

# LAMIVUDINE VIATRIS

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## Consumer Medicine Information (CMI) summary

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

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### 1. Why am I taking LAMIVUDINE VIATRIS?

LAMIVUDINE VIATRIS contains the lamivudine. LAMIVUDINE VIATRIS are used to slow down the progression of human

immunodeficiency virus (HIV) infection.

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

### 2. What should I know before I take LAMIVUDINE VIATRIS?

Do not take LAMIVUDINE VIATRIS 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 health problems, take any other medicines, are pregnant or breastfeeding, or plan to become pregnant or breastfeed.**

For more information, see Section [2. What should I know before I take LAMIVUDINE VIATRIS?](#) in the full CMI.

### 3. What if I am taking other medicines?

Some medicines may interfere with LAMIVUDINE VIATRIS 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 LAMIVUDINE VIATRIS?

- The usual dosage of LAMIVUDINE VIATRIS is one 150 mg tablet twice a day or 300 mg once a day. For younger children between 3 months to 12 years of age the dose of LAMIVUDINE VIATRIS will depend on their weight in kilograms (kg).
- Swallow the tablet whole with a glass of water.
- Your doctor may prescribe a different dosage or provide additional instructions.

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

### 5. What should I know while taking LAMIVUDINE VIATRIS?

<b>Things you must do</b>	<ul style="list-style-type: none"><li>• Tell your doctor, dentist or pharmacist you visit that you are taking LAMIVUDINE VIATRIS.</li></ul>
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	<ul style="list-style-type: none"> <li>• Tell your doctor if you become pregnant or are trying to become pregnant.</li> <li>• Tell your doctor if, for any reason, you have not taken your medicine as prescribed.</li> </ul>
<b>Things you must not do</b>	<ul style="list-style-type: none"> <li>• Do not stop taking LAMIVUDINE VIATRIS suddenly or change the dose without talking to your doctor.</li> <li>• Do not give LAMIVUDINE VIATRIS to anyone else.</li> <li>• Do not take LAMIVUDINE VIATRIS to treat any other complaints.</li> </ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"> <li>• Be careful driving or operating machinery until you know how LAMIVUDINE VIATRIS affect you.</li> </ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"> <li>• Store in a cool, dry place below 30°C. Keep the tablets where children cannot reach them. Do not store the tablets,</li> </ul>

	or any other medicine in a bathroom, near a sink, in the car or on window sills. Keep LAMIVUDINE VIATRIS in the bottle with the cap tightly closed until you take them.
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For more information, see Section [5. What should I know while taking LAMIVUDINE VIATRIS?](#) in the full CMI.

## **6. Are there any side effects?**

Common side effects that have been reported include nausea, vomiting, diarrhoea, upper abdominal pain, headache, high temperature, lethargy, fatigue, hair loss, joint and muscle pain, skin rash and increased bruising or bleeding. Serious side effects include lumpy skin rash or "hives", swelling of the face, lips, mouth, or throat, wheezing, chest pain or tightness, and fainting, which may indicate an allergic reaction. Severe stomach pain or cramps, nausea or vomiting may indicate pancreatitis.

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.

# LAMIVUDINE VIATRIS

Active ingredient(s): *lamivudine*

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## Consumer Medicine Information (CMI)

This leaflet provides important information about taking LAMIVUDINE VIATRIS. **Speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about taking LAMIVUDINE VIATRIS.**

**Where to find information in this leaflet:**

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

## 1. Why am I taking LAMIVUDINE VIATRIS?

LAMIVUDINE VIATRIS contain the active ingredient lamivudine.

Lamivudine belongs to a group of medicines called antivirals.

**LAMIVUDINE VIATRIS are used together with other antivirals to slow down the progression of human immunodeficiency virus (HIV), which can lead to Acquired Immune Deficiency Syndrome (AIDS) and other related illnesses (e.g. AIDS-related Complex or ARC).**

LAMIVUDINE VIATRIS do not cure AIDS or kill the HIV virus but prevents further damage to the immune system by stopping production of new viruses.

Your doctor may have prescribed LAMIVUDINE VIATRIS for another reason.

Ask your doctor if you have any questions about why LAMIVUDINE VIATRIS tablets have been prescribed for you.

## **2. What should I know before I take LAMIVUDINE VIATRIS?**

### **Warnings**

#### **Do not take LAMIVUDINE VIATRIS if:**

- you are allergic to lamivudine, or any of the ingredients listed at the end of this leaflet.  
Always check the ingredients to make sure you can take LAMIVUDINE VIATRIS.

- the expiry date printed on the pack has passed as the tablets may not work as well.
- the packaging is torn or shows signs of tampering.

### **Check with your doctor if you:**

- are allergic to foods, dyes, preservatives, or any other medicines.
- you have, or have ever had, liver problems, for example jaundice, hepatitis, virus affecting the liver, enlarged liver or liver scarring (cirrhosis) or if you have any risk factors for liver problems, e.g. excessive alcohol intake, illegal intravenous drug use with shared equipment, iron or copper storage disorders.
- you have, or have ever had, kidney problems.
- you have, or have ever had, problems with your pancreas.
- you have diabetes.
- you have any other illness, including those that you think are not related to HIV infection.

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**

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

Tell your doctor if you are breastfeeding or plan to breastfeed.

Your doctor will discuss the risks and benefits of using LAMIVUDINE VIATRIS if you are pregnant or breastfeeding.

## **If you stop taking LAMIVUDINE VIATRIS**

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 VIATRIS, your doctor is likely to arrange tests from time to time to check how well your liver is working and to measure virus levels.

**LAMIVUDINE VIATRIS are not addictive.**

### **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 VIATRIS. This may affect how they work and/or cause more side effects.**

**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 VIATRIS.**



## **4. How do I take LAMIVUDINE VIATRIS?**

### **How much and when to take LAMIVUDINE VIATRIS**

- The usual dosage of LAMIVUDINE VIATRIS in adults and adolescents 12 years and older is one 150 mg tablet twice a day or 300 mg once a day. Your doctor may prescribe a different dosage.
- For younger children between 3 months to 12 years of age the dose of LAMIVUDINE VIATRIS will depend on their weight in kilograms (kg). If you are giving LAMIVUDINE VIATRIS to a child, follow your doctor's instructions.
- Follow the instructions provided and use LAMIVUDINE VIATRIS until your doctor tells you to stop.

### **How to take LAMIVUDINE VIATRIS**

- Tablets should be swallowed whole with a glass of water.
- If you cannot swallow the tablet(s), you may crush and combine them with a small amount of food or drink and take all of the dose immediately.

### **How long to take LAMIVUDINE VIATRIS**

- LAMIVUDINE VIATRIS 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 VIATRIS**

LAMIVUDINE VIATRIS should be used regularly at the same time each day. If you miss your dose at the usual time, take it as soon as you remember, then go back to taking it as you would normally.

**If 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 many LAMIVUDINE VIATRIS**

If you think that you or anyone else has taken too many LAMIVUDINE VIATRIS, urgent medical attention may be needed.

**You must immediately:**

- phone the Poisons Information Centre **(by calling 13 11 26)** for advice, or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

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

## **5. What should I know while taking LAMIVUDINE VIATRIS?**

### **Things you must do**

- **Tell your doctor if, for any reason, you have not taken your medicine exactly as prescribed.**

Otherwise, your doctor may think it was not effective and change your treatment unnecessarily.

- **Use proper precautions to prevent passing on HIV virus.**

You can still pass on the virus when taking LAMIVUDINE VIATRIS, by sexual activity or by contamination with infected blood, although the risk is lowered by effective antiretroviral therapy. Discuss with your doctor the precautions needed to avoid infecting other people.

- **Keep in regular contact with your doctor.**

While taking LAMIVUDINE VIATRIS and/or any other therapy for HIV disease, you may continue to develop other infections and other complications of HIV infection.

### **Call your doctor straight away if you:**

- Become pregnant or are trying to become pregnant.
- Generally feel 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 VIATRIS tablets.

- Have any problems while taking LAMIVUDINE VIATRIS, even if you do not think the problems relate to LAMIVUDINE VIATRIS or are not listed in this leaflet.

Tell your doctor, dentist or pharmacist you visit that you are taking LAMIVUDINE VIATRIS.

## **Things you must not do**

- Do not stop taking LAMIVUDINE VIATRIS suddenly or change the dose without first checking with your doctor.
- Do not give LAMIVUDINE VIATRIS to anyone else, even if their symptoms seem similar to yours.
- Do not take LAMIVUDINE VIATRIS to treat any other complaints unless your doctor says to.

## **Driving or using machines**

**Be careful before you drive or use any machines or tools until you know how LAMIVUDINE VIATRIS affects you.**

LAMIVUDINE VIATRIS may cause lethargy or fatigue in some people.

## **Drinking alcohol**

**Tell your doctor if you drink alcohol.**

## **Looking after your medicine**

- Keep LAMIVUDINE VIATRIS in the bottle with the cap tightly closed until you take them.
- If you take LAMIVUDINE VIATRIS out of their pack, they may not keep well.
- Heat and dampness can destroy some medicines.

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

Store it in a cool dry place where it stays below 30°C, 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.

**Keep it where young children cannot see or reach it.**

A locked cupboard at least one-and-a-half meters above the ground is a good place to store medicines.

## **When to dispose of your medicine**

- If you no longer need to take it
- After the expiry date

## **Getting rid of any unwanted medicine**

Take it to any pharmacy for safe disposal.

## 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.

### Less serious side effects

Less serious side effects	What to do
<b>Gastrointestinal:</b> <ul style="list-style-type: none"><li>• Nausea</li><li>• Vomiting</li><li>• Diarrhoea</li><li>• Upper abdominal pain</li></ul> <b>Musculoskeletal and connective tissue:</b> <ul style="list-style-type: none"><li>• Joint and muscle pain</li><li>• Breakdown of muscle tissue</li></ul> <b>Nervous system:</b> <ul style="list-style-type: none"><li>• Headache</li><li>• High temperature</li></ul>	<b>Speak to your doctor if you have any of these less serious side effects.</b>  <b>Should any change in body shape be noticed, seek medical advice.</b>

Less serious side effects	What to do
<ul style="list-style-type: none"> <li>• Numbness or weakness of the arms and legs</li> <li>• Unusual feelings in any part of the body, such as numbness, burning, tingling or pins and needles</li> </ul> <p><b>Skin and subcutaneous tissue:</b></p> <ul style="list-style-type: none"> <li>• Skin rash (without any other illness)</li> <li>• Increased bruising or bleeding</li> </ul> <p><b>General:</b></p> <ul style="list-style-type: none"> <li>• Lethargy</li> <li>• Fatigue</li> <li>• Hair loss</li> <li>• Fat loss or weight gain has been observed with combined antiretroviral therapy. Changes in fat distribution have been reported in association with combination antiretroviral therapy. A causal relationship for this has not yet been established.</li> </ul>	

Less serious side effects	What to do
<p><b>Hepatobiliary:</b></p> <ul style="list-style-type: none"> <li>• Increases in enzymes produced by the liver</li> </ul> <p><b>Blood and lymphatic system:</b></p> <ul style="list-style-type: none"> <li>• Anaemia or severe anaemia (low red blood cell count). If the production of red blood cells is reduced, you may have symptoms of tiredness or breathlessness.</li> <li>• Neutropenia (low white blood cell count). A reduction in your white blood cell count can make you more prone to infection.</li> <li>• Reduction in the number of platelets (blood cells important for blood clotting). If you have a low platelet count, you may notice that you bruise more easily.</li> <li>• Other effects that may show up in blood tests include increased blood</li> </ul>	



<b>Less serious side effects</b>	<b>What to do</b>
<p>levels of sugar, fatty acids (triglycerides) and cholesterol.</p> <p><b>Digestive and endocrine:</b></p> <ul style="list-style-type: none"> <li>• Increases of an enzyme called amylase</li> <li>• Inflammation of the pancreas (pancreatitis)</li> </ul> <p><b>Metabolic:</b></p> <ul style="list-style-type: none"> <li>• Lactic acidosis</li> </ul>	

## **Serious side effects**

<b>Serious side effects</b>	<b>What to do</b>
<p><b>Immune system:</b></p> <ul style="list-style-type: none"> <li>• 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 and high temperature) which may resemble</li> </ul>	<p><b>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.</b></p>

<b>Serious side effects</b>	<b>What to do</b>
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.	

## **Very Serious side effects**

<b>Very Serious side effects</b>	<b>What to do</b>
<p><b>Allergic reaction:</b></p> <ul style="list-style-type: none"> <li>• Skin troubles such as lumpy skin rash or "hives"</li> <li>• Swelling of the face, lips, mouth, or throat which may cause difficulty in swallowing or breathing</li> <li>• Wheezing, chest pain or tightness</li> <li>• Fainting</li> </ul> <p><b>Pancreatitis:</b></p> <ul style="list-style-type: none"> <li>• Severe stomach pain or cramps</li> <li>• Nausea</li> <li>• Vomiting</li> </ul>	<p><b>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these very serious side effects.</b></p> <p><b>Do not take any more LAMIVUDINE VIATRIS.</b></p> <p><b>All these side effects are very rare.</b></p>

Very Serious side effects	What to do
<p><b>Lactic acidosis:</b></p> <ul style="list-style-type: none"> <li>• If you become very sick, with fast breathing you may have lactic acidosis. The fast breathing is due to high acid levels in the blood.</li> <li>• Your liver may not be working properly and may become large and fatty.</li> <li>• This illness occurs more often in women than men.</li> </ul>	

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

Some people may have side effects that are not listed here.

## **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](http://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**

LAMIVUDINE VIATRIS is only available with a doctor's prescription.

### **What LAMIVUDINE VIATRIS contains**

<b>Active ingredient (main ingredient)</b>	lamivudine
<b>Other ingredients (inactive ingredients)</b>	Microcrystalline cellulose Sodium starch glycollate Type A Magnesium stearate Propylene glycol Opadry Complete Film Coating System 03H58736 White (ID 106640).

**Do not take LAMIVUDINE VIATRIS if you are allergic to any of these ingredients.**

## **What LAMIVUDINE VIATRIS looks like**

LAMIVUDINE VIATRIS 150 mg is a white to off-white film-coated, capsule shaped, biconvex tablet debossed with "M105" on one side of the tablet and a score line on the other side. (AUST R 167591).

LAMIVUDINE VIATRIS 300 mg is a white to off-white, film-coated, oval shaped, biconvex tablet debossed with "M300" on one side of the tablet and blank on the other side. (AUST R 167594).

LAMIVUDINE VIATRIS 150 mg is available in bottles of 60 tablets.

LAMIVUDINE VIATRIS 300 mg is available in bottles of 30 tablets.

## **Who distributes LAMIVUDINE VIATRIS**

Alphapharm Pty Ltd trading as Viatris

Level 1, 30 The Bond

30-34 Hickson Road

Millers Point NSW 2000

[www.viatris.com.au](http://www.viatris.com.au)

Phone: 1800 274 276

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