well as the side effects listed below for Epivir, other conditions can develop during combination therapy for HIV.

It is important to read the information later in this section under ‘Other possible side effects of combination therapy for HIV’.

Common side effects

These may affect **up to 1 in 10** people:

- headache
- feeling sick (*nausea*)
- being sick (*vomiting*)
- diarrhoea
- stomach pains
- tiredness, lack of energy
- fever (high temperature)
- general feeling of being unwell
- muscle pain and discomfort
- joint pain
- difficulty in sleeping (*insomnia*)
- cough
- irritated or runny nose
- rash
- hair loss (*alopecia*).

Uncommon side effects

These may affect **up to 1 in 100** people:

Uncommon side effects that may show up in blood tests are:

- a decrease in the number of cells involved in blood clotting (*thrombocytopenia*)
- a low red blood cell count (*anaemia*) or low white blood cell count (*neutropenia*)
- an increase in the level of liver enzymes.

Rare side effects

These may affect **up to 1 in 1000** people:

- serious allergic reaction causing swelling of the face, tongue or throat which may cause difficulty in swallowing or breathing
- inflammation of the pancreas (*pancreatitis*)
- breakdown of muscle tissue
- inflammation of the liver (*hepatitis*).

A rare side effect that may show up in blood tests is:

- increase in an enzyme called amylase.

Very rare side effects

These may affect **up to 1 in 10,000** people:

- Lactic acidosis (excess lactic acid in the blood)
- tingling or numbness of the arms, legs, hands or feet.

A very rare side effect that may show up in blood tests is:

- a failure of the bone marrow to produce new red blood cells (*pure red cell aplasia*).

If you get side effects

Tell your doctor or pharmacist if any of the side effects gets severe or troublesome, or if you notice any side effects not listed in this leaflet.

Other possible side effects of combination therapy for HIV

Combination therapy such as Epivir may cause other conditions to develop during HIV treatment.

Old infections may flare up

People with advanced HIV infection (AIDS) have weak immune systems and are more likely to develop serious infections (opportunistic infections). When these people start treatment, they may find that old, hidden infections flare up, causing signs and symptoms of inflammation. These symptoms are probably caused by the body's immune system becoming stronger, so that the body starts to fight these infections.

In addition to the opportunistic infections, autoimmune disorders (a condition that occurs when the immune system attacks healthy body tissue) may also occur after you start taking medicines for the treatment of your HIV infection. Autoimmune disorders may occur many months after the start of treatment. If you notice any symptoms of infection or other symptoms such as muscle weakness, weakness beginning in the hands and feet and moving up towards the trunk of the body, palpitations, tremor or hyperactivity, please inform your doctor immediately to seek necessary treatment.

If you get any symptoms of infection while you are taking Epivir:

Tell your doctor immediately. Do not take other medicines for the infection without your doctor's advice.

You may have problems with your bones

Some people taking combination therapy for HIV develop a condition called osteonecrosis. With this condition, parts of the bone tissue die because of reduced blood supply to the bone. People may be more likely to get this condition:

- if they have been taking combination therapy for a long time
- if they are also taking anti-inflammatory medicines called corticosteroids
- if they drink alcohol

- if their immune systems are very weak
- if they are overweight.

Signs of osteonecrosis include:

- stiffness in the joints
- aches and pains (especially in the hip, knee or shoulder)
- difficulty moving.

If you notice any of these symptoms:

Tell your doctor.

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 the 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 Epivir

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 container.

Discard one month after first opening.

Do not store above 25°C.

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

6. Contents of the pack and other information

What Epivir contains

The active substance is lamivudine.

The oral solution also contains the following other ingredients: sugar (sucrose 3 g/15 ml), methyl parahydroxybenzoate, propyl parahydroxybenzoate, anhydrous citric acid, sodium citrate, propylene glycol, water, artificial strawberry and banana flavourings.

This medicine contains 300 mg propylene glycol in each 15ml.

What Epivir looks like and the contents of the pack

Epivir oral solution is supplied in a white polyethylene bottle containing 240 ml of solution. An oral dosing syringe and a plastic adapter for the bottle is included in the pack.

Marketing Authorisation Holder and Manufacturer

Manufacturer

Glaxo Operations UK Ltd
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United Kingdom

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	Epivir 10 mg/ml oral solution
Reference number	35728/0031

This is a service provided by the Royal National Institute of Blind People.

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