

LAMYROX TABLET 150MG

Lamivudine (150mg)

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What Lamyrox Tablet 150mg is used for

Lamyrox Tablet 150mg is used with other antiretroviral medicines, to slow down the progression of Human Immunodeficiency Virus (HIV) infection in adults and children. HIV can lead to Acquired Immune Deficiency Syndrome (AIDS) and other related illnesses.

How Lamyrox Tablet 150mg works

Treatment with Lamyrox Tablet 150mg can hinder the growth of human immunodeficiency virus. In this way it stops ongoing damage to the body's immune system (which fights infection) by stopping production of new viruses.

Before you use Lamyrox Tablet 150mg

-When you must not use it

Do not take Lamyrox Tablet 150mg if you have an allergy to any medicine containing lamivudine or any of the other ingredient (listed at the end of the leaflet).

Do not take this medicine if you are pregnant or trying to become pregnant, without first talking to your doctor. 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 Lamyrox Tablet 150mg because:

- lamivudine may enter the breast milk and there is a possibility your baby may be affected
- there is a risk of passing the HIV infection to your baby.

Do not take this medicine after the expiry date printed on the pack or if the packaging is damaged 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 lower dose of Lamyrox Tablet 150mg.

If you are not sure whether you should start taking this medicine, talk to your doctor.

-Before you start to use it

Tell your doctor if you are allergic to foods, dyes, preservatives or any other medicines.

Tell your doctor if you have or have ever had any of the following medical conditions:-

- kidney problem
- liver problem
- hepatitis B infection
- inflammation of pancreas
- very low white blood cell count (neutropenia)

- very low blood cell count (anemia) or reduced haemoglobin levels.

If you have not told your doctor about any of the above, tell him/her before you start taking Lamyrox Tablet 150mg.

- 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.

Some medicines and Lamyrox Tablet 150mg may interfere with each other. These include:

- Emtricitabine, medicines used to prevent and treat HIV infection.

These medicines may be affected by Lamyrox Tablet 150mg 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 use Lamyrox Tablet 150mg

-How much to use

Lamivudine therapy should be initiated by a physician experienced in management of HIV infection

Lamyrox Tablet 150mg should be swallowed with a drink of water and it can be taken with or without food.

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- **Adults, adolescents and children weighing at least 25kg**

The recommended dose of lamivudine is 300mg daily. This may be administered as 150mg (1 x 150mg tablet) twice daily or 300mg (2 x 150mg tablet) once daily.

- **Elderly**

No specific data are available, however special care is advised in this age group due to age associated changes such as decrease in renal function and alteration of haematological parameters.

- **Renal impairment**

Lamivudine plasma concentrations (AUC) are increased in patients with moderate to severe renal impairment due to decreased clearance. The dosage should therefore be reduced for patients with a creatinine clearance of less than 50ml/min.

- **Hepatic impairment**

No dose adjustment is necessary in patients with moderate or severe hepatic impairment unless accompanied by renal impairment

-When to use it

Follow the direction label carefully and as instructed by your doctor or pharmacist.

-How long to use it

Follow the direction label carefully and as instructed by your doctor or pharmacist

-If you forget to use it

Take the missed dose as soon as you remember. 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 that you missed. This may increase the chance of you getting unwanted side effects.

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

-If you take too much (overdose)

Immediately call your doctor or go to the emergency department at your nearest hospital if you or anyone else has taken a large amount of this medication. Do this even if there are no signs of discomfort or poisoning. Take the bottle with you if you can. You may need urgent medical attention.

While you are using Lamyrox Tablet 150mg

-Things you must do

If you are about to be started on new medicine, remind your doctor or pharmacist that you are taking Lamyrox Tablet 150mg.

Tell any doctors, dentist, and pharmacist who treat you that you are taking this medicine.

If you are going to have a 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.

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 Lamyrox Tablet 150mg to treat any other complaints unless your doctor tells you to.

Do not give Lamyrox Tablet 150mg to anyone else, even if they have the same condition as you.

Do not stop taking Lamyrox Tablet 150mg or change the dosage without checking with your doctor.

-Things to be careful of

Be careful driving or operating machinery until you know how Lamyrox Tablet 150mg 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 Lamyrox Tablet 150mg.

It may be difficult to tell whether side effects are the result of taking Lamyrox Tablet 150mg, 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 Lamyrox Tablet 150mg.

All medicines can have side effects. If they occur, they are most likely to be minor and temporary. However, some may

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be serious and need medical attention.

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.

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.

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

- nausea, vomiting
- abdominal pain
- diarrhoea
- headache
- muscle or joint pain
- rash
- hair loss
- fatigue
- fever.

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
- signs of infection such as fever, chills, and/or influenza-like symptoms.

The above list includes serious side effects that may require medical attention. Some side effects can occur many months after you start to take Lamyrox Tablet 150mg.

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 hospitalization.

If you are taking medicines for HIV and become very sick, with fast breathing, stop taking Lamyrox Tablet 150mg and consult your doctor immediately. You may have 'lactic acidosis', a condition which results in high lactic 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.

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.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website npra.moh.gov.my (Public → Reporting Medicinal Problems / Side Effects / AEFT).

Storage and disposal of Lamyrox Tablet 150mg

-Storage

Keep your tablets in the container until it is time to take them. If you keep the tablets out of the container they may not keep well.

Keep out of the reach and sight of children.

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

Heat and dampness can destroy some medicines. Do not store the tablets in the bathroom or near a sink. Do not leave it on a window sill or in the car.

Do not use this medicine after the expiry date imprinted on the product packaging.

-Disposal

Medicines should not be disposed of via wastewater or household waste. 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. These measures will help to protect the environment.

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Product description

-What it looks like

White to off white, biconvex, oval shaped, film coated tablet with Pharmaniaga icon on one side and plain on the other.

Ingredients:

-Active ingredients:

Each film coated tablet contains Lamivudine 150mg.

-Inactive ingredients:

Microcrystalline cellulose PH102, Sodium Starch Glycolate, Colloidal Silicon Dioxide (Aerosil 200) and Magnesium Stearate and Opadry II White.

-MAL Number:

MALXXXXXXXXXX

Manufacturer:

Pharmaniaga Manufacturing Berhad (60016-D),
11A, Jalan P/1, Kawasan Perusahaan Bangi, 43650 Bandar Baru Bangi, Selangor Darul Ehsan, Malaysia.

Product Registration Holder:

Pharmaniaga Manufacturing Berhad (60016-D),
11A, Jalan P/1, Kawasan Perusahaan Bangi, 43650 Bandar Baru Bangi, Selangor Darul Ehsan, Malaysia.

Date of revision:

29/01/2018

Serial Number:

NPRA (Rx/x)xxxxxx/xxxxx