

ZEFFIX[®] Tablets

Lamivudine 100 mg

New Zealand Consumer Medicine Information

What is in this leaflet?

Please read this leaflet carefully before you start taking ZEFFIX tablets.

This leaflet answers some common questions about ZEFFIX tablets. 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 tablets.

You may need to read it again.

What ZEFFIX tablets are used for

ZEFFIX tablets contain lamivudine which belongs to a group of medicines called antivirals.

ZEFFIX is used to treat patients with long term (chronic) viral infection of the liver caused by hepatitis B and evidence of hepatitis B virus replication.

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 tablets are not addictive. Your doctor may have prescribed ZEFFIX tablets 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 tablets have been prescribed for you, ask your doctor.

Before you take ZEFFIX tablets

When you must not take ZEFFIX

Do not take ZEFFIX tablets 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 tablets 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 tablets if you are pregnant or breastfeeding.

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

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

Before you start taking ZEFFIX tablets

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 tablets 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 tablets

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

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

How much to take

The normal adult dose (12 years and over) is one 100 mg tablet once a day. Children 2-11 years the recommended dose is 3 mg/kg up to a maximum of 100 mg/day. 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 tablets are not recommended for children under 2 years of age.

How to take it

ZEFFIX tablets should be swallowed whole with a glass of water, and can be taken with or without food.

How long to take it

ZEFFIX tablets help control your condition, but do not cure it. Therefore you must take ZEFFIX tablets every day. Continue taking the tablets 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 many ZEFFIX tablets. 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 tablets

Things you must do

Tell your doctor or pharmacist that you are taking ZEFFIX tablets 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.

Things you must not do

Do not stop taking ZEFFIX tablets, 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 tablets to treat any other complaints unless your doctor says to.

Side Effects

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

Like other medicines, ZEFFIX tablets 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 tablets 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 tablets. 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 tablets

Storage

Keep the tablets where children cannot reach them.

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

Keep ZEFFIX tablets in a cool, dry place where it stays below 30°C.

Do not store the tablets in the bathroom or near a sink.

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

Keep your ZEFFIX tablets in the blister pack until you take them.

If you take ZEFFIX tablets out of the pack they may not keep well.

Disposal

If your doctor tells you to stop taking ZEFFIX tablets, or the tablets have passed their expiry date, ask your pharmacist what to do with any tablets left over.

Product description

What ZEFFIX tablets look like

The tablets are butterscotch coloured, film-coated, capsule shaped, biconvex tablets engraved "GX CG5" on one face.

ZEFFIX tablets are supplied in foil blisters. The foil blisters contain 28 tablets, for oral use only, and are in a carton.

Ingredients

ZEFFIX tablets contain 100 mg of lamivudine. Your tablets also contain the following inactive ingredients:

Microcrystalline cellulose (460), magnesium stearate (572), titanium dioxide (171), hypromellose (464), sodium starch glycollate, polyethylene glycol, polysorbate 80 (433), yellow iron oxide CI 77192 and red iron oxide CI 77491.

ZEFFIX tablets do not contain lactose or gluten.

Supplier

Your ZEFFIX tablets are supplied by:

GlaxoSmithKline NZ Limited
Private Bag 106600
Downtown
Auckland
New Zealand

Ph: (09) 367 2900

Fax (09) 367 2910

Further Information

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

ZEFFIX is also available as an oral solution.

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
7 April 2017.

Version 5.0

The information provided applies
only to: ZEFFIX[®] tablets.

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