

LAMIVUDINE ALPHAPHARM

contains the active ingredient lamivudine

CONSUMER MEDICINE INFORMATION

What is in this leaflet

Please read this leaflet carefully before you start LAMIVUDINE ALPHAPHARM tablets.

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

It does not take the place of talking to your doctor or pharmacist (also known as a chemist).

All medicines have benefits and risks. Some new risks are found even when a medicine has been used for many years. Your doctor has weighed the risks of you taking LAMIVUDINE ALPHAPHARM tablets against the expected benefits expected for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the tablets.

You may need to read it again.

What LAMIVUDINE ALPHAPHARM tablets are used for

LAMIVUDINE ALPHAPHARM tablets contain lamivudine which belongs to a group of medicines called antivirals.

Lamivudine 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 (e.g. AIDS-related Complex or ARC).

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

You can still pass on HIV 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.

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 ALPHAPHARM tablets 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 ALPHAPHARM tablets are not addictive.

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

Before you take LAMIVUDINE ALPHAPHARM tablets

When you must not take them

- **Do not take LAMIVUDINE ALPHAPHARM tablets if you have ever had an allergic reaction to lamivudine or any of the ingredients listed at the end of this leaflet.**

Read the Side Effects section to find out symptoms of allergy.

- **Do not take LAMIVUDINE ALPHAPHARM tablets if you are pregnant, trying to become pregnant or breastfeeding, unless your doctor says you should.**

Your doctor will discuss the risks and benefits of using LAMIVUDINE ALPHAPHARM tablets if you are pregnant or breast feeding.

- **Do not use LAMIVUDINE ALPHAPHARM tablets to treat any other conditions unless your doctor says that you should do so.**
- **Do not give LAMIVUDINE ALPHAPHARM tablets to anyone else, even though their symptoms may sound similar to yours.**
- **Do not take LAMIVUDINE ALPHAPHARM tablets after the expiry or "use by" date (EXP) printed on the pack.**

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

- **Do not take LAMIVUDINE ALPHAPHARM tablets if the packaging is torn or shows signs of tampering.**

If you're not sure whether you should be taking LAMIVUDINE ALPHAPHARM tablets talk to your doctor.

Before you start to take them

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, 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.**

When you stop taking LAMIVUDINE ALPHAPHARM tablets

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 ALPHAPHARM tablets, 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 that 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 ALPHAPHARM tablets with other medicines.

How to take LAMIVUDINE ALPHAPHARM tablets

Your doctor will tell you how many LAMIVUDINE ALPHAPHARM tablets to take and how often to take them. You will also find this information on the label of your medicine.

Do not take extra tablets. Do not take the tablets more often than you have been told.

How much to take

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 ALPHAPHARM will depend on their weight in kilograms (kg). If you are giving LAMIVUDINE ALPHAPHARM tablets to a child, follow your doctor's instructions.

How to take them

LAMIVUDINE ALPHAPHARM 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 the dose immediately.

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 that 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 you or anyone else may have taken too many LAMIVUDINE ALPHAPHARM tablets. Do this even if there are no signs of discomfort or poisoning.

This 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 ALPHAPHARM tablets

Things you must do

Tell your doctor or pharmacist that you are taking LAMIVUDINE ALPHAPHARM tablets 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 ALPHAPHARM tablets 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 ALPHAPHARM tablets to treat any other complaints unless your doctor tells you to.

Things to be careful of

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

Side effects

Check with your doctor as soon as possible if you have any problems while taking LAMIVUDINE ALPHAPHARM tablets, even if you do not think the problems are connected with the medicine or are not listed in this leaflet.

Like all medicines, LAMIVUDINE ALPHAPHARM tablets 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.

The most common side-effects (could affect at least one to ten in every 100 people) are:

- nausea, vomiting
- diarrhoea
- upper abdominal pain
- headache
- high temperature

- lethargy, fatigue
- hair loss
- joint and muscle pain
- skin rash (without any other illness)
- increased bruising or bleeding.

Uncommon side-effects (could affect less than one in every 100 people) are:

- increases in enzymes produced by the liver
- anaemia (low red blood cell count)
- neutropenia (low white blood cell count)
- reduction in the number of platelets (blood cells important for blood clotting).

If the production of red blood cells is reduced, you may have symptoms of tiredness or breathlessness.

A reduction in your white blood cell count can make you more prone to infection.

If you have a low platelet count, you may notice that you bruise more easily.

Rare side-effects (could affect less than one in every 1,000 people) are:

- breakdown of muscle tissue
- increases of an enzyme called amylase
- inflammation of the pancreas (pancreatitis)
- lactic acidosis

Very rare side-effects (could affect less than one in every 10,000 people) are:

- unusual feelings in any part of the body, such as numbness, burning, tingling or pins and needles
- numbness or weakness of the arms and legs
- severe anaemia

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.

A causal relationship for this has not been established. Should any change in body shape be noticed, seek medical advice.

Other effects may show up in blood tests including increased blood levels of sugar, fatty acids (triglycerides) and cholesterol.

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.

Some people are allergic to medicines.

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

- skin troubles such as lumpy skin rash or "hives".
- 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. All these side effects are very rare.

If you have any of the following symptoms soon after starting to take your medicine, DO NOT TAKE ANY MORE LAMIVUDINE ALPHAPHARM TABLETS 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 ALPHAPHARM tablets 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 ALPHAPHARM tablets.

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 ALPHAPHARM tablets. 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 ALPHAPHARM 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 LAMIVUDINE ALPHAPHARM tablets in a cool dry place where the temperature stays below 30°C.

Do not store the tablets 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 LAMIVUDINE ALPHAPHARM tablets in the bottle with the cap tightly closed until you take them.

If you take LAMIVUDINE ALPHAPHARM tablets out of their pack they may not keep well.

Disposal

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

Product description

What LAMIVUDINE ALPHAPHARM tablets looks like

LAMIVUDINE ALPHAPHARM lamivudine 150 mg tablets are white to off-white film-coated, capsule shaped, biconvex tablets debossed with "M105" on one side of the tablet and a score line on the other.

LAMIVUDINE ALPHAPHARM lamivudine 300 mg tablets are white to off-white film-coated, oval shaped, biconvex tablets debossed with "M300" on one side of the tablet and blank on the other side.

LAMIVUDINE ALPHAPHARM tablets are supplied in 60 tablet bottles for 150 mg strength and 30 tablet bottles for the 300 mg strength.

Ingredients

LAMIVUDINE Alphapharm tablets contain either 150 mg or 300 mg of lamivudine as the active ingredient.

It also contains the following inactive ingredients:

- Microcrystalline cellulose.
- Sodium starch glycollate Type A.
- Magnesium stearate.
- Propylene glycol (film coating).
- Opadry Complete Film Coating System 03H58736 White (Proprietary Ingredient Number 106640).

This medicine does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

Supplier

LAMIVUDINE ALPHAPHARM tablets are supplied in Australia by:

Alphapharm Pty Ltd

Level 1, 30 The Bond

30 - 34 Hickson Road

Millers Point NSW 2000

www.mylan.com.au

Australian registration numbers:

LAMIVUDINE ALPHAPHARM lamivudine 150 mg film-coated tablet bottle: AUST R 167591

LAMIVUDINE ALPHAPHARM lamivudine 300 mg film-coated tablet bottle: AUST R 167594

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