

Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) – 1986

The medicine is dispensed according to a physician's prescription only.

Epivir Oral Solution

Each ml of oral solution contains Lamivudine 10 mg.

For the list of the inactive and allergenic ingredients, see section 2 - "Important information about some of the ingredients of Epivir" and section 6 - "Additional information".

Read the entire leaflet carefully before using the medicine. This leaflet contains concise information about the medicine. If you have any other questions, refer to the physician or the 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 it seems to you that their illness is similar.

1. What is the medicine intended for?

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

Therapeutic group: 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 physician will monitor the effectiveness of your treatment.

2. Before using the medicine

Do not use the medicine:

- If you are sensitive (allergic) to lamivudine or to any of the additional ingredients contained in the medicine (listed in section 6).
- **Check with your physician** if you think this applies to you.

Special warnings regarding the use of the medicine

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 using Epivir without your physician'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 physician 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

If you are taking, or have recently taken, **other medicines** including non-prescription medicines and food supplements, **tell the physician or the pharmacist.**

Remember to inform your physician 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 physician** if you are being treated with any of these.

Pregnancy, Breast-feeding and fertility

Pregnancy

If you are pregnant, become pregnant, or are planning to become pregnant, talk to your physician 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 physician 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 of 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 **consult with your physician 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 physician that you have an intolerance to some sugars, contact your physician before taking Epivir. Sucrose may be harmful to the teeth.

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

This medicine contains 300 mg propylene glycol in every 15 ml of medicine.

Epivir contains sodium

This medicine contains 39 mg sodium in each 15 ml. This is equivalent to 1.9% of the recommended maximum daily dietary intake of sodium for an adult.

3. How should you use the medicine?

Always use according to the physician's instructions. You should check with the physician or the pharmacist if you are unsure.

Do not exceed the recommended dose

Epivir can be taken with or without food.

Stay in regular contact with your physician

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 physician and do not stop taking Epivir** without your physician's advice.

The dosage and treatment regimen will be determined only by the physician. **The recommended dosage is usually: Adults, adolescents and children weighing at least 25 kg The recommended dosage of Epivir is usually 30 ml a day (300 mg) to be taken as 15 ml (150 mg) twice a day** (at intervals of approximately 12 hours between each dose) **or as approximately 30 ml (300 mg) once a day.**

Children from 3 months of age, weighing less than 25 kg

The dosage depends on the child's weight.

The recommended dosage of Epivir is usually 0.5 ml/kg (5 mg/kg) twice daily (at intervals of 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/adaptor.
2. Remove the adaptor from the syringe.
3. **Remove the bottle cap.** Keep it safely. Opening instructions - to remove the cap, press down, while simultaneously twisting to the left (turning counterclockwise).
4. Hold the bottle firmly. **Push the plastic adaptor into the neck of the bottle.**
5. **Insert the syringe** firmly into the adaptor.
6. Turn the bottle upside down.
7. **Pull out the 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 adaptor.
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, to avoid choking.
10. **Repeat steps 3 to 7** 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 syringes 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 adaptor in place. Closing instructions - replace cap on top of open end of the bottle and twist to the right (turning clockwise) until it locks tight enough.

Discard the oral solution one month after first opening.

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

→ **Talk to your physician** if this applies to you or your child.

If you accidentally have taken a higher dosage

If you have taken an overdose or if a child has accidentally swallowed the medicine, refer immediately to a physician or to a hospital emergency room and bring the package of the medicine with you.

If you forgot to take the medicine

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.

Adhere to the treatment as recommended by the physician.

Do not take medicines in the dark! Check the label and the dose each time you take a medicine. Wear glasses if you need them.

If you have any other questions regarding the use of the medicine, consult the physician or the pharmacist.

4. 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 health and life style, and in the case of blood lipids, sometimes to the HIV medicines themselves. Your physician will test for these changes.

As with any medicine, use of Epivir may cause side effects in some of the users. Do not be alarmed by reading the list of side effects. You may not experience any of 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 physician 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
- nausea
- vomiting
- diarrhoea
- stomach pains
- tiredness, lack of energy
- fever
- 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 1,000** 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*).

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 a weak immune

system 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 physician immediately to receive the necessary treatment.

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

→ **Tell your physician immediately.** Do not take other medicines for the infection without your physician'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 system is 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 physician.**

If a side effect has appeared, if any of the side effects get worse or when **you suffer from a side effect** that has not been mentioned in the leaflet, you should consult the physician.

Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment" found on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects, or by entering the link:

<https://sideeffects.health.gov.il>

5. How to store the medicine?

- Avoid poisoning! This medicine and any other medicine should be kept in a closed place out of the sight and reach of children and/or infants in order to avoid poisoning. Do not induce vomiting without an explicit instruction from the physician.
- Do not use the medicine after the expiry date (exp. date) appearing on the package. The expiry date refers to the last day of that month.
- Discard one month after first opening.
- Do not store above 25°C.

6. Additional information

• In addition to the active ingredient the medicine also contains:

Sucrose (20% w/v), propylene glycol, sodium citrate, methyl parahydroxybenzoate, citric acid (Anhydrous), artificial strawberry flavour, artificial banana flavour, propyl parahydroxybenzoate, purified water.

• What does the medicine look like and what is the content of the package:

Epivir oral solution is supplied in a white polyethylene bottle containing 240 ml of solution. An oral dosing syringe and a plastic adaptor for the bottle are included in the pack. The bottle is closed with a child-resistant cap.

- License Holder and Importer: GlaxoSmithKline (Israel) Ltd., 25 Basel St., Petach Tikva.
- Manufacturer: Viiv Healthcare UK Limited, Brentford, UK.
- Registration number of the medicine in the National Drug Registry of the Ministry of Health: 124-08-28843.

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