LAMIVUDINE/ZIDOVUDINE VIATRIS 150/300

Consumer Medicine Information (CMI) summary

The <u>full CMI</u> on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I taking LAMIVUDINE/ ZIDOVUDINE VIATRIS 150/300?

LAMIVUDINE/ZIDOVUDINE VIATRIS 150/300 contains the active ingredients lamivudine and zidovudine. LAMIVUDINE/ZIDOVUDINE VIATRIS 150/300 is used alone or in combination 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 (ARC)). For more information, see Section <u>1. Why am I taking</u>

LAMIVUDINE/ZIDOVUDINE VIATRIS 150/300? in the full CMI.

2. What should I know before I take LAMIVUDINE/ZIDOVUDINE VIATRIS 150/300?

Do not take if you have ever had an allergic reaction to LAMIVUDINE/ZIDOVUDINE VIATRIS 150/300 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 <u>2. What should I</u> know before I take LAMIVUDINE/ZIDOVUDINE VIATRIS <u>150/300?</u> in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with LAMIVUDINE/ ZIDOVUDINE VIATRIS 150/300 and affect how it works.

A list of these medicines is in Section <u>3. What if I am</u> <u>taking other medicines?</u> in the full CMI.

4. How do I take LAMIVUDINE/ ZIDOVUDINE VIATRIS 150/300?

- The usual dosage of LAMIVUDINE/ZIDOVUDINE VIATRIS 150/300 is one tablet twice a day.
- Swallow the tablet whole with a full glass of water.

More instructions can be found in Section <u>4. How do I</u> <u>take LAMIVUDINE/ZIDOVUDINE VIATRIS 150/300?</u> in the full CMI.

5. What should I know while taking LAMIVUDINE/ZIDOVUDINE VIATRIS 150/300?

Things you should do	 Remind any doctor, dentist or pharmacist that you are taking LAMIVUDINE/ ZIDOVUDINE VIATRIS 150/300. For as long as you are taking LAMIVUDINE/ ZIDOVUDINE VIATRIS 150/300, your doctor will arrange for you to have regular blood tests to check for side effects.
Things you should not do	 Do not stop taking this medicine suddenly or change the dose without talking to your doctor. Do not take this medicine to treat any other complaints.

	 Do not give this medicine to children under the age of 12.
Driving or using machines	 Be careful before you drive or use any machines or tools until you know how LAMIVUDINE/ ZIDOVUDINE VIATRIS 150/300 affects you. LAMIVUDINE/ ZIDOVUDINE VIATRIS 150/300 may cause headaches and tiredness in some people.
Looking after your medicine	 Store LAMIVUDINE/ ZIDOVUDINE VIATRIS 150/300 in a cool dry place below 30°C. Keep this medicine in the bottle until it is time to take it.

For more information, see Section <u>5. What should I</u> know while taking LAMIVUDINE/ZIDOVUDINE VIATRIS <u>150/300?</u> in the full CMI.

6. Are there any side effects?

Less serious side effects: flu-like symptoms, cough, sore throat, chills, feeling faint, skin disorders, constipation, blood in stool, severe headaches, loss of appetite, loss of mental clarity, depression, vision problems, muscle aches, difficulty in swallowing, hair loss. More serious side effects: reduced red or white blood cell count, severe stomach pain, nausea, vomiting, becoming unwell with fast breathing or swelling of lips/ tongue, wheezing and difficulty breathing. This is not a complete list of side effects.

For more information, including what to do if you have any side effects, see Section <u>6. Are there any side</u> <u>effects?</u> in the full CMI.

LAMIVUDINE/ZIDOVUDINE VIATRIS 150/300

Active ingredients: lamivudine and zidovudine

Consumer Medicine Information (CMI)

This leaflet provides important information about using LAMIVUDINE/ZIDOVUDINE VIATRIS 150/300. You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using LAMIVUDINE/ZIDOVUDINE VIATRIS 150/300.

Where to find information in this leaflet:

1. Why am I taking LAMIVUDINE/ZIDOVUDINE VIATRIS 150/300?

2. What should I know before I take LAMIVUDINE/ ZIDOVUDINE VIATRIS 150/300?

3. What if I am taking other medicines?

4. How do I take LAMIVUDINE/ZIDOVUDINE VIATRIS 150/300?

5. What should I know while taking LAMIVUDINE/ ZIDOVUDINE VIATRIS 150/300?

6. Are there any side effects?

7. Product details

1. Why am I taking LAMIVUDINE/ ZIDOVUDINE VIATRIS 150/300?

LAMIVUDINE/ZIDOVUDINE VIATRIS 150/300 contains the active ingredients lamivudine and zidovudine.

LAMIVUDINE/ZIDOVUDINE VIATRIS 150/300 belongs to a group of medicines known as antiretrovirals.

LAMIVUDINE/ZIDOVUDINE VIATRIS 150/300 is used alone or in combination 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 (ARC)).

LAMIVUDINE/ZIDOVUDINE VIATRIS 150/300 does not cure AIDS or HIV infection, however it slows down production of HIV in the body. In this way it stops ongoing damage to the body's immune system which fights infection.

You can still pass on HIV when taking this medicine through sexual activity or through passing on blood or bodily secretions which carry the HIV virus, although the risk is lowered by taking antiretroviral therapy.

You should take proper precautions to prevent this from occurring. 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, 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/zidovudine combination tablets are not known.

Please note that lamivudine is available as a stand-alone tablet (as LAMIVUDINE VIATRIS 150/300 lamivudine 150mg and 30mg tablets).

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.

2. What should I know before I take LAMIVUDINE/ZIDOVUDINE VIATRIS 150/300?

Warnings

Do not take LAMIVUDINE/ZIDOVUDINE VIATRIS 150/300 if you:

- are allergic to lamivudine, 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")
- fainting

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

- have kidney or liver disease
- have a reduced red blood cell count (anaemia) or white blood cell count (neutropenia)
- are pregnant, trying to become pregnant or breastfeeding.

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.

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

Check with your doctor if you:

- have any other medical conditions
- have or have had hepatitis B or liver problems

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/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.

- have taken or take any medicines for any other condition
- are allergic to any other foods, dyes, preservatives or any other medicines

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 <u>6. Are there any side effects</u>?

Pregnancy and breastfeeding

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

Check with your doctor if you are pregnant or intend to become pregnant.

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

Your doctor can discuss with you the benefits and risks of taking LAMIVUDINE/ZIDOVUDINE VIATRIS 150/300 whilst pregnant or breastfeeding.

Symptoms of infection and inflammation

People with advanced HIV infection (AIDS) have weak immune systems and are more likely to develop serious infections (opportunistic infections). When they start treatment, the immune system becomes stronger and so the body starts to fight infections. Symptoms of infection and inflammation may develop, caused by either:

- old, hidden infections flaring up as the body fights them
- the immune system attacking healthy body tissue (autoimmune disorders)

The symptoms of autoimmune disorders may develop many months after you start taking medications to treat your HIV infection.

Symptoms may include:

- muscle weakness and/or muscle pain
- joint pain or swelling
- weakness beginning in the hands or feet and moving towards the trunk of the body
- palpitations or tremor
- hyperactivity (excessive restlessness and movement)

If you get symptoms of infection or if you notice any of the symptoms above, tell your doctor immediately.

Do not take other medicines for the infection without your doctor's advice.

Children or adolescents

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

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 LAMIVUDINE/ ZIDOVUDINE VIATRIS 150/300 and affect how it works.

If you take ribavirin (e.g. Ibavyr) and LAMIVUDINE/ ZIDOVUDINE VIATRIS 150/300 together it may cause or worsen anaemia (low red blood cells). Tell 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 how 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 or pharmacist if you are taking any of the medicines below:

• paracetamol, a medicine used to treat pain

- other medicines used to treat pain such as aspirin, codeine, morphine, methadone, indometacin, ketoprofen, naproxen
- ribavirin
- medicines used in epilepsy including phenytoin
- medicines used to treat anxiety and insomnia including oxazepam, lorazepam
- rifampicin, a medicine used to treat tuberculosis
- cimetidine, a medicine used to treat heartburn, stomach ulcers
- clofibrate, a medicine used to treat high cholesterol, high triglycerides
- probenecid, a medicine used in the treatment of gout
- antimicrobial medicines such as pentamidine, atovaquone
- medicines used to treat parasite infections including pyrimethamine, dapsone
- medicines used to treat fungal infections, amphotericin B, flucytosine
- other antiviral medicines such as aciclovir, ganciclovir, interferon, inosine pranobex, stavudine, zalcitabine, emtricitabine
- antibacterial medicines, clarithromycin, sulfamethoxazole, trimethoprim and ciprofloxacin
- medicines used in the treatment of cancer including adriamycin, vincristine, vinblastine and doxorubicin
- sorbitol-containing medicines (usually liquids) which are used regularly

LAMIVUDINE/ZIDOVUDINE VIATRIS 150/300 should not be taken with stavudine or zalcitabine.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect LAMIVUDINE/ ZIDOVUDINE VIATRIS 150/300.

4. How do I take LAMIVUDINE/ ZIDOVUDINE VIATRIS 150/300?

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.

When to take LAMIVUDINE/ZIDOVUDINE VIATRIS 150/300

• Your doctor or pharmacist will tell you when to take LAMIVUDINE/ZIDOVUDINE VIATRIS 150/300 each day.

How to take LAMIVUDINE/ZIDOVUDINE VIATRIS 150/300

- Swallow the tablet whole with a full glass of water.
- Do not halve the tablet.

How long to take LAMIVUDINE/ZIDOVUDINE VIATRIS 150/300

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 LAMIVUDINE/ZIDOVUDINE VIATRIS 150/300

LAMIVUDINE/ZIDOVUDINE VIATRIS 150/300 should be taken regularly at the same time each day.

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 you medicine as you would normally.

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

If you take too much LAMIVUDINE/ZIDOVUDINE VIATRIS 150/300

If you think that you or anyone else have taken too much LAMIVUDINE/ZIDOVUDINE VIATRIS 150/300, 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.

Keep telephone number for these places handy.

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

5. What should I know while taking LAMIVUDINE/ZIDOVUDINE VIATRIS 150/300?

Things you should do

Ensure you have blood tests when you are meant to. It is important that your doctor monitors your health and checks the levels of red and white blood cells. If you develop anaemia or neutropenia your doctor may reduce your dose or stop LAMIVUDINE/ZIDOVUDINE VIATRIS 150/300.

Call your doctor straight away if you:

- become pregnant or intend to become pregnant
- have not been taking LAMIVUDINE/ZIDOVUDINE VIATRIS 150/300 as intended

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.

Remind any doctor, dentist or pharmacist you visit that you are taking LAMIVUDINE/ZIDOVUDINE VIATRIS 150/300.

This is especially important for any medicines that might have an effect on your liver, kidneys, red or white blood cells or other cells in the body.

Things you should not do

- Do not stop taking his medicine or change the dosage without checking with your doctor first.
- Do not give this medicine to anyone else, even if their symptoms seem similar to yours or have the same condition as you.
- Do not take this medicine to treat any other complaints unless your doctor tells you do.
- Do not give this medicine to children under the age of 12.

 Do not take this medicine if the packaging is torn or shows signs of tampering.

Stay in regular contact with your doctor

LAMIVUDINE/ZIDOVUDINE VIATRIS 150/300 helps to control your condition, but it is not a cure for HIV infection. You need to keep taking it every day to stop your illness from getting worse. Because LAMIVUDINE/ ZIDOVUDINE VIATRIS 150/300 does not cure HIV infections, you may still develop other infections and illnesses linked to HIV.

Driving or using machines

Be careful before you drive or use any machines or tools 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.

LAMIVUDINE/ZIDOVUDINE VIATRIS 150/300 may cause headaches or tiredness in some people.

Looking after your medicine

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

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

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

6. Are there any 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 the problems are not connected with the medicine or are not listed in this leaflet.

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. 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 new symptoms, or any changes in your health after starting HIV treatment, discuss with your doctor immediately.

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.

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 this list of possible side effects. You may not experience any of them.

Less serious side effects

Less serious side effects	What to do
Psychiatric disorders:	Speak to your doctor if
 confusion, depression, nervousness, loss of mental clarity 	you have any of these less serious side effects and they worry you.
Nervous system disorders:	
 dizziness, seizures, severe headaches 	
 unusual feelings in any part of the body such as numbness, burning, tingling, or pins and needles 	
 vision problems, sensitivity to light 	
 hearing loss 	
Gastrointestinal disorders:	
 constipation, gas from the stomach or bowel, blood in the stool, diarrhoea, abdominal discomfort and pain vomiting or nausea 	

Less serious side effects	What to do
 difficulty in swallowing, mouth ulcers bleeding gums heartburn 	
Skin disorders:	
 acne, itchiness, skin rash, changes in nail, skin or mouth colour 	
Metabolic disorders:	
 weight loss, loss of appetite 	
Respiratory disorders:	
 cough, sore throat, hay fever, sinus problems, hoarseness, changes to perception of taste 	
Blood system disorders:	
 widening of blood vessels leading to low blood pressure and feeling faint, fainting increased bruising or bleeding blood chemistry changes, with excess acidity of blood 	

Less serious side effects	Wh
 reduction in all blood cells 	
Musculoskeletal disorders:	
 muscle aches or pains, muscle shaking or spasm or twitching, muscle disease 	
Urinary disorders:	
 passing too much urine pain, difficulty or increased frequency of urination 	
General disorders:	
 generally feeling unwell flu-like symptoms, fever, sweating, chills weakness, 	
sleeplessness, fatigue or tiredness	
 increased sensitivity to pain, back pain, enlarged glands, chest pain 	
Side effects that may show up in blood tests:	

Less serious side effects	What to do
 abnormal results of liver function blood tests, enlarged fatty liver 	
Other:	
 body odour 	
 hair loss 	
 swelling of the lips/ 	
tongue	
 breast enlargement in men 	

Serious side effects

Serious side effects	What to do
 Blood system disorders: 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 	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.

Serious side effects	What to do
150/300 in the later stages of HIV disease.	
Allergic reactions:	
 swelling of the lips, tongue, wheezing or difficulty breathing, lumpy rash (hives), fainting. 	
Pancreatitis:	
 signs of an inflamed pancreas (pancreatitis) such as severe stomach pain or cramps, nausea, vomiting. If you experience any of these symptoms soon after starting treatment 	
stop taking this medicine and contact your doctor immediately.	
Change in body shape:	
Treatment with LAMIVUDINE/ ZIDOVUDINE VIATRIS 150/300 may cause a loss of fat from the legs, arms and face (lipoatrophy), or an increased fat appearing	

Serious side effects	What to do
in areas such as abdomen (belly) and other internal organs, breasts and back of the neck. If this occurs tell your doctor and they will assess if you should stop taking LAMIVUDINE/ ZIDOVUDINE VIATRIS 150/300 and your HIV treatment to be changed. If you stop taking LAMIVUDINE/ ZIDOVUDINE VIATRIS 150/300 it may take several months to see any lost fat return and you might not regain it all.	
Lactic acidosis:	
If you are taking medication for HIV and become unwell with fast breathing, stop taking LAMIVUDINE/ ZIDOVUDINE VIATRIS 150/300 and talk to your doctor immediately. This might be a condition known as 'lactic acidosis'. The fast breathing is due to high acid levels in the	

Serious side effects	What to do
blood. Your liver may not	
be working properly and	
gets big and fatty which	
can be life threatening.	
This illness occurs more	
often in women than men.	

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

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

Other side effects not listed here may occur in some people.

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.

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 <u>www.tga.gov.au/reporting-problems</u>.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.

LAMIVUDINE/ZIDOVUDINE VIATRIS 150/300 is not addictive.

What LAMIVUDINE/ZIDOVUDINE VIATRIS 150/300 contains

Active ingredient	Lamivudine 150 mg and
(main ingredient)	Zidovudine 300 mg per tablet
Other ingredients	Magnesium stearate
(inactive ingredients)	Microcrystalline cellulose
	Sodium starch glycollate type A
	Colloidal anhydrous silica
	Propylene glycol (film coating)

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

What LAMIVUDINE/ZIDOVUDINE VIATRIS 150/300 looks like

LAMIVUDINE/ZIDOVUDINE VIATRIS 150/300 are white to off-white, capsule shaped, bi-convex film-coated tablets, debossed with "M" on left of the scoreline and "103" on right, on one side and scored on the other side. (AUST R 167477).

Each bottle contains 60 tablets.

Who distributes LAMIVUDINE/ZIDOVUDINE VIATRIS 150/300

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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