

LAMIVUDINE RBX

Lamivudine Tablets

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about LAMIVUDINE RBX. It does not contain all of the available information.

It does not take the place of talking to your doctor or pharmacist.

This leaflet was last updated on the date at the end of this leaflet. More recent information may be available. The latest Consumer Medicine Information is available from <https://www.ebs.tga.gov.au/> and may contain important information about the medicine and its use of which you should be aware.

All medicines have benefits and risks. Your doctor has weighed the risks of you taking LAMIVUDINE RBX against the benefits it is expected to 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 RBX is used for

LAMIVUDINE RBX contains the medicine lamivudine which belongs to a group of medicines called antivirals.

LAMIVUDINE RBX is used together with other antivirals to slow down the progression of human immunodeficiency virus (HIV) infection, which can lead to Acquired Immune Deficiency Syndrome (AIDS) and other related illnesses (eg AIDS-related Complex or ARC).

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

LAMIVUDINE RBX does not reduce the risk of passing the infection to others. You will still be able to pass on the HIV virus by sexual activity or by contamination with infected blood. You should still use proper precautions.

While taking LAMIVUDINE RBX 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 who is looking after you.

LAMIVUDINE RBX tablets are not addictive.

Your doctor may have prescribed LAMIVUDINE RBX for another reason.

Ask your doctor if you have any questions about why LAMIVUDINE RBX has been prescribed for you.

Before you take LAMIVUDINE RBX

When you must not take it

- **Do not take LAMIVUDINE RBX if you have ever had an allergic reaction to lamivudine or 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 in breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin.
- **Do not take LAMIVUDINE RBX if you are pregnant, trying to become pregnant or breast-feeding, unless your doctor says you should.** Your doctor will discuss the risks and benefits of using LAMIVUDINE RBX if you are pregnant or breast-feeding.
- **Do not use LAMIVUDINE RBX to treat any other conditions unless your doctor tells you to.**
- **Do not give LAMIVUDINE RBX tablets to anyone else, even though their symptoms may sound similar to yours.**
- **Do not take LAMIVUDINE RBX after the expiry date (EXP) 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're not sure whether you should be taking LAMIVUDINE RBX, talk to your doctor.**

Before you start to take it

You must tell 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, problems with your kidney or pancreas.
- you have diabetes.
- you have any other illness, including those that you think are not related to HIV infection.

When you stop taking LAMIVUDINE RBX

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 RBX, 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 if you are taking any other medicines, including medicines you buy without a prescription from a pharmacy, supermarket or health food shop.

Some medicines may affect the way others work. Your doctor or pharmacist will be able to tell you what to do when taking LAMIVUDINE RBX with other medicines.

Lamivudine is not recommended to be used in combination with zalcitabine (used for the treatment of HIV infection).

HOW to take LAMIVUDINE RBX

Your doctor will tell you how many LAMIVUDINE RBX tablets to take and how often to take them. **Do not take extra tablets or take the tablets more often than you have been told.**

How much to take

For adults and adolescents 12 years and older, the usual dose 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 RBX will depend on their weight in kilograms (kg). If you are giving LAMIVUDINE RBX to a child, follow your doctor's instructions.

How to take it

LAMIVUDINE RBX 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 the entire dose immediately.

How long to take it

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 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, then go back to taking it as you would normally.

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

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26), or go to the Emergency Department at your nearest hospital, if you think that you or anyone else may have taken too much LAMIVUDINE RBX. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention. Keep telephone numbers for these places handy.

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

While you are taking LAMIVUDINE RBX

Things you must do

Tell your doctor or pharmacist that you are taking LAMIVUDINE RBX if you are about to be started on any other medicines.

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 RBX, or change the dose without first checking with your doctor.

Do not give this medicine to anyone else, even if their symptoms seem similar to yours.

Do not use LAMIVUDINE RBX to treat any other complaints unless your doctor says to.

Things to be careful of

Be careful driving or operating machinery until you know how LAMIVUDINE RBX affects you.

Side Effects

Tell your doctor as soon as possible if you don't feel well while taking LAMIVUDINE RBX, even if the problems do not seem to be related to the medicine or are not listed in this leaflet.

Like all medicines, LAMIVUDINE RBX 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.

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

- Headache
- Diarrhoea
- Fatigue/tiredness
- Abdominal discomfort and pain
- Rash
- Fever
- Unusual feelings in any part of the body, such as numbness, burning, tingling or pins and needles
- Increased bruising or bleeding
- Joint or muscle pain

Changes in fat distribution have been reported in association with combination antiretroviral therapy, and may result in:

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

Ask your doctor or pharmacist to answer any questions you may have.

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

- Lumps, rash or "hives" on your skin
- Swelling of the face, lips, mouth or throat which may cause difficulty in swallowing or breathing
- Wheezing, chest pain or tightness
- Fainting

These are very serious side effects. If you have them, you may have a serious allergic reaction. You may need urgent medical attention or hospitalisation. These side effects are very rare.

If you have any of the following symptoms soon after starting to take LAMIVUDINE RBX, DO NOT TAKE ANY MORE LAMIVUDINE RBX and tell your doctor IMMEDIATELY or go to the 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 RBX 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 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 RBX.

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

Some people may get other side effects while taking LAMIVUDINE RBX. If you are concerned, talk to your doctor or pharmacist.

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 taking LAMIVUDINE RBX

Storage

Keep the tablets where children cannot reach them. A locked cupboard at least one-and-a-half metres above the ground is a good place to store them.

Keep LAMIVUDINE RBX in a cool, dry place where it stays below 25°Celsius. Do not store the tablets, or any other medicine, in a bathroom or near a sink. Do not leave them in the car or on window sills. Heat and dampness can destroy some medicines.

Keep your LAMIVUDINE RBX tablets in the bottle with the cap tightly closed until you take them. If you take LAMIVUDINE RBX out of their pack they may not keep well.

Disposal

If your doctor tells you to stop taking LAMIVUDINE RBX, or the tablets have passed their expiry date, ask your pharmacist what to do with any tablets left over.

Product description

What LAMIVUDINE RBX looks like

LAMIVUDINE RBX 150 mg tablets are white, film-coated, modified diamond-shaped tablets, debossed with "RF & 96" on either side of the breakline on one side and a breakline on the other side. Available in bottles of 60 tablets.

LAMIVUDINE RBX 300 mg tablets are grey, film-coated, modified diamond-shaped tablets, debossed with "RF97" on one side and plain on the other side. Available in bottles of 30 tablets.

Ingredients

Active ingredient

LAMIVUDINE RBX tablets contain either 150 mg or 300 mg of lamivudine per tablet.

Inactive ingredients

- Microcrystalline cellulose
- Sodium starch glycollate type A
- Magnesium stearate
- Hypromellose

- Titanium dioxide
- Macrogol PEG 400
- Polysorbate 80
- Black iron oxide (E172) (only 300 mg tablets).

LAMIVUDINE RBX tablets do not contain gluten, lactose or sugar.

Sponsor

Ranbaxy Australia Pty Ltd.
9-13 Waterloo Road
Macquarie Park NSW 2113

Australian Registration Numbers

- LAMIVUDINE RBX 150 mg
- AUST R 172813
- LAMIVUDINE RBX 300 mg
- AUST R 172817

This leaflet was prepared in October 2013.

Further Information

This is not all the information that is available on LAMIVUDINE RBX. If you have any more questions or are not sure about anything, ask your doctor or pharmacist. They are the best people to provide individual advice for you. You may also be able to find out more information about your disease from books, for example in public libraries. Counselling is also available from your local AIDS council.