

ZEFFIX ORAL SOLUTION®

Lamivudine

Consumer Medicine Information

What is in this leaflet?

Please read this leaflet carefully before you take Zeffix Oral Solution.

This leaflet answers some common questions about Zeffix Oral Solution. It does not contain all of the available information.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the expected benefits of you taking Zeffix against the risks this medicine could have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What is Zeffix used for?

Zeffix belongs to a group of medicines called antivirals.

Zeffix is used to treat patients 2 years of age or over with long term (chronic) viral infection of the liver caused by hepatitis B.

Hepatitis B is a virus which damages the liver. Treatment with Zeffix can reduce the amount of hepatitis B virus in your body. This should lead to less liver damage.

Zeffix has not been shown to reduce the risk of passing hepatitis B to others. You will still be able to pass on the hepatitis virus by sexual contact or through your blood. You should use appropriate precautions.

Your doctor may have prescribed Zeffix for another reason.

Zeffix is not addictive.

If you are already taking this medicine lamivudine for HIV infection (3TC®, Combivir®), your doctor will continue to treat you with the higher dose for that treatment.

Before you take Zeffix

Do not take if:

You must not take Zeffix if:

- you have ever had an allergic reaction to lamivudine or any of the ingredients listed toward the end of this leaflet. (See "Ingredients")
- **you are taking zalcitabine.**
- **the expiry date (EXP) printed on the pack has passed.**
- **the packaging is torn or shows signs of tampering**

Tell your doctor if:

You must tell your doctor if:

- **you are allergic to foods, dyes, preservatives or any other medicines.**
- **you have, or have ever had, kidney problems**
- **you have, or have ever had, problems with your pancreas.**
- **you are taking any other medicines, including medicines you buy without a prescription.**
- **you are breastfeeding, pregnant or trying to become pregnant.**

How do I take Zeffix?

How much to take

Take Zeffix as directed by your doctor or pharmacist.

The normal dose for adults and children aged 12 years or above is 20 mL of the solution, equivalent to 100 mg of lamivudine, once a day. For younger children, aged 2 years or above, the correct dose of Zeffix will depend on their weight in kilograms (kg). Your doctor will tell you exactly how much medicine is needed to give the correct dose.

If you are a diabetic, please note that each dose of Zeffix (100 mg =20 mL) contains 4 g sugar.

Your doctor may prescribe a different dosage, for example if you have kidney problems. Each patient responds to the treatment differently. Your doctor will check you by taking regular blood samples. The results will help decide when you should stop taking Zeffix.

How to take it

Zeffix oral solution can be swallowed if desired with a glass of water, and can be taken with or without food.

To measure your dose of Zeffix oral solution accurately use the oral dosing syringe supplied with the pack as follows:

1. Remove the bottle cap. Keep it safely.
2. Hold the bottle firmly. Push the plastic adapter into the neck of the bottle.
3. Insert the syringe firmly into the adapter.
4. Turn the bottle upside down.
5. Pull out the syringe plunger until the syringe contains the first part of your full dose.
6. Turn the bottle the correct way up. Remove the syringe from the adapter.
7. 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. Don't push too hard and squirt the liquid into the back of your throat or you may choke.
8. 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 syringe-fulls of medicine.
9. Take the syringe out of the bottle and wash it thoroughly in clean water. Let it dry completely before you use it again.
10. Close the bottle tightly with the cap, leaving the adaptor in place.

How long to take it for

Zeffix oral solution helps control your condition, but does not cure it. Therefore you must take Zeffix oral solution every day. Continue taking the solution for as long as your doctor tells you to.

What do I do if I take too much? (Overdose)

Immediately telephone your doctor or Poisons Information Centre (telephone 131126) for advice, if you think you or anyone else may have taken too much Zeffix, even if there are no signs of discomfort or poisoning.

If you are not sure what to do, contact your doctor or pharmacist.

While you are taking Zeffix

Things you must do

Tell your doctor if, for any reason, you have not taken your medicine exactly as directed.

Otherwise, your doctor may think that it was not working as it should and change your treatment unnecessarily.

If you forget to take a dose, do not take a double dose to make up for the dose that you missed.

Things you must not do

Do not stop taking Zeffix oral solution, or change the dose without first checking with your doctor. If you stop taking Zeffix your hepatitis may get worse.

This can cause serious illness particularly if your liver is already not working very well. If you do have to stop taking Zeffix your doctor is likely to arrange tests over the following four months to check how well your liver is working.

Do not give this medicine to anyone else, even if their symptoms seem similar to yours.

Do not use Zeffix to treat any other complaints unless your doctor says to.

What are the side-effects?

Check with your doctor as soon as possible if you think you are experiencing any side effects or allergic reactions due to taking Zeffix, even if the problem is not listed below.

Like other medicines, Zeffix can cause some side-effects. If they occur, they are most likely to be minor and temporary. However, some may be serious and need medical attention.

The most commonly reported side-effects are:

- Headache.
- Vomiting and Diarrhoea.
- Nausea.
- Fatigue/tiredness.
- Abdominal discomfort and pain.
- Coughing, with phlegm, not associated with a cold or flu.
- Dizziness
- Abnormal Liver function tests
- Muscle disorders, (including muscle pain and cramps).

Tell your doctor immediately if you notice any of the following:

Wheezing, swelling of the lips/mouth, difficulty in breathing, hayfever, lumpy rash (hives) or fainting. These could be symptoms of an allergic reaction.

This is not a complete list of all possible side-effects. Others may occur in some people and there may be some side-effects not yet known.

Do not be alarmed by this list of possible side-effects. You may not experience any of them.

How do I store Zeffix?

Keep this medicine where children cannot reach it, such as in a locked cupboard.

Do not leave in a car, on a window sill or in the bathroom.

Keep Zeffix oral solution in a cool, dry place where it stays below 25°C.

Keep Zeffix oral solution in the bottle with the cap tightly closed until it's time to take it.

Return any unused or expired medicine to your pharmacist.

Product description

What Zeffix oral solution looks like

The oral solution is a clear, colourless to pale yellow solution with strawberry and banana flavouring.

Zeffix oral solution is supplied in a white polyethylene bottle with a child resistant cap. The bottle contains 240 mL of solution for oral use and is in a carton.

The pack includes an oral dosing syringe and syringe-adapter.

Ingredients

Zeffix oral solution contains 5 mg of lamivudine in each mL. Your oral solution also contains the following inactive ingredients:

Sugar (20% sucrose), methyl hydroxybenzoate, propyl hydroxybenzoate, citric acid, propylene glycol, sodium citrate dihydrate, artificial strawberry flavouring, artificial banana flavouring and purified water.

Supplier

Your Zeffix is supplied by:

Arrow Pharma Pty Ltd
15-17 Chapel Street
Cremorne VIC 3121
Australia.

Where to go for further information

Pharmaceutical companies are not in a position to give people an individual diagnosis or medical advice. Your doctor or pharmacist is the best person to give you advice on the treatment of your condition.

This leaflet was prepared in May 2016

The information provided applies only to:
Zeffix® oral solution.

Zeffix oral solution: AUST R 66829

Version 4.0