

LAMIVUDINE/ ZIDOVUDINE VIATRIS 150/300

lamivudine and zidovudine

CONSUMER MEDICINE INFORMATION

What is in this leaflet

Please read this leaflet carefully before you start LAMIVUDINE/ZIDOVUDINE VIATRIS 150/300. This leaflet answers some common questions about LAMIVUDINE/ZIDOVUDINE VIATRIS 150/300.

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/ZIDOVUDINE VIATRIS 150/300 against the benefits they expect it will have on 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 LAMIVUDINE/ ZIDOVUDINE VIATRIS 150/300 is used for

LAMIVUDINE/ZIDOVUDINE VIATRIS 150/300 contains lamivudine and zidovudine which belong to a group of medicines called antiretrovirals.

Please note that lamivudine is available as a stand alone tablet (as

LAMIVUDINE VIATRIS 150/300 lamivudine 150mg & 300mg tablets).

Lamivudine with zidovudine is used alone or with other antiretrovirals, to slow down the progression of human immunodeficiency virus (HIV) infection, which can lead to Acquired Immune Deficiency Syndrome (AIDS) and other related illnesses (e.g. AIDS-related Complex or ARC).

Lamivudine with zidovudine does not cure AIDS or HIV infection, but slows production of human immunodeficiency virus. In this way it stops ongoing damage to the body's immune system, which fights infection.

Lamivudine with zidovudine does not reduce the risk of passing HIV infection to others. You can still pass on the HIV virus when taking this medicine, although the risk is lowered by effective antiretroviral therapy. Discuss with your doctor the precautions needed to avoid infecting other people.

While taking LAMIVUDINE/ZIDOVUDINE VIATRIS 150/300 and/or any other therapy for HIV disease, you may continue to develop other infections and other complications of HIV infection. You should keep in regular contact with the doctor. The long-term risks and benefits of taking lamivudine / zidovudine combination tablets are not known.

Your doctor may have prescribed LAMIVUDINE/ZIDOVUDINE

VIATRIS 150/300 for another reason. Ask your doctor if you have any questions about why it has been prescribed for you.

LAMIVUDINE/ZIDOVUDINE VIATRIS 150/300 is not addictive.

Before you take LAMIVUDINE/ ZIDOVUDINE VIATRIS 150/300

When you must not take them

Do not take LAMIVUDINE/ZIDOVUDINE VIATRIS 150/300 if you have an allergy to:

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

Symptoms of an allergic reaction may be mild or severe. They usually include some or all of the following: wheezing, swelling of the lips/mouth, difficulty in breathing, hay fever, lumpy rash ("hives") or fainting.

- **Do not take LAMIVUDINE/ZIDOVUDINE VIATRIS 150/300 if you are pregnant, trying to become pregnant or breastfeeding, unless your doctor says you should.**

Your doctor should discuss with you the risks and benefits of using LAMIVUDINE/ZIDOVUDINE VIATRIS 150/300 if you are pregnant or breast feeding.

- **Do not take LAMIVUDINE/ZIDOVUDINE VIATRIS 150/300 if you have.**
 - **Kidney disease**
 - **Liver disease**
 - **Reduced red blood cell count (anaemia),**
 - **Reduced white blood cell count (neutropenia).**

If you have certain health conditions, your doctor may advise that you take a lower dose of lamivudine and/or zidovudine, the active ingredients in LAMIVUDINE/ZIDOVUDINE VIATRIS 150/300 tablets.

Lamivudine and zidovudine are available as separate dosage forms. Ask your doctor if you are not sure whether you should take LAMIVUDINE/ZIDOVUDINE VIATRIS 150/300.

- **Do not take LAMIVUDINE/ZIDOVUDINE VIATRIS 150/300 after the expiry date (EXP) printed on the pack.**

If you take them after the expiry date has passed, it may not work as well.

- **Do not take LAMIVUDINE/ZIDOVUDINE VIATRIS 150/300 if the packaging is torn or shows signs of tampering.**

If you're not sure whether you should be taking LAMIVUDINE/ZIDOVUDINE VIATRIS 150/300 talk to your doctor.

Before you start to take them

You must tell your doctor if:

- **you are allergic to any other medicines, foods, preservatives or dyes.**
- **You are taking or have taken any other medicines.**

- **You have, or have ever had, hepatitis B infection.**
- **You have, or ever had, liver problems.**

When you stop taking LAMIVUDINE/ZIDOVUDINE VIATRIS 150/300

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 your LAMIVUDINE/ZIDOVUDINE VIATRIS 150/300, 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 a pharmacy, supermarket or health food shop.

If you take ribavirin and LAMIVUDINE/ZIDOVUDINE VIATRIS 150/300 together it may cause or worsen anaemia. Please contact your doctor if you notice symptoms of anaemia (such as tiredness and shortness of breath). Your doctor will advise you whether you should stop taking LAMIVUDINE/ZIDOVUDINE VIATRIS 150/300.

There is little information about the way other medicines might affect the way LAMIVUDINE/ZIDOVUDINE VIATRIS 150/300 works, or how LAMIVUDINE/ZIDOVUDINE VIATRIS 150/300 affects other medicines.

Particular care is needed when taking the painkiller, paracetamol.

Your doctor or pharmacist will be able to tell you what to do when taking LAMIVUDINE/ZIDOVUDINE VIATRIS 150/300 with other medicines.

Tell your doctor if you are taking any of the medicines below:

- Ribavirin, paracetamol
 - Phenytoin, oxazepam, lorazepam.
 - Aspirin, codeine, morphine, methadone, rifampicin, indomethacin, ketoprofen, naproxen, cimetidine, clofibrate, probenecid.
 - Pentamidine, pyrimethamine, dapsone, atovaquone, amphotericin B (amphotericin), flucytosine, ganciclovir, interferon, trimethoprim, sulfamethoxazole, clarithromycin.
 - Vincristine, vinblastine and doxorubicin
 - Aciclovir, inosine pranobex, adriamycin, ciprofloxacin
 - Stavudine, zalcitabine or emtricitabine
 - Sorbitol-containing medicines (usually liquids) used regularly.
- LAMIVUDINE/ZIDOVUDINE VIATRIS 150/300 should not be taken with stavudine or zalcitabine.

Use in children

LAMIVUDINE/ZIDOVUDINE VIATRIS 150/300 is not recommended for use in children under 12 years of age. Because it is a fixed dose combination tablet it cannot be adjusted according to the size and weight of the patient.

How to take LAMIVUDINE/ZIDOVUDINE VIATRIS 150/300

Your doctor will tell you have many LAMIVUDINE/ZIDOVUDINE VIATRIS 150/300 to take and how often to take them. You will also find this information on the label of your medicine.

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 box, ask your doctor or pharmacist for help.

How much to take

The usual dosage of LAMIVUDINE/ZIDOVUDINE VIATRIS 150/300 is one tablet twice a day.

How to take them

Swallow the LAMIVUDINE/ZIDOVUDINE VIATRIS 150/300 whole with a full glass of water. Do not divide.

When to take them

Your doctor or pharmacist will be able to tell you when you should take your LAMIVUDINE/ZIDOVUDINE VIATRIS 150/300 tablets.

How long to take them

Because your medicine helps to control your condition, but does not cure it, you will need to take the tablets every day. Do not stop taking your medicine without first talking to your doctor.

If you forget to take them

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 you missed.

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 LAMIVUDINE/ZIDOVUDINE VIATRIS 150/300.

Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

Keep telephone number for these places handy.

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

While you are using LAMIVUDINE/ZIDOVUDINE VIATRIS 150/300

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/ZIDOVUDINE VIATRIS 150/300.

There is little information about the way other medicines might affect the way that LAMIVUDINE/ZIDOVUDINE VIATRIS 150/300 works. You must tell your doctor or pharmacist that you are taking LAMIVUDINE/ZIDOVUDINE VIATRIS 150/300 before you start taking medicines you buy from a pharmacy, health food shop or supermarket. This is especially important regarding medicines which might have an effect on the kidneys, liver, red or white blood cells or other body cells.

Tell your doctor if you become pregnant or are trying to become pregnant.

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 LAMIVUDINE/ZIDOVUDINE VIATRIS 150/300 or change the dosage without first checking with your doctor.

Do not give LAMIVUDINE/ZIDOVUDINE VIATRIS 150/300 to anyone else, even if they have the same condition as you.

Do not take LAMIVUDINE/ZIDOVUDINE VIATRIS 150/300 to treat any other complaints unless your doctor tells you to.

Do not give this medicine to children under 12 years of age. Because it is a fixed dose combination tablet it cannot be adjusted according to the size and weight of the patient.

Things to be careful of

Be careful driving or operating machinery until you know how LAMIVUDINE/ZIDOVUDINE VIATRIS 150/300 affects you.

LAMIVUDINE/ZIDOVUDINE VIATRIS 150/300 taken alone generally do not cause any problems with your ability to drive a car or operate machinery. However, as with many other medicines, LAMIVUDINE/ZIDOVUDINE VIATRIS 150/300 may cause headache and tiredness in some people.

Side effects

Check with your doctor or pharmacist as soon as possible if you do not feel well while you are taking LAMIVUDINE/ZIDOVUDINE VIATRIS 150/300, even if you think that the problems are not connected with the medicine or are not listed in this leaflet.

Like all medicines, LAMIVUDINE/ZIDOVUDINE VIATRIS 150/300 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 serious side effects include:

- Reduced red blood cell count (anaemia).
- Reduced white blood cell count (neutropenia).

The frequency and severity of anaemia and neutropenia are greater in patients with advanced HIV disease, or in patients who start taking LAMIVUDINE/ZIDOVUDINE VIATRIS 150/300 in the later stages of HIV disease.

While you are taking LAMIVUDINE/ZIDOVUDINE VIATRIS 150/300, 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. If you develop anaemia or neutropenia, your doctor may reduce or stop the dose of LAMIVUDINE/ZIDOVUDINE VIATRIS 150/300, or recommend standard treatment for these conditions. Ask your doctor any questions which you may have.

It is not known whether many of these side effects are due to taking LAMIVUDINE/ZIDOVUDINE VIATRIS 150/300 or taking LAMIVUDINE/ZIDOVUDINE VIATRIS 150/300 while taking other medicines. Some of these symptoms may occur as part of HIV infection, AIDS or AIDS-related Complex.

The side effects listed below have been reported:

- Body odour, sweating, chills, swelling of lips and/or tongue, flu-like symptoms, fever, increased sensitivity to pain, back pain, enlarged glands, chest pain, weakness, weight loss, generally feeling unwell, breast enlargement in male patients.
- Widening of blood vessels, possibly leading to low blood pressure or feeling faint.
- Constipation, difficulty in swallowing, gas from stomach or bowel, diarrhoea, bleeding gums or nose, blood in stools, mouth

ulcers, heartburn, vomiting, loss or reduction in appetite, nausea.

- Abdominal discomfort and pain.
- Muscle aches or pains, muscle shaking or spasm or twitching, muscle disease.
- Enlarged fatty liver, abnormal results of blood tests of liver function, inflammation of the pancreas.
- Confusion, depression, nervousness, fainting, loss of mental clarity, dizziness, seizures, severe headache, sleeplessness, fatigue/tiredness.
- Cough, sore throat, hay fever, sinus problems, hoarseness, change to perception of taste.
- Acne, itchiness, skin rash, changes in nail, skin or mouth colour.
- Vision problems, hearing loss, sensitivity to light.
- Passing too much urine, pain, difficulty or increased frequency of passing urine.
- Reduction in all blood cells.
- Increased bruising or bleeding.
- Blood chemistry changes, with excess acidity of the blood.
- Unusual feelings in any part of the body, such as numbness, burning, tingling or pins and needles.
- Hair loss.

Changes in fat distribution have been reported in association with combination antiretroviral therapy. These may include:

- Loss of body fat from areas such as legs, arms and face.
- Increased fat appearing in areas such as abdomen (belly) and other internal organs, breasts and the back of the neck.

Within the first few weeks of treatment with anti-HIV medicines, some people, particularly those that have been HIV positive for some time, may develop inflammatory reactions (e.g., pain, redness, swelling, high temperature) which

may resemble an infection and may be severe. It is thought that these reactions are caused by a recovery in the body's ability to fight infections, previously suppressed by HIV. If you become concerned about any of the new symptoms, or any changes in your health after starting HIV treatment, please discuss with your doctor immediately.

Ask your doctor or pharmacist to answer any questions you may have. If you experience any of these side effects, and they concern you, see your doctor or pharmacist.

If you think you are having an allergic reaction to LAMIVUDINE/ZIDOVUDINE VIATRIS 150/300, TELL YOUR DOCTOR IMMEDIATELY or go to the nearest Accident and Emergency department at your nearest hospital. Symptoms usually include some or all of the following:

- Wheezing
- Swelling of the lips/mouth
- Difficulty in breathing
- Hay fever
- Lumpy rash ("hives")
- Fainting

If you have any of the following symptoms soon after starting to take your medicine, DO NOT TAKE ANY MORE LAMIVUDINE/ZIDOVUDINE VIATRIS 150/300 and tell your doctor IMMEDIATELY or go to the nearest accident and emergency department at your nearest hospital:

- Severe stomach pain or cramps.
- Nausea.
- Vomiting.

These side effects may be due to a condition called pancreatitis.

If you are on medication for HIV and become very sick, with fast breathing, stop taking LAMIVUDINE/ZIDOVUDINE VIATRIS 150/300 and consult your doctor immediately. You may have

a condition known as "lactic acidosis". The fast breathing is due to high acid levels in the blood. Your liver may not be working properly and gets big and fatty. This can be life threatening. This illness occurs more often in women than men.

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

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

Side effects may depend on whether you take LAMIVUDINE/ZIDOVUDINE VIATRIS 150/300 alone, or also have taken other antiretroviral medication(s). Less is known about possible side effects of taking LAMIVUDINE/ZIDOVUDINE VIATRIS 150/300 with other antiretrovirals.

Tell your doctor if you notice anything else that is making you feel unwell, even if it is not on this list.

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 using LAMIVUDINE/ZIDOVUDINE VIATRIS 150/300 tablets

Storage

Keep this medicine 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 a cool dry place where the temperature stays below 30°C.

Do not store LAMIVUDINE/ZIDOVUDINE VIATRIS 150/300 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.

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.

Disposal

If your doctor tells you to stop taking LAMIVUDINE/ZIDOVUDINE VIATRIS 150/300 or the expiry date has passed, ask your pharmacist what to do with any tablets left over.

Product description

What it looks like

LAMIVUDINE/ZIDOVUDINE VIATRIS 150/300 is a white to off-white, capsule shaped, biconvex film coated tablet, debossed with "M" on left of the scoreline and "103" on right, on one side and scored on the other side.

LAMIVUDINE/ZIDOVUDINE VIATRIS 150/300 is supplied in 60 tablet bottles.

Ingredients

LAMIVUDINE/ZIDOVUDINE VIATRIS 150/300 contains 150 mg of lamivudine and 300 mg of zidovudine as the active ingredient.

It also contains the following inactive ingredients:

- Microcrystalline cellulose.
- Sodium starch glycollate type A.

- Magnesium stearate.
- Colloidal anhydrous silica.
- Propylene glycol (film coating).
- Opadry Complete Film Coating System 03H58736 White (ARTG PI No: 106640).

Supplier

LAMIVUDINE/ZIDOVUDINE VIATRIS 150/300 is supplied in Australia by:

Alphapharm Pty Ltd trading as Viatris

Level 1, 30 The Bond

30-34 Hickson Road

Millers Point NSW 2000

www.viatris.com

Phone: 1800 274 276

Australian registration numbers:

LAMIVUDINE/ZIDOVUDINE VIATRIS 150/300 bottle:

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