

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

The medicine is dispensed with a physician's prescription only

Zeffix Oral Solution

Each 1 ml of oral solution contains 5 mg lamivudine.

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

Read this 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.

This medicine is intended for adults and children above the age of 2 years.

1. WHAT IS THE MEDICINE INTENDED FOR?

Zeffix is a medicine used to treat chronic hepatitis B virus (HBV) in adults and children above the age of 2 years.

It is not known if Zeffix is safe and effective for:

- people with chronic HBV who have a severely damaged liver that is unable to work properly (decompensated liver disease)
- people with HIV-1, hepatitis C virus or hepatitis D (delta) virus
- people who have had a liver transplant

Therapeutic group: Nucleoside analogue reverse transcriptase inhibitors (*NRTIs*).

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).

Special warnings regarding use of this medicine

Before beginning treatment with Zeffix, tell your physician about all of your health conditions, including if:

- You have an HIV-1 infection.
- You have kidney problems.
- You have diabetes. Each 20 ml (100 mg) dose of Zeffix Oral Solution contains 4 grams sucrose.
- You are pregnant or plan to become pregnant. It is not known whether Zeffix will harm your unborn baby.
- You are breastfeeding or plan to breastfeed. Zeffix can pass into your breast milk and harm your baby. You and your physician should decide whether you will take Zeffix or breastfeed.

Risk of HIV-1 resistance in people with undiagnosed HIV-1 infection or in people with untreated HIV-1 infection. If you have or get an HIV-1 (human immunodeficiency virus type 1) infection that is not being treated with medicines while taking Zeffix, the HIV-1 virus may develop resistance to certain HIV-1 medicines and will be harder to treat.

- Your physician should offer you counseling and diagnostic testing for HIV-1 infection before you start treatment, as well as during treatment, for hepatitis B with Zeffix.
- Zeffix Oral Solution contains a lower dose of lamivudine than other medicines that contain lamivudine and are used to treat HIV-1 infection.

Zeffix does not stop you from spreading HBV to others by sexual contact, sharing needles, or upon exposure to your blood. Avoid doing things that can spread HBV infection to others.

Other medicines and Zeffix Oral Solution

If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the physician or pharmacist. Particularly if you are taking:

- Trimethoprim (antibiotic)
- Preparations containing sorbitol – concomitant use of Zeffix and sorbitol may lead to decreased exposure to Zeffix.

Certain medicines interact with Zeffix. **Keep a list of your medicines to show the physician or pharmacist.**

- You can ask your physician or pharmacist for a list of medicines that interact with Zeffix.

- Do not start taking a new medicine without consulting the physician. Your physician can tell you if it is safe to take Zeffix with other medicines.

Do not take Zeffix if you are taking other medicines that contain lamivudine or emtricitabine.

Pregnancy and breastfeeding

- Tell your physician if you are pregnant or plan to become pregnant. It is not known if Zeffix will harm your unborn baby.
- Tell your physician if you are breastfeeding or plan to breastfeed. Zeffix can pass into your breast milk and may harm your baby.

You and your physician should decide if you will take Zeffix or breastfeed.

Important information about some of the ingredients of the medicine

Zeffix contains sugar, preservatives, propylene glycol and sodium

If you are diabetic, please note that each dose of Zeffix (100 mg = 20 ml) contains 4 grams of sucrose.

Zeffix contains sucrose. If you have been told by your physician that you have an intolerance to certain sugars, refer to your physician before taking Zeffix. Sucrose may be harmful to the teeth.

Zeffix contains preservatives (*parahydroxybenzoates*) which may cause allergic reactions (possibly a delayed reaction).

This medicine contains 400 mg propylene glycol in each 20 ml.

This medicine contains 58.8 mg sodium (the main ingredient in cooking/table salt) in each 20 ml. This is equivalent to 2.9% of the recommended maximum daily dietary intake of sodium for adults.

3. HOW SHOULD YOU USE THE MEDICINE?

- Always use according to the physician's instructions.
- Check with the physician or pharmacist if you are uncertain regarding the preparation dosage and treatment regimen.
- Zeffix can be taken with or without food.
- It is important to be under medical supervision when taking Zeffix.

The dosage and treatment regimen will be determined by the physician only.

- The usual dosage for adults is 20 ml (100 mg lamivudine), once a day.
- Children aged 2-17 years – your physician will prescribe a Zeffix dosage in accordance with your child's weight. The recommended dosage is 3 mg/kg body weight, once a day, up to a maximum of 100 mg per day.
- Your physician may prescribe a lower dosage if you have problems with your kidneys.

Do not exceed the recommended dose

If you accidentally take a higher dosage

If you **took** too much Zeffix, or if a child has accidentally swallowed the medicine, refer immediately to your physician or proceed to the nearest hospital emergency room and bring the package of the medicine with you.

If you forget to take the medicine

If you forgot to take this medicine at the required time, take a dose as soon as you remember. Do not take a double dose or more than what your physician has told you to take.

Adhere to the treatment regimen as recommended by the physician.

Even if there is an improvement in your health, do not stop treatment with this medicine without consulting the physician.

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

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

4. SIDE EFFECTS

As with any medicine, use of Zeffix 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.

Zeffix may cause serious side effects, including:

Build-up of lactic acid in your blood (lactic acidosis). Lactic acidosis can happen in some people who take Zeffix. Lactic acidosis is a serious medical emergency that can lead to death. **Refer to your physician immediately if you experience any of the following symptoms that could be signs of lactic acidosis:**

- feel weak or tired
- unusual (not normal) muscle pains
- trouble breathing
- stomach pain with nausea and vomiting
- feel cold, especially in the arms and legs
- dizziness
- fast or irregular heartbeat

Severe liver problems. Severe liver problems can happen in people who take Zeffix or similar medicines. In some cases, these liver problems can lead to death. Your liver may become large (hepatomegaly) and you may develop fat in your liver (fatty liver) when you take Zeffix. **Refer to your physician immediately if you experience any of the following symptoms of liver problems:**

- your skin or the white part of your eyes turns yellow (jaundice)
- dark or "tea-colored" urine
- light-colored stools (bowel movements)
- lack of appetite for several days or longer

- nausea
- pain or tenderness in the upper right abdominal area

It is more likely that you will experience lactic acidosis or severe liver problems if you are very overweight (obese) or if you are a woman.

Worsening liver disease. Your hepatitis B infection may become worse after stopping treatment with Zeffix. Worsening liver disease can be serious and may lead to death. If you stop treatment with Zeffix, your physician will monitor your health and do blood tests to check your liver for at least several months after you stop taking Zeffix.

Resistant hepatitis B virus (HBV). The hepatitis B virus can change (mutate) during treatment with Zeffix and become harder to treat (resistant). If this happens, your liver disease can become worse and lead to death. Tell your physician immediately if you have any new symptoms.

Additional side effects

The most common side effects of Zeffix include:

- ear, nose, and throat infections
- sore throat
- diarrhea
- abnormal blood tests

Side effects of unknown frequency:

- anemia, thrombocytopenia, enlarged spleen, lymph node disturbances
- inflammation of the oral mucosa (stomatitis)
- increased blood glucose levels
- severe allergic reaction (anaphylaxis), hives (urticaria)
- peripheral neuropathy
- cramps, rhabdomyolysis
- wheezing and abnormal breath sounds
- alopecia, rash, pruritus

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.

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>

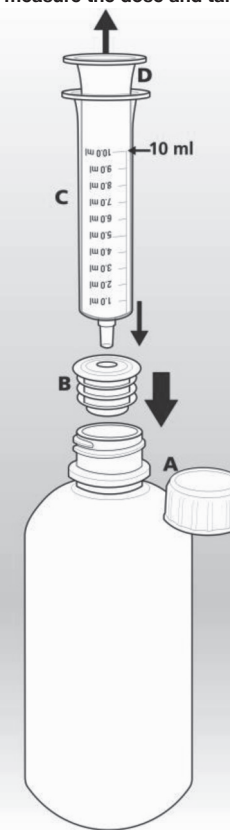
5. HOW SHOULD THE MEDICINE BE STORED?

- Avoid poisoning! This medicine, and any other medicine, should be kept in a safe 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.
- Do not store above 25°C.
- After first opening, can be used for one month but no later than the expiry date of the preparation. Discard one month after first opening.

6. FURTHER INFORMATION

- In addition to the active ingredient, the medicine also contains: Sucrose, propylene glycol, sodium citrate, methyl parahydroxybenzoate (E218), citric acid, artificial strawberry flavour, artificial banana flavour, propyl parahydroxybenzoate (E216), purified water.
- What the medicine looks like and the contents of the package: Zeffix Oral Solution comes in a carton package which contains a white polyethylene bottle, with a child-proof cap. The solution is clear, colorless to pale yellow, with strawberry/banana flavouring. The bottle contains 240 ml lamivudine solution (5 mg/ml). The package contains a dosing syringe for oral administration and a syringe adaptor that must be attached to the bottle before use.
- License Holder: GlaxoSmithKline (Israel) Ltd., 25 Basel St., Petach Tikva.
- Manufacturer: GlaxoSmithKline (Ireland) Limited, Dublin, Ireland.
- Registration number of the medicine in the National Drug Registry of the Ministry of Health: 114-12-29545.
- Revised in October 2021 according to MOH guidelines.

How to measure the dose and take the medicine



Use the oral dosing syringe supplied with the package to measure your dose accurately (see also section 3). When the syringe is full, it contains **10 ml of solution**.

1. Remove the plastic wrap from the applicator/adaptor.
 2. Remove the adaptor from the applicator.
 3. **Remove the child-proof cap (A)** and keep it safely.
- Opening instructions: to remove the cap, press down, while simultaneously twisting to the left (turning counterclockwise).
4. Hold the bottle. **Push the adaptor (B) firmly into the neck of the bottle, as far as it will go.**
 5. **Insert the syringe (C)** firmly into the adaptor.
 6. Turn the bottle upside down.
 7. **Pull out the syringe plunger (D)** until the syringe contains the first part of your full dose.
 8. Turn the bottle the right 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, 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 20 ml, you need to take 2 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. Leave the adaptor in the bottle.
 12. **Close the bottle tightly** with the cap.
- Closing instructions: Close the bottle tightly with the cap - twist to the right (turning clockwise) until fully closed.

Discard oral solution one month after first opening.

Trade marks are owned by or licensed to the GSK group of companies.

©2021 GSK group of companies or its licensor.