

NEW ZEALAND CONSUMER MEDICINE INFORMATION

LAMIVUDINE 150 MG ZIDOVUDINE 300 MG ALPHAPHARM

Lamivudine and Zidovudine Film Coated Tablets
150mg + 300mg



What is in this leaflet

This leaflet answers some common questions about LAMIVUDINE 150 MG ZIDOVUDINE 300 MG ALPHAPHARM tablets.

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 LAMIVUDINE 150 MG ZIDOVUDINE 300 MG ALPHAPHARM 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 LAMIVUDINE 150 MG ZIDOVUDINE 300 MG ALPHAPHARM is used for

LAMIVUDINE 150 MG ZIDOVUDINE 300 MG ALPHAPHARM is used alone or with other antiretroviral medicines, to slow down the progression of Human Immunodeficiency Virus (HIV) infection. HIV can lead to Acquired Immune Deficiency Syndrome (AIDS) and other related illnesses.

LAMIVUDINE 150 MG ZIDOVUDINE 300 MG ALPHAPHARM tablets contain two active ingredients, lamivudine and

zidovudine, which belong to a group of medicines called antiretrovirals. LAMIVUDINE 150 MG ZIDOVUDINE 300 MG ALPHAPHARM does not cure or prevent AIDS or HIV infection, but hinders the growth of human immunodeficiency virus. In this way it stops on going damage to the body's immune system, which fights infection.

LAMIVUDINE 150 MG ZIDOVUDINE 300 MG ALPHAPHARM does not prevent or reduce your risk of passing HIV infection to others. You will still be able to pass on the HIV virus by sexual activity or by passing on blood or bodily secretions which carry the HIV virus. You should continue to take all appropriate precautions.

While taking LAMIVUDINE 150 MG ZIDOVUDINE 300 MG ALPHAPHARM and/or any other therapy for HIV, you may continue to develop other infections and other complications of HIV infection. You should keep in regular contact with your doctor.

The long-term risks and benefits of taking LAMIVUDINE 150 MG ZIDOVUDINE 300 MG ALPHAPHARM are not known.

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.

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

LAMIVUDINE 150 MG ZIDOVUDINE 300 MG ALPHAPHARM tablets are not

recommended for use in children under 12 years of age.

Before you take LAMIVUDINE 150 MG ZIDOVUDINE 300 MG ALPHAPHARM

When you must not take it

Do not take LAMIVUDINE 150 MG ZIDOVUDINE 300 MG ALPHAPHARM if you have an allergy to:

- any medicine containing lamivudine
- any medicine containing zidovudine
- 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 have:

- kidney disease
- liver disease
- very low white blood cell count (neutropenia)
- very low blood cell count (anaemia) or reduced haemoglobin levels.

Ask your doctor if you have any questions about these.

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

you should.

Your doctor should discuss with you the risks and benefits of taking these tablets if you are pregnant.

Breastfeeding is not recommended while you are taking LAMIVUDINE 150 MG ZIDOVUDINE 300 MG ALPHAPHARM because:

- lamivudine and zidovudine medicines enter the breast milk and there is a possibility your baby may be affected
- it is recommended that HIV infected women do not breastfeed their infants, to avoid risking potential passing of HIV infection to the infant.

Talk to your doctor if you have any questions about pregnancy or breastfeeding.

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 have certain health conditions, your doctor may advise that you take a lower dose of lamivudine and/or zidovudine, the two active ingredients in LAMIVUDINE 150 MG ZIDOVUDINE 300 MG ALPHAPHARM tablets. These medicines are also available separately.

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:

- liver problems
- hepatitis B infection.

If you have not told your doctor about any of the above, tell him/her before you start taking LAMIVUDINE 150 MG ZIDOVUDINE 300 MG ALPHAPHARM.

If you have a long-standing viral infection of your liver (hepatitis B) it may flare up. This can cause serious illness particularly if your liver is already not working very well. If you have both HIV and hepatitis B, when you stop taking LAMIVUDINE 150 MG ZIDOVUDINE 300 MG ALPHAPHARM, your doctor is likely to arrange tests from time to time to check how well your liver is working and to measure virus levels.

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.

Particular care is needed when taking the painkiller paracetamol. Some medicines and LAMIVUDINE 150 MG ZIDOVUDINE 300 MG ALPHAPHARM may interfere with each other. These include:

- co-trimoxazole or trimethoprim antibiotics
- clarithromycin antibiotic
- some medicines used to treat HIV such as zalcitabine, emtricitabine and stavudine
- atovaquone, a medicine to treat some types of pneumonia and malaria
- phenytoin, a medicine used to prevent seizures
- probenecid, a medicine used for gout and other conditions
- ribavirin, an antiviral medicine
- rifampicin, a medicine for tuberculosis and infections
- some medicines for chemotherapy like vincristine and doxorubicin
- anti-inflammatories such as aspirin, naproxen, indomethacin, ketoprofen
- pain medicines such as codeine, morphine, methadone

- oxazepam or lorazepam, sometimes used for anxiety.
- medicines containing sorbitol (a sweetener)

These medicines may be affected by LAMIVUDINE 150 MG ZIDOVUDINE 300 MG ALPHAPHARM 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 LAMIVUDINE 150 MG ZIDOVUDINE 300 MG ALPHAPHARM

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 dosage of LAMIVUDINE 150 MG ZIDOVUDINE 300 MG ALPHAPHARM is one tablet twice daily.

How to take it

Swallow the tablets whole with a drink of water.

When to take it

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

Take your medicine at about the same time(s) each day.

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

When you are taking LAMIVUDINE 150 MG ZIDOVUDINE 300 MG ALPHAPHARM twice daily, try to

take it in the morning and at night, approximately every 12 hours.

If you need to take clarithromycin antibiotic, take it at least 2 hours before or 2 hours after your dose of LAMIVUDINE 150 MG ZIDOVUDINE 300 MG ALPHAPHARM.

Clarithromycin can reduce the absorption of zidovudine.

How long to take it

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

Because this medicine helps to control your condition, but does not cure it, take the tablets every day, as prescribed by your doctor.

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 LAMIVUDINE 150 MG ZIDOVUDINE 300 MG ALPHAPHARM. Do this even if there are no signs of discomfort or poisoning. Take the medicine bottle with you if you can. You may need urgent medical attention.

While you are using LAMIVUDINE 150 MG ZIDOVUDINE 300 MG ALPHAPHARM

Things you must do

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking LAMIVUDINE 150 MG ZIDOVUDINE 300 MG ALPHAPHARM.

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. It may interfere with the results of some tests.

Keep all of your doctor's appointments so that your progress can be checked. Your doctor may do some tests such as blood tests 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 LAMIVUDINE 150 MG ZIDOVUDINE 300 MG ALPHAPHARM 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.

Things to be careful of

Be careful driving or operating machinery until you know how

LAMIVUDINE 150 MG ZIDOVUDINE 300 MG ALPHAPHARM affects you.

Like many medicines, this medicine may cause headaches and tiredness in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking LAMIVUDINE 150 MG ZIDOVUDINE 300 MG ALPHAPHARM.

It may be difficult to tell whether side effects are the result of taking LAMIVUDINE 150 MG ZIDOVUDINE 300 MG ALPHAPHARM, effects of the HIV disease, or side effects of other medicines you may be taking. For this reason, it is very important for you to inform your doctor of any change in your condition. Your doctor may need to change your dose or advise you to stop taking LAMIVUDINE 150 MG ZIDOVUDINE 300 MG ALPHAPHARM.

Like all medicines, this medicine may have unwanted side effects in some 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.

Some side effects can only be found when your doctor does tests from time to time to check your progress. These may include:

- reduced red blood cell count (anaemia)
- reduced white blood cell count (neutropenia)

- changes in liver function tests
- changes in thyroid function tests
- increased blood sugar
- increased blood lipid levels.

The frequency and severity of anaemia and neutropenia are greater in patients with advanced HIV disease, or in patients who start taking this medicine in later stages of HIV disease.

While you are taking this medicine, it is very important that your doctor keeps a close check on your health and takes blood samples to monitor levels of red and white blood cells as these are two of the most serious side effects.

If you develop anaemia or neutropenia, your doctor may reduce or stop the dose of your medicine, or recommend standard treatment for these conditions. Ask your doctor any questions you may have.

It is not known whether many of the side effects are due to taking the LAMIVUDINE 150 MG ZIDOVUDINE 300 MG ALPHAPHARM, or due to the medicine being taken with other medicines. Some of the symptoms may result as a part of HIV infection, AIDS, or AIDS related complex.

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

- nausea or vomiting
- abdominal pain
- diarrhoea
- headache
- muscle or joint pain
- fatigue
- hair loss
- fever
- passing gas from bowel or stomach.

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:

- generalised weakness

- muscle weakness or paralysis (reduced ability to move the muscles)
- change in appetite or unexplained weight loss
- tiredness, being short of breath when exercising, dizziness and looking pale (possible symptoms of anaemia or reduced red blood cell count)
- bleeding or bruising more easily than normal
- tingling or numbness in hands or feet
- convulsions
- sleepiness or sleeplessness
- anxiety or depression, confusion, loss of mental clarity
- signs of infection such as fever, chills, and/or influenza-like symptoms
- cough
- change in skin, nail or mouth colour
- increased frequency of passing urine.

The above list includes serious side effects that may require medical attention. Serious side effects are generally uncommon. Some side effects can occur many months after you start to take LAMIVUDINE 150 MG ZIDOVUDINE 300 MG ALPHAPHARM.

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

- 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
- severe stomach pain, nausea or vomiting.

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

If you are taking medicines for HIV and become very sick, with fast breathing, stop taking LAMIVUDINE 150 MG ZIDOVUDINE 300 MG ALPHAPHARM and consult your doctor immediately. You may have 'lactic acidosis', a condition which

results in high acid levels in the blood which causes the fast breathing. Your liver may not be working properly and this condition can be life threatening. This illness occurs more often in women than in men.

See your doctor if you feel generally unwell with loss of appetite, nausea, vomiting, itching, yellowness of the skin or eyes, dark coloured urine, or if the blood tests of your liver function are abnormal. It is likely you will have to stop taking the LAMIVUDINE 150 MG ZIDOVUDINE 300 MG ALPHAPHARM tablets.

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.

After using LAMIVUDINE 150 MG ZIDOVUDINE 300 MG ALPHAPHARM

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 damp conditions can destroy some medicines. Do not store LAMIVUDINE 150 MG ZIDOVUDINE 300 MG ALPHAPHARM 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

30 May 2017 (based on data sheet dated 30 May 2017).

What it looks like

LAMIVUDINE 150 MG
ZIDOVUDINE 300 MG
ALPHAPHARM tablets are white to off-white capsule-shaped, film coated tablets.

The tablets are marked with 'M' on the left of the score-line and '103' on the right on one side of the tablet, and scored on the other side. The tablets may be halved.

The tablets are supplied in bottles of 60 tablets.

Ingredients

Each LAMIVUDINE 150 MG
ZIDOVUDINE 300 MG
ALPHAPHARM tablet contains 150 mg of lamivudine and 300 mg of zidovudine as the active ingredients.

It also contains:

- microcrystalline cellulose
- sodium starch glycollate
- colloidal silicon dioxide
- magnesium stearate
- hypromellose
- propylene glycol
- titanium dioxide.

This medicine does not contain lactose, sucrose or gluten.

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

Date of Information