

Consumer Medicine Information (CMI) summary

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

1. Why am I taking ZETLAM?

ZETLAM contains the active ingredient lamivudine. 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.

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

2. What should I know before I take ZETLAM?

Do not take if you have ever had an allergic reaction to lamivudine 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 take ZETLAM?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with ZETLAM 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 take ZETLAM?

- The normal dose for adults and children aged 12 years or above is one 100 mg tablet once a day.
- Swallow the tablet whole with a glass of water.

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

5. What should I know while taking ZETLAM?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are taking ZETLAM.
Things you should not do	<ul style="list-style-type: none">• Do not stop taking this medicine or change the dose without first checking with your doctor.
Driving or using machines	<ul style="list-style-type: none">• Be careful before you drive or use any machines or tools until you know how ZETLAM affects you.• ZETLAM may cause dizziness and tiredness in some people.
Looking after your medicine	<ul style="list-style-type: none">• Store ZETLAM below 30°C in a cool dry place.• Keep the tablets in the original container until it is time to take them.

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

6. Are there any side effects?

Common side effects: headache, vomiting and diarrhoea, nausea, fatigue/tiredness, abdominal discomfort and pain, coughing with phlegm not associated with cold and flu, dizziness, abnormal liver function tests, muscle disorder (including muscle pain and cramps).

More serious side effects: wheezing, swelling of the lips, mouth, eyelids or face, rapid or difficulty breathing, hay fever, lumpy rash (hives) or fainting, unusual weakness or tiredness, persistent nausea or vomiting, stomach pain, feeling cold, dizziness, irregular heartbeat, pale skin, frequent infections, fever or sore throat, difficulty in swallowing, bleeding or bruising more easily than usual, severe abdominal pain often with nausea and vomiting, muscle weakness or paralysis, tingling or numbness of the arms or legs, breakdown of muscle tissue, excess lactic acid in blood or worsening of liver disease after ZETLAM is stopped, or during treatment if the hepatitis B virus becomes resistant to ZETLAM.

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.

Consumer Medicine Information (CMI)

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

Where to find information in this leaflet:

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

1. Why am I taking ZETLAM?

ZETLAM contains the active ingredient lamivudine.

ZETLAM belongs to a group of medicines called nucleoside analogues, which are antiviral medicines.

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.

ZETLAM is not addictive.

If you are already taking the medicine lamivudine for HIV infection (3TC™, Combivir™), your doctor will continue to treat you with the higher dose for that treatment.

2. What should I know before I take ZETLAM?

Warnings

Do not take ZETLAM if:

- you are allergic to lamivudine or any of the ingredients listed at the end of this leaflet. Symptoms of an allergic reaction may include:
 - o shortness of breath
 - o wheezing or difficulty breathing
 - o swelling of the face, lips, tongue or other parts of the body
 - o rash, itching or hives on the skin.

Always check the ingredients to make sure you can take this medicine.

- **If you are taking zalcitabine, it is not recommended that you take ZETLAM at the same time.**
- the expiry date on the pack has passed or the packaging is torn or shows signs of tampering.

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

Check with your doctor if you:

- have or have ever had any other medical conditions including:
 - o kidney problems
 - o pancreas problems
- take any medicines for any other condition
- have allergies to any other medicines, foods, preservatives or dyes
- have or have had advanced liver disease, a liver transplant, hepatitis C, or HIV infection
- are seriously overweight, particularly if you are a woman, as you may require additional monitoring
- are taking medicines that suppress the immune system, including cancer chemotherapy
- have untreated HIV infection while taking the 100 mg hepatitis B dose of lamivudine as HIV may become resistant to some HIV medicines and become harder to treat.

Tell your doctor if you have, or think you may have, HIV infection.

Your healthcare professional may offer counselling and testing for HIV infection before and during treatment with lamivudine for hepatitis B

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.

The safety of ZETLAM has not been established in human pregnancy. Use in pregnancy should be considered only if the benefit outweighs the risk.

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

The safety of ZETLAM has not been established in breast fed infants. ZETLAM should only be used if the expected benefit justifies the potential risk to the baby.

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 interfere with ZETLAM and affect how it works. These include:

- zalcitabine, used to treat HIV infection (sometimes called the AIDS virus).
- medicines (usually liquids) containing sorbitol and other sugar alcohols (such as xylitol, mannitol, lactitol or maltitol).
- other medicines containing lamivudine, used to treat HIV infection (sometimes called the AIDS virus).
- Emtricitabine, used to treat HIV infection or hepatitis B infection.
- cladribine, used to treat hairy cell leukaemia
- co-trimoxazole or trimethoprim, antibiotics used to treat infections.

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

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

4. How do I take ZETLAM?

Follow all directions given to you by your doctor and pharmacist carefully and take ZETLAM until your doctor tells you to stop.

They may differ from the information contained in this leaflet.

How much to take

- 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.

When to take ZETLAM

- Your doctor or pharmacist will tell you when to take ZETLAM 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.

How to take ZETLAM

- Swallow the tablet whole with a glass of water.
- ZETLAM can be taken with or without food.

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.

How long to take ZETLAM

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 forget to take ZETLAM

ZETLAM should be taken regularly at the same time each day.

If you miss your dose at the usual time and 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 take too much ZETLAM

If you think that you or anyone else has taken too much ZETLAM, urgent medical attention may be needed.

You should immediately:

- phone the Poisons Information Centre (Australia telephone 13 11 26) for advice, 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 taking ZETLAM?

Things you should do

Tell your doctor immediately if your hepatitis symptoms worsen while you are taking ZETLAM. Your doctor will perform regular blood tests to check the amount of hepatitis B virus and how well your liver is working.

Tell your surgeon or anaesthetist that you are taking ZETLAM if you are going to have surgery.

Call your doctor straight away if you:

- become pregnant or intend to become pregnant
- have not been taking ZETLAM exactly as directed. Otherwise, your doctor may think that it was not working as it should and change your treatment unnecessarily.

Remind any doctor, dentist or pharmacist you visit that you are taking ZETLAM.

Tell your doctor that you are taking ZETLAM before having blood tests.

Keep all medical appointments. Your doctor may perform regular blood tests and may check your liver and kidneys during treatment and after treatment is stopped.

In some people, the hepatitis B virus may become resistant to ZETLAM, and the medicine may become less effective. Your doctor will monitor your blood-test results and may change or add another antiviral medicine if necessary.

Things you should not do

- Do not stop taking ZETLAM or change the dosage without first checking with your doctor. If you stop taking ZETLAM 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.

Each patient responds to treatment differently. Your doctor will check you by taking regular blood samples. The results will help decide when you should stop taking ZETLAM.

- Do not give your medicine to anyone else, even if their symptoms seem similar to yours or they have the same condition as you.
- Do not take ZETLAM to treat any other complaints unless your doctor tells you to.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how ZETLAM affects you.

ZETLAM may cause dizziness and tiredness in some people.

Looking after your medicine

- Store below 30°C.
- Keep your tablets in the bottle until it is time to take them.

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

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

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

Heat and dampness can destroy some medicines.

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.

Getting rid of any unwanted medicine

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

Do not take this medicine after the expiry date printed on the packaging.

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.

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

Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none"> • Headache • Hair loss or alopecia • Joint pain or arthralgia • Itching or pruritic • Fever and increased blood sugar • Vomiting and diarrhoea • Nausea • Swollen glands • Throat and tonsil discomfort • Fatigue/tiredness • Abdominal discomfort and pain • Coughing with phlegm, not associated with a cold or flu • Dizziness • Abnormal liver function tests or abnormal pancreatic enzymes or raised amylase • Muscle disorders (including muscle pain and cramps) • Skin rash or hives • Respiratory tract infection 	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p> <p>This list includes the more common side effects of your medicine.</p>

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> • Symptoms of an allergic reaction such as wheezing, swelling of the lips/ mouth, difficulty in breathing, hay fever, lumpy rash (hives) or fainting. • Unusual weakness or tiredness, persistent nausea or vomiting, stomach pain, rapid or difficult breathing, feeling cold, dizziness, or an irregular heartbeat. These may be symptoms of lactic acidosis or serious liver problems. Lactic acidosis is a very rare but serious side effect. • Unusual tiredness, pale skin, shortness of breath, frequent infections, fever or sore throat. These may be signs of changes in the number of red or white blood cells. • Swelling of the eyelids or face, difficulty swallowing. • Bleeding or bruising more easily than usual. This may be associated with a reduced number of blood-clotting cells (thrombocytopenia). • Severe abdominal pain or cramps, nausea, vomiting which are the signs of an inflamed pancreas (pancreatitis). 	<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>

Serious side effects	What to do
<ul style="list-style-type: none"> Muscle weakness or paralysis, tingling or numbness of the arms or legs, or breakdown of muscle tissue. Persistent tingling, numbness, burning pain or weakness in the hands or feet. These may be signs of nerve damage. Worsening of liver disease after ZETLAM is stopped, or during treatment if the hepatitis B virus becomes resistant to ZETLAM. This can be serious and may be fatal in some people. 	

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

Other side effects not listed here may occur in some people and there may be some side effects not yet known.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

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 ZETLAM contains

Active ingredient (main ingredient)	Lamivudine
Other ingredients (inactive ingredients)	Microcrystalline cellulose Sodium starch glycollate Type A Magnesium stearate Propylene glycol (film coating) Opadry Complete Film Coating System 03H520008 Yellow (ID 107420).

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

What ZETLAM looks like

ZETLAM is a peach, film-coated, capsule shaped, biconvex bevelled edge tablet debossed with "LN1" on one side and "M" on the other side (AUST R 180504).

The tablets are available in bottles of 28 tablets.

Who distributes ZETLAM

Alphapharm Pty Ltd trading as Viatris
Level 1, 30 The Bond
30-34 Hickson Road
Millers Point NSW 2000
www.viatris.com.au
Phone: 1800 274 276

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ZETLAM® is a Viatris company trade mark

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