

HOVID-LAMIVUDINE TABLET

Lamivudine (150mg, 300 mg)

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What hovid-Lamivudine Tablet is used for

hovid-Lamivudine Tablet is used in combination with other antiretroviral medicine to treat Human Immunodeficiency Virus (HIV) infected adults and children.

How hovid-Lamivudine Tablet works

Lamivudine belongs to a group of antiviral medicines, also known as antiretrovirals, called nucleoside analogue reverse transcriptase inhibitors (NRTIs).

Lamivudine reduces the amount of HIV virus in your body, and keeps it at a low level. It prevents HIV virus from multiplying in your body. Its main mode of action is as a chain terminator of viral reverse transcription.

Before you use hovid-Lamivudine Tablet

- When you must not use it

Do not take this medicine if:

- you are allergic to lamivudine or any of the ingredients listed at the end of this leaflet.
- you are breastfeeding.

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

- Before you start to use it

Tell your doctor/pharmacist:

- if you have liver disease. Patients with chronic hepatitis B or C and treated with antiretroviral agents are at increased risk for severe and potentially fatal liver adverse events and may require blood tests for control of liver function.
- if you have kidney disease. The standard recommended dose may have to be reduced.
- if you are pregnant, or plan to become pregnant. Lamivudine Tablet may cause side effects in unborn babies.

- Taking other medicines

hovid-Lamivudine Tablet may affect or be affected by other medicines you are taking. Talk to your doctor or pharmacist if you are taking any other medicines in any form including any that you buy or obtained without a prescription.

Remember to tell your doctor or pharmacist if you begin taking a new medicine while you're taking hovid-Lamivudine Tablet.

These medicines should not be used with hovid-Lamivudine Tablet:

- Zalcitabine, Emtricitabine (used to treat HIV infection)
- Cladribine (used to treat hairy cell leukaemia)
- Lamivudine and tenofovir in combination with either abacavir or didanosine (to treat HIV infection)
- Other medicines containing Lamivudine

How to use hovid-Lamivudine Tablet

- How much to use

Follow all directions given to you by your doctor and pharmacist carefully.

Swallow the tablet whole, with some water. hovid-Lamivudine Tablet can be taken with or without food.

The usual daily dose is:

Adults, adolescents and children weighing at least 25kg

300 mg daily, administered as either 300 mg once daily or 150 mg twice daily.

Children weighing ≤ 25kg

Your doctor will adjust your dose according to your body weight.

If you have kidney problem

Your doctor will adjust your dose according to your kidney function.

If you have liver problem

There is no change in dosing unless accompanied by kidney problem.

- When to use it

Use as directed by your doctor or pharmacist. Check with your doctor or pharmacist if you are not sure.

- How long to use it

You need to take hovid-Lamivudine Tablet every day to stop your illness getting worse. You may still develop other infections and illnesses linked to HIV infection.

Keep in touch with your doctor, and don't stop taking hovid-Lamivudine Tablet without your doctor's advice.

- If you forget to use it

If you forget to take your dose, take it as soon as you remember. Skip the missed dose if it is almost time for your next

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dose. Do not take double dose to make up for a forgotten dose.

- If you use too much (overdose)

Accidentally taking too much hovid-Lamivudine Tablet is unlikely to cause any serious problems. If you accidentally take too much, tell your doctor or your pharmacist, or contact your nearest hospital emergency department for further advice.

While you are using hovid-Lamivudine Tablet

- Things you must do

Tell your doctor:

- If you experience allergic reactions/ any of the unwanted side effects while taking the medicine.
- If you become pregnant while taking this medication
- If you develop stomach pain, nausea or vomiting. Your doctor would most likely stop your medication and perform blood test to eliminate pancreatitis (swelling and inflammation of the pancreas).

Take your medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

- Things you must not do

Do not:

- give hovid-Lamivudine Tablet to anyone else even if they have the same condition as you
- breast-feed your baby since lamivudine pass into breast milk and there is potential for serious side effects and HIV transmission to the baby.
- stop taking the medicine unless advised by your doctor

- Things to be careful of

Driving and using machines

hovid-Lamivudine Tablet is unlikely to affect your ability to drive or use machines.

Contact your doctor if you are feeling abnormal or unusual problems.

Side effects

Like all medicines, hovid-Lamivudine Tablet can cause side effects, although not everybody gets them.

When you're being treated for HIV, it can be hard to tell whether a symptom is a side effect of hovid-Lamivudine Tablet or other medicines you are taking, or an effect of the HIV disease itself. So it is very important to talk to your doctor about any changes in your health.

As well as the side effects listed below, other conditions can develop during combination therapy for HIV. It is important to read the information under 'Other possible side effects of HIV therapy'.

Common side effects:

- Stomach pain
- Nausea
- Vomiting
- Diarrhoea
- Headache
- Fever
- Rash
- Hair loss (*alopecia*)
- Difficult in sleeping (*insomnia*)
- Cough
- Irritated or runny nose
- Joint pain
- Muscle pain and discomfort

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

Other possible side effects of HIV therapy

Lamivudine Tablets and related medicines (NRTIs) may cause other

conditions to develop during HIV treatment.

Old infections may flare up

People with advanced HIV infection (AIDS) have weak immune systems, and are more likely to develop serious infections (opportunistic infections). When these people start treatment, they may find that old, hidden infections flare up, causing signs and symptoms of inflammation. These symptoms are probably caused by the body's immune system becoming stronger, so that the body starts to fight these infections.

Lactic acidosis is a rare but serious side effect

Some people taking Lamivudine Tablets, or other medicines like it (NRTIs), develop a condition called lactic acidosis, together with an enlarged liver.

Lactic acidosis is caused by a build-up of lactic acid in the body. It is rare; if it happens, it usually develops after a few months of treatment. It can be life-threatening, causing failure of internal organs.

Lactic acidosis is more likely to develop in people who have liver disease, or in obese (very overweight) people, especially women.

Signs of lactic acidosis include:

- Deep, rapid, difficult breathing
- Drowsiness
- Numbness or weakness in the limbs
- Nausea, vomiting
- Stomach pain

Your body shape may change

People taking combination therapy for HIV may find that their body shape changes, because of changes in fat distribution:

- Fat may be lost from the legs, arms or face.
- Extra fat may build up around the tummy (abdomen), or on the breasts or internal organs.

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- Fatty lumps (sometimes called buffalo hump) may appear on the back of the neck.

You may have problems with your bones

Some people taking combination therapy for HIV develop a condition called osteonecrosis. With this condition, parts of the bone tissue die because of reduced blood supply to the bone.

Signs of osteonecrosis include:

- stiffness in the joints
- aches and pains (especially in the hip, knee or shoulder)
- difficulty in moving.

Other effects may show up in blood tests

Combination therapy for HIV can also cause:

- increased levels of lactic acid in the blood, which on rare occasions can lead to lactic acidosis
- increased levels of sugar and fats (triglycerides and cholesterol) in the blood
- resistance to insulin (so if you are diabetic, you may have to change your insulin dose to control your blood sugar).

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 portal.bpfk.gov.my (Consumers→Reporting)”

Storage and Disposal of hovid-Lamivudine Tablet

- Storage

Keep out of reach of children.

Store below 30°C.

- Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product description

- What it looks like

hovid-Lamivudine Tablet 150 mg:

Oval, orange film-coated tablet, shallow convex, “H” and “D” embossed on each side separated with a score line on the same face.

hovid-Lamivudine Tablet 300 mg:

Caplet-shaped orange film-coated tablet, bevel-edged, shallow convex with break bar embossed on one face.

- Ingredients

- Active ingredients

hovid-Lamivudine Tablet 150mg
contains Lamivudine 150 mg

hovid-Lamivudine Tablet 300mg
contains Lamivudine 300 mg

- Inactive ingredients

Microcrystalline Cellulose
Crospovidone
Magnesium Stearate
Hydroxypropyl Methylcellulose
Talc
Titanium Dioxide
Iron Oxide Yellow
Red Iron Oxide
Propylene Glycol

- MAL Number (s)

MALXXXXXXXXXA

Manufacturer

HOVID Bhd.

Lot 56442, 7 ½ Miles, Jalan Ipoh/
Chemor, 31200 Chemor, Malaysia.

Product Registration Holder

HOVID Bhd.

121, Jalan Tunku Abdul Rahman,
30010 Ipoh, Malaysia.

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02/05/2017