

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using ZEFFIX?

ZEFFIX contains the active ingredient lamivudine. 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.

For more information, see Section [1. Why am I using ZEFFIX?](#) in the full CMI.

2. What should I know before I use ZEFFIX?

Do not use if you have ever had an allergic reaction to ZEFFIX or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use ZEFFIX?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with ZEFFIX and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use ZEFFIX?

- It is usual for the dose of ZEFFIX Oral Solution to start at quite low level and be slowly increased during the first few weeks of treatment.
- The doses that your doctor prescribes will generally depend on any other medications you are taking and your response to ZEFFIX Oral Solution.

More instructions can be found in Section [4. How do I use ZEFFIX?](#) in the full CMI.

5. What should I know while using ZEFFIX?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist, pharmacist or nurse you visit that you are using ZEFFIX.• Tell your doctor immediately if you become pregnant or intend to become pregnant whilst using ZEFFIX.
Things you should not do	<ul style="list-style-type: none">• Do not stop using this medicine suddenly without checking with your doctor.• Do not use ZEFFIX Oral Solution to treat any other complaints unless your doctor says to.
Looking after your medicine	<ul style="list-style-type: none">• Store it in a cool dry place at 25°C away from moisture, heat or sunlight.

For more information, see Section [5. What should I know while using ZEFFIX?](#) in the full CMI.

6. Are there any side effects?

Side effects that have been reported to be less serious include headache, dizziness, vomiting, rash and muscle disorders. More serious side effects are skin rash or hives, fainting and wheezing, chest pain or tightness.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

ZEFFIX®

Active ingredient: Lamivudine

Consumer Medicine Information (CMI)

This leaflet provides important information about using ZEFFIX. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using ZEFFIX.**

Where to find information in this leaflet:

- [1. Why am I using ZEFFIX?](#)
- [2. What should I know before I use ZEFFIX?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use ZEFFIX?](#)
- [5. What should I know while using ZEFFIX?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using ZEFFIX?

ZEFFIX contains the active ingredient 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 medicines containing lamivudine for HIV infection (3TC, Combivir), your doctor will continue to treat you with the higher dose for that viral infection.

If you have any questions about why ZEFFIX Oral Solution has been prescribed for you, ask your doctor.

2. What should I know before I use ZEFFIX?

Warnings

Do not use ZEFFIX if:

- you have ever had an allergic reaction to ZEFFIX Oral Solution (See "Side-Effects") or any of the ingredients listed toward the end of this leaflet. (See "Ingredients").
- 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.
- the expiry date (EXP) printed on the pack has passed.
- the packaging is torn or shows signs of tampering.

Check with your doctor if you:

- are allergic to foods, dyes, preservatives or any other medicines.
- have, or have ever had, kidney problems
- have, or have ever had, problems with your pancreas.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

Your doctor will discuss the risks and benefits of using ZEFFIX Oral Solution if you are breastfeeding.

Children

ZEFFIX is not recommended for treatment of long term (chronic) viral infection of the liver caused by hepatitis B in children under 2 years of age.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may affect how ZEFFIX works or make it more likely that you'll have side effects. These include:

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

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

Some medicines may interfere with ZEFFIX and affect how it works.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect ZEFFIX.

4. How do I use ZEFFIX?

How much to take

Take ZEFFIX Oral Solution as directed by your doctor or pharmacist. Never change the dose yourself. Do not increase the dose more quickly than you have been told.

Your doctor and pharmacist will be able to tell you:

- The normal adult dose (12 years and over) is one 100 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.

The label on the container that the Oral Solution was supplied in will give the same information. If there is something that you do not understand ask either your doctor or pharmacist.

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

How to take ZEFFIX

ZEFFIX Oral Solution can be swallowed 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:

Remove the plastic wrap from the syringe/adaptor.

Remove the adaptor from the syringe.

Remove the bottle cap and keep it safe.

Hold the bottle firmly. Push the plastic adaptor into the neck of the bottle.

Insert the syringe firmly into the adaptor.

Turn the bottle upside down.

Pull out the syringe plunger until the syringe contains the first part of your full dose.

Turn the bottle the correct way up. Remove the syringe from the adaptor.

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.

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.

Take the syringe out of the bottle and wash it thoroughly in clean water. Let it dry completely before you use it again.

Close the bottle tightly with the cap, leaving the adaptor in place.

Discard oral solution one month after first opening.

ZEFFIX Oral Solution can help control your condition, but not cure it. Therefore, you must take ZEFFIX Oral Solution every day. Continue taking the Oral Solution for as long as your doctor tells you to.

If you forget to use ZEFFIX

ZEFFIX should be used regularly at the same time each day as instructed by your doctor.

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

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

If you use too much ZEFFIX

If you think that you have taken too much ZEFFIX, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (**by calling 0800 764 766**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using ZEFFIX?

Things you should do

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

Your doctor or pharmacist will be able to tell you whether there are any special instructions while you are taking ZEFFIX Oral Solution.

Call your doctor straight away if you:

- are planning to become pregnant. There may be an increased risk of babies developing a cleft lip or cleft palate if ZEFFIX Oral Solution is taken during the first few months of pregnancy.
- are breast feeding or planning to breast feed.
- for any reason, you have not taken your medicine exactly as directed.

Remind any doctor, dentist, pharmacist or nurse you visit that you are using ZEFFIX.

Things you should not do

- stop taking ZEFFIX Oral Solution just because you feel better.
- stop using this medicine suddenly or lower the

dosage without checking with your doctor your hepatitis may get worse.

- take ZEFFIX to treat any other complaints unless your doctor tells you to.
- give your medicine to anyone else, even if they have the same condition as you.

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.

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.

Looking after your medicine

- Store in the original package container in order to protect from moisture and do not open the cap until you take it.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture where the temperature stays below 25°C, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

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

When to discard your medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
<p>Nervous system disorders:</p> <ul style="list-style-type: none"> • dizziness • headache <p>Gastrointestinal disorders:</p> <ul style="list-style-type: none"> • nausea • vomiting and diarrhoea • abdominal discomfort and pain <p>General disorders:</p> <ul style="list-style-type: none"> • tiredness or fatigue <p>Respiratory disorders:</p> <ul style="list-style-type: none"> • respiratory tract infections • throat and tonsil discomfort <p>Skin and subcutaneous disorders:</p> <ul style="list-style-type: none"> • lumpy skin rash or hives <p>Musculoskeletal disorders:</p> <ul style="list-style-type: none"> • Muscle disorders (including muscle pain and cramps) 	<p>Check with your doctor as soon as possible if you have any health 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.</p> <p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

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

Serious side effects

Serious side effects	What to do
<p>Allergic reaction</p> <ul style="list-style-type: none"> • Swelling of the face, lips, mouth or throat which may cause difficulty in swallowing or breathing. • Wheezing, chest pain or tightness • Fainting 	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

All these side effects are rare.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects via <https://nzphvc.otago.ac.nz/reporting>.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What ZEFFIX Oral Solution contains

Active ingredient (main ingredient)	lamivudine 5 mg in each mL
Other ingredients (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.
Potential allergens	none

ZEFFIX Oral Solution do not contain lactose or gluten.

Do not take this medicine if you are allergic to any of these ingredients.

What ZEFFIX 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.

Who distributes ZEFFIX

GlaxoSmithKline NZ Ltd
Private Bag 106600
Downtown
Auckland 1143
New Zealand
Phone: (09) 367 2900
Facsimile: (09) 367 2910

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