

ZEFFIX Oral Solution

Lamivudine 5 mg/mL

New Zealand Consumer Medicine Information

What is in this leaflet?

Please read this leaflet carefully before you start taking ZEFFIX Oral Solution.

This leaflet answers some common questions about ZEFFIX. 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 risks of you taking ZEFFIX against the benefits this medicine is expected to have for you.

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

Keep this leaflet with the oral solution.

You may need to read it again.

What ZEFFIX Oral Solution is used for

ZEFFIX Oral Solution contains lamivudine which belongs to a group of medicines called antivirals.

ZEFFIX is used to treat patients 16 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 does not 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.

ZEFFIX Oral Solution is not addictive.

Your doctor may have prescribed ZEFFIX Oral Solution for another reason.

If you are already taking other medicines containing lamivudine for HIV infection (3TC, Combivir), your doctor will continue to treat you with the higher dose for that viral infection.

Ask your doctor if you have any questions about why ZEFFIX Oral Solution has been prescribed for you.

Before you take ZEFFIX Oral Solution

When you must not take it

Do not take ZEFFIX Oral Solution if you have ever had an allergic reaction to lamivudine or any of the ingredients listed at the end of this leaflet.

Read the Side Effects section to find out about the symptoms of allergy.

Do not take ZEFFIX Oral Solution if you are pregnant, trying to become pregnant or breastfeeding, unless your doctor says you should.

Your doctor will discuss the risks and benefits of using ZEFFIX oral

solution if you are pregnant or breastfeeding.

Do not take ZEFFIX Oral Solution after the expiry or “use by” date (EXP) printed on the pack.

If you take it after the expiry date has passed, it may not work as well.

Do not take ZEFFIX Oral Solution if the packaging is torn or shows signs of tampering.

If you're not sure whether you should be taking ZEFFIX Oral Solution, talk to your doctor.

Before you start taking ZEFFIX Oral Solution

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.

Taking other medicines

Some medicines may affect the way others work. Your doctor or pharmacist will be able to tell you what to do when taking ZEFFIX Oral Solution with other medicines.

You must tell your doctor if:

- You are taking any other medicines, including medicines

you buy without a prescription from a pharmacy, supermarket or health food shop

- You are being given treatment to suppress your immune system, such as chemotherapy
- You are taking medicines (usually liquids) containing sorbitol, used regularly
- You are taking any antibacterial medicines called trimethoprim or sulphamethoxazole
- You are taking any medicines for the treatment of HIV infection called zidovudine or emtricitabine.

How to take ZEFFIX Oral Solution

Your doctor will tell you how to take ZEFFIX Oral Solution and how often. You will also find this information on the label of your medicine.

Do not take extra oral solution. Do not take the oral solution more often than you have been told.

How much to take

The normal adult dose (12 years and over) is 20 mL of the solution, equivalent to 100 mg of lamivudine, once a day. Children (2-11 years): the recommended dose is 3 mg/kg once daily up to a maximum of 100 mg daily.

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.

ZEFFIX Oral Solution is not recommended for children under 2 years of age.

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 plastic wrap from the syringe/adaptor.
2. Remove the adapter from the syringe.
3. Remove the bottle cap and keep it safe.
4. Hold the bottle firmly. Push the plastic adaptor into the neck of the bottle.
5. Insert the syringe firmly into the adapter.
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 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. Don't 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

How long to take it

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.

If you forget to take it

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to. Otherwise, take it as soon as you remember, then go back to taking it as you would normally.

Do not take a double dose to make up for the dose that you missed.

If you take too much (overdose)

Immediately telephone your doctor or Poisons Information Centre (0800 POISON 0800 764 766) or go to accident and emergency at your nearest hospital, if you think you or anyone else may have taken too much ZEFFIX Oral Solution. Do this even if there are no signs of discomfort or poisoning. This may need urgent medical attention.

Keep telephone numbers for these places handy.

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

While you are taking ZEFFIX Oral Solution

Things you must do

Tell your doctor or pharmacist that you are taking ZEFFIX Oral Solution if you are about to be started on any other medicines.

Tell your doctor if you become pregnant or are trying to

become pregnant or are breastfeeding.

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

Otherwise, your doctor may think that it was not effective and change your treatment unnecessarily.

If you are diabetic, blood sugar levels should be monitored, as each dose (20 mL) contains 4 g of sugar.

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 Oral Solution to treat any other complaints unless your doctor says to.

Side Effects

Check with your doctor as soon as possible if you have any problems while taking ZEFFIX Oral Solution, even if you do not think the problems are connected with the medicine or are not listed in this leaflet.

Like other medicines, ZEFFIX Oral Solution 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 common reported side effects are:

- Headache
- Vomiting and Diarrhoea
- Nausea
- Fatigue/tiredness
- Abdominal discomfort and pain
- Respiratory tract infections, throat and tonsil discomfort
- Dizziness
- Rash
- Muscle disorders, (including muscle pain and cramps).

If any of these side effects persist, or are troublesome, see your doctor.

If any of the following happen, stop taking ZEFFIX Oral Solution and tell your doctor immediately, or go to accident and emergency at your nearest hospital:

- Skin troubles such as lumpy skin rash or "hives"
- Swelling of the face, lips, mouth or throat which may cause difficulty in swallowing or breathing
- Wheezing, chest pain or tightness
- Fainting.

These are very serious side effects. If you have them, you may have a serious allergic reaction. You may need urgent medical attention or hospitalisation. All these side effects are very rare.

This is not a complete list of side effects.

Tell your doctor if you notice anything else that is making you feel unwell, even if it is not on this list.

Some people may get other side effects while taking ZEFFIX Oral

Solution. If you are concerned, talk to your doctor or pharmacist.

Ask your doctor or pharmacist if you don't understand anything in this list.

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

After taking ZEFFIX Oral Solution

Storage

Keep the oral solution where children cannot reach it.

A locked cupboard at least one-and-a half metres above the ground is a good place to store them.

Keep ZEFFIX Oral Solution in a cool, dry place where it stays at or below 25°C.

Do not store the oral solution, in the bathroom or near a sink.

Do not leave it in the car or on window sills. Heat and dampness can destroy some medicines.

Keep your ZEFFIX Oral Solution in the bottle with the cap tightly closed until you take it.

If you take ZEFFIX Oral Solution out of its pack it may not keep well.

Disposal

If your doctor tells you to stop taking ZEFFIX Oral Solution, or the oral solution has passed its expiry date, ask your pharmacist what to do with any oral solution left over.

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 anhydrous, propylene glycol, sodium citrate, artificial strawberry flavouring, artificial banana flavouring and purified water.

ZEFFIX Oral Solution does not contain lactose or gluten.

SUPPLIER

Your ZEFFIX Oral Solution is supplied by:

GlaxoSmithKline NZ Limited
Private Bag 106600
Downtown
Auckland
New Zealand

ZEFFIX is also available as tablets (100 mg lamivudine).

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. You may also be able to find general information about your disease and its treatment from books, for example in public libraries.

Do not throw this leaflet away.

You may need to read it again.

This leaflet was prepared on 30 June 2021.

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The information provided applies only to: ZEFFIX Oral Solution.

ZEFFIX is a registered trade mark of the GSK group of companies.

3TC and Combivir are registered trade marks of the ViiV Healthcare group of companies.

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Further Information

This is not all the information that is available on ZEFFIX Oral Solution. If you have any more questions or are not sure about anything, ask your doctor or pharmacist.