

PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS'
REGULATIONS (PREPARATIONS) – 1986

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

Epivir 150 mg

Film-coated tablets

Each tablet contains Lamivudine 150 mg

Epivir 300 mg

Film-coated tablets

Each tablet contains Lamivudine 300 mg

For the list of the inactive and allergenic ingredients in the medicine, see section 2 – “Important information about some of the ingredients in the medicine” and section 6 – “Additional information”.

Read the leaflet carefully in its entirety before using the medicine. This leaflet contains concise information about the medicine. If you have further questions, refer to the physician or pharmacist.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them even if it seems to you that their medical condition 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: 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 Eпивir 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 this medicine (listed in section 6).

→ **Tell your physician** if you think any of these may apply to you.

Special warnings regarding use of the medicine

Some people taking Eпивir 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 Eпивir 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 Eпивir.

→ **Read the information "Other possible side effects of combination therapy for HIV" in section 4 of this leaflet.**

Protect other people

HIV infection is spread by sexual contact with someone who has the infection, or by transfer of infected blood (for example, by sharing injection needles). You can still

pass on HIV when taking this medicine, although the risk is lowered by effective anti-retroviral therapy.

Discuss with your physician the precautions needed to avoid infecting other people.

Drug interactions

If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the physician or 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 and breast-feeding

Pregnancy

If you are pregnant, if you become pregnant, or are planning to have a baby, 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

Women who are HIV-positive must not breast-feed, 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:

→ **Talk to your physician immediately.**

Driving and using machines

It is unlikely that this medicine will affect your ability to drive or use machines.

Important information about some of the ingredients in the medicine

This medicine contains less than 1 mmol sodium (23 mg) per dose, so it is essentially sodium-free.

3. HOW SHOULD YOU USE THE MEDICINE?

Always use the preparation according to the physician's instructions. Check with the physician or pharmacist if you are uncertain about the preparation dosage and treatment regimen.

Swallow the tablets with water. Epivir can be taken with or without food.

If you cannot swallow the tablets whole, you may crush and combine them with a small amount of food or drink, and take all the dose immediately.

Epivir 150 mg tablets: Can be crushed and halved. There is no information about chewing.

Epivir 300 mg tablets: Can be crushed. There is no information about halving and chewing.

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 by the physician only.

The recommended dosage is usually:

Adults, adolescents and children who weigh at least 25 kg:

The recommended Epivir dosage is 300 mg per day.

It can be taken in one of the following ways:

- **It can be taken as a single 150 mg tablet, twice a day** (at intervals of approximately 12 hours between each dose) or two 150 mg tablets, once a day, as recommended by your physician.
- **One Epivir 300 mg tablet, once a day.**

Children weighing at least 20 kg and less than 25 kg:

The recommended Epivir dosage is 225 mg per day, given as 75 mg (half (½) a 150 mg tablet) in the morning and 150 mg (one full 150 mg tablet) in the evening, or 225 mg (one and a half 150 mg tablets) once a day, as recommended by your physician.

Children weighing at least 14 kg and less than 20 kg:

The recommended Epivir dosage is 150 mg per day, given as 75 mg (half (½) a 150 mg tablet) twice a day (at intervals of approximately 12 hours between each dose) or 150 mg (one full 150 mg tablet) once a day, as recommended by your physician.

An oral solution is also available for the treatment of children over 3 months of age, or for people who need a lower dose than usual, or who cannot take tablets.

Do not exceed the recommended dose.

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

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

If you accidentally have taken a higher dosage you should

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 this 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 regimen recommended by your 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 further questions regarding use of the medicine, consult the physician or 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 Eпивir may cause side effects in some users. Do not be alarmed by reading the list of side effects. You may not suffer from any of them.

When you are being treated for HIV, it can be hard to tell whether a symptom is a side effect of Eпивir 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 Eпивir, 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
- liver inflammation (hepatitis).

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

- an 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 including Efavirenz 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 necessary treatment.

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

- **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 occurs, if one of the side effects worsens, or if you suffer from a side effect not mentioned in this leaflet, consult with the physician.

Reporting side effects

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 reach and sight of children and/or infants in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the physician.
- Do not use the medicine after the expiry date (exp. date) that appears on the package. The expiry date refers to the last day of that month.
- Epivir 300 mg: Use within 3 months after opening.
- Do not store above 30°C.
- Do not discard medicines in the wastewater or household waste bin. Ask the pharmacist how to dispose of medicines that are no longer in use. These measures will help protect the environment.

6. ADDITIONAL INFORMATION

- In addition to the active ingredient, the medicine also contains:

Tablet core:

Microcrystalline cellulose (E460), sodium starch glycolate (Type A), magnesium stearate,

Film-coat:

Hypromellose (E464), titanium dioxide (E171), macrogol 400, polysorbate 80
Epivir 300 mg tablets also contain black iron oxide (E172)

Also see section 2 in this leaflet – "Important information about some of the ingredients in the medicine".

- What the medicine looks like and the contents of the package:

Epivir 150 mg: film-coated tablets, supplied in white bottles containing 60 tablets.

They are white, diamond shaped, scored, film-coated tablets, marked with the code 'GXCJ7' on both sides.

Epivir 300 mg: film-coated tablets, supplied in white bottles containing 30 tablets.

They are grey, diamond shaped, film-coated tablets, marked with the code 'GXEJ7' on one side.

The film-coated tablets are provided in a bottle closed with a child-resistant cap.

Directions for opening: In order to remove the cap, press down while turning it to the left at the same time (counterclockwise).

Directions for closing: Close the bottle well with the cap; turn it to the right (clockwise) until it is completely closed.

- License Holder: GlaxoSmithKline (Israel) Ltd., 25 Basel St., Petach Tikva.

- Manufacturer:

Epivir 150 mg: ViiV Healthcare UK Ltd., Brentford, UK.

Epivir 300 mg: GlaxoSmithKline Pharmaceuticals S.A., Poznan, Poland.

- Registration number of the medicine in the National Drug Registry of the Ministry of Health:

Epivir 150 mg: 102-54-28844.

Epivir 300 mg: 131-64-31036.

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