

ZETLAM

contains the active ingredient lamivudine

Consumer Medicine Information

What is in this leaflet

Please read this leaflet carefully before you take ZETLAM tablets.

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

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

Keep this leaflet with your medicine.

You may need to read it again.

What ZETLAM is used for

ZETLAM belongs to a group of medicines called antivirals.

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

ZETLAM 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.

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.

This medicine is not addictive.

It is available only with a doctor's prescription.

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 ZETLAM

Do not take if

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

You must not take ZETLAM if you are taking zalcitabine.

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn 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 ever had any of the following medical conditions:

- kidney problems
- pancreas problems

Tell your doctor if you are pregnant or plan to become pregnant or are breastfeeding.

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

How to take ZETLAM

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

They may differ from the information contained in this leaflet.

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

How much to take

Take ZETLAM as directed by your doctor or pharmacist.

The normal dose for adults and children age 12 years or above, is one 100 mg tablet once a 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 ZETLAM.

How to take it

Swallow the tablets whole with a glass of water.

For patients who are unable to swallow tablets, the ZETLAM tablets may be crushed and 100% of the crushed tablets could be added to a small amount of semi-solid food or liquid, all of which should be consumed immediately.

When to take it

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

In order for ZETLAM to be effective, you must take ZETLAM every day for as long as your doctor says you should take them.

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) 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.

You may need urgent medical attention.

While you are taking ZETLAM

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 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 first checking with your doctor.

If you stop taking it suddenly, your hepatitis may worsen.

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

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well or are experiencing any side effects or allergic reactions while you are taking ZETLAM.

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 list 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:

- 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).

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:

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

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

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

After taking ZETLAM

Storage

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.

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.

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.

Heat and dampness can destroy some 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.

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Australian registration numbers:

ZETLAM lamivudine 100 mg

Bottle - AUST R 180504

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Product description

What it looks like

ZETLAM lamivudine 100mg tablets are peach coloured, film-coated, capsule shaped, biconvex bevelled edge tablets, debossed with "LN1" on one side and "M" on the other side.

The tablets are available in bottles of 28 tablets.

Ingredients

ZETLAM contains 100 mg of lamivudine as the active ingredient.

It also contains the following inactive ingredients:

- Microcrystalline cellulose
- Sodium starch glycollate Type A
- Magnesium stearate
- Propylene glycol (film coating)
- Opadry Complete Film Coating System 03H520008 yellow (Proprietary Ingredient Number 107420).

This medicine does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

Supplier

ZETLAM is supplied in Australia by: