

NEW ZEALAND CONSUMER MEDICINE INFORMATION

ZETLAM

Lamivudine Film-Coated Tablets 100mg



What is in this leaflet

This leaflet answers some common questions about ZETLAM.

It does not contain all 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 ZETLAM against the benefits they expect it will 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 ZETLAM is used for

ZETLAM is used to treat patients with long term (chronic) viral infection of the liver caused by hepatitis B and evidence of hepatitis B virus (HBV) replication in adults and adolescents 12 years and older. Hepatitis B is a virus which damages the liver.

ZETLAM contains the active ingredient lamivudine. It belongs to a group of medicines called nucleoside analogues, which are antiviral medicines.

Treatment with ZETLAM can reduce the amount of hepatitis B virus in your body. This should lead to less liver damage.

ZETLAM 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.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

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

ZETLAM tablets are not addictive.

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

This medicine is not expected to affect your ability to drive a car or operate machinery.

Before you take ZETLAM

When you must not take it

Do not take ZETLAM if you have an allergy to:

- any medicine containing lamivudine
- any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include: shortness of breath; wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin.

Do not take this medicine if you are pregnant or trying to become pregnant, unless your doctor says you should.

It may affect your developing baby if you take it during pregnancy. Your doctor can discuss with you the risks and benefits involved.

Do not breast-feed if you are taking this medicine unless your doctor says you should.

The active ingredient in ZETLAM passes into breast milk and there is a possibility that your baby may be affected. Your doctor can discuss with you the risks and benefits involved.

Do not take this medicine after the expiry date printed on the pack or if the packaging is damaged or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you start to take it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have or have had any of the following medical conditions:

- kidney problems
- pancreas problems
- advanced liver disease
- liver transplant
- HIV (human immunodeficiency virus).

Tell your doctor if you are taking any immunosuppressant medicines, including cancer chemotherapy.

If you have not told your doctor about any of the above, tell him/her before you start taking ZETLAM.

Taking other medicines

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

Some medicines and ZETLAM may

interfere with each other. These include:

- co-trimoxazole or trimethoprim antibiotics
- emtricitabine, medicine used to treat HIV
- sorbitol-containing medicines.

These medicines may be affected by ZETLAM or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

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

How to take ZETLAM

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

How much to take

The usual dose for adults and adolescents aged 12 years and over is one tablet (100mg) once daily.

Your doctor may prescribe a different dosage, for example if you have kidney problems.

How to take it

Swallow the tablets whole with a full glass of water.

When to take it

ZETLAM tablets are usually taken once a day.

Take your medicine at about the same time each day.

Taking it at the same time each day will have the best effect. It will also help you remember when to take it.

It does not matter if you take this medicine before or after food.

How long to take it

Continue taking your medicine for as long as your doctor tells you.

This medicine helps to control your condition, but does not cure it. It is important to keep taking your medicine every day even if you feel well.

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 ZETLAM.

If your doctor tells you to stop taking ZETLAM, your doctor will monitor your blood tests for signs of recurrent or worsening hepatitis.

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, and then go back to taking your medicine as you would normally.

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

This may increase the chance of you getting an unwanted side effect.

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

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

If you take too much (overdose)

Immediately telephone your doctor or the National Poisons Information Centre (0800 POISON or 0800 764 766) for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much ZETLAM. Do this even if there are no signs of discomfort or poisoning. Take the bottle with you if you can. You may need urgent medical attention.

While you are taking ZETLAM

Things you must do

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking ZETLAM.

Tell any other doctors, dentists, and pharmacists who treat you that you are taking this medicine.

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine. It may affect other medicines used during surgery.

If you become pregnant while taking this medicine, tell your doctor immediately.

If you are about to have any blood tests, tell your doctor that you are taking this medicine.

Keep all of your doctor's appointments so that your progress can be checked. Your doctor may do some tests to check your kidneys and liver from time to time to make sure the medicine is working and to prevent unwanted side effects.

Things you must not do

Do not take ZETLAM to treat any other complaints unless your doctor tells you to.

Do not give your medicine to anyone else, even if they have the same condition as you.

Do not stop taking your medicine or change the dosage without checking with your doctor. If you stop taking it, your condition may worsen.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking ZETLAM.

This medicine helps most people with hepatitis B, but it may have unwanted side effects in a few

people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- feeling tired and fatigued, or generally unwell
- headache
- abdominal discomfort or pain
- nausea or vomiting
- diarrhoea
- respiratory tract infections, throat or tonsil discomfort
- muscle pain or cramps.

The above list includes the more common side effects of your medicine.

Tell your doctor as soon as possible if you notice any of the following:

- bleeding or bruising more easily than usual
- paralysis or weakness of muscles
- tingling or numbness of arms and legs
- severe abdominal pain, often with nausea and vomiting.

The above list includes serious side effects that may require medical attention.

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- rash, itching or hives
- swelling of the face, lips, tongue or other parts of the body
- shortness of breath, wheezing or difficulty breathing.

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation.

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

Other side effects not listed above may also occur in some people.

Some side effects (for example, changes in liver function and other blood tests) can only be found when your doctor does tests from time to time to check your progress.

After taking ZETLAM

Storage

Keep your tablets in the bottle until it is time to take them.

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

Keep your tablets in a cool dry place where the temperature stays below 30°C.

Heat and dampness can destroy some medicines. Do not store ZETLAM or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.

Keep it where children cannot reach it.

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

Disposal

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What it looks like

ZETLAM is a peach coloured, film-coated, capsule shaped, biconvex bevelled edge tablet debossed with "LN1" on one side and "M" on the other side.

ZETLAM tablets are supplied in bottles containing 28 tablets.

Ingredients

Each ZETLAM tablet contains 100mg of lamivudine as the active ingredient.

Each ZETLAM tablet also contains:

- microcrystalline cellulose
- sodium starch glycolate
- magnesium stearate
- hypromellose
- titanium dioxide
- propylene glycol
- iron oxide yellow
- iron oxide red.

This medicine does not contain lactose, sucrose, gluten or tartrazine.

If you want to know more

Should you have any questions regarding this product, please contact your pharmacist or doctor.

Who supplies this medicine

Distributed in New Zealand by:

Mylan New Zealand Ltd,
PO Box 11183,
Ellerslie,
Auckland.

Telephone: (09) 579 2792

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