Package leaflet: Information for the patient

Lamivudine Sandoz® 150 mg, filmomhulde tabletten
lamivudine

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any of the side effects talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1 What [Nationally completed name] is and what it is used for

[Nationally completed name] is used to treat HIV (human immunodeficiency virus) infection in adults and children.

The active ingredient in [Nationally completed name] is lamivudine. [Nationally completed name] is a type of medicine known as an anti-retroviral. It belongs to a group of medicines called nucleoside analogue reverse transcriptase inhibitors (NRTIs).

[Nationally completed name] does not completely cure HIV infection; it reduces the amount of virus in your body, and keeps it at a low level. It also increases the CD4 cell count in your blood. CD4 cells are a type of white blood cells that are important in helping your body to fight infection.

Not everyone responds to treatment with [Nationally completed name] in the same way. Your doctor will monitor the effectiveness of your treatment.

2 What you need to know before you take [Nationally completed name]

Do not take [Nationally completed name]:
- if you are allergic to lamivudine or any of the other ingredients of this medicine (listed in Section 6).

Check with your doctor if you think this applies to you.

Take special care with [Nationally completed name]

Some people taking [Nationally completed name] or other combination treatments for HIV are more at risk of serious side effects. You need to be aware of the extra risks:

- if you have ever had **liver disease,** including hepatitis B or C (if you have hepatitis B infection, do not stop [Nationally completed name] without your doctor's advice, as your hepatitis may come back)
- if you are seriously **overweight** (especially if you are a woman)
- **if you or your child has a kidney problem**, your dose may be altered.

Talk to your doctor if any of these apply to you. You may need extra check-ups, including blood tests, while you are taking your medicine. **See Section 4 for more information.**

Look out for important symptoms

Some people taking medicines for HIV infection develop other conditions, which can be serious. You need to know about important signs and symptoms to look out for while you are taking [Nationally completed name].

Read the information 'Other possible side effects of combination therapy for HIV' in Section 4 of this leaflet.

Other medicines and [Nationally completed name]

Tell your doctor or pharmacist if you are taking any other medicines, or if you have taken any recently, including herbal medicines or other medicines you bought without a prescription.

Remember to tell your doctor or pharmacist if you begin taking a new medicine while you are taking [Nationally completed name].

These medicines should not be used with [Nationally completed name]:
- medicines (usually liquids) containing sorbitol and other sugar alcohols (such as xylitol, mannitol, lactitol or maltitol), if taken regularly
- other medicines containing lamivudine, (used to treat **HIV infection** or **hepatitis B infection)**
- emtricitabine (used to treat **HIV infection**)
- high doses of **co-trimoxazole**, an antibiotic
- cladribine (used to treat hairy cell leukaemia).

Tell your doctor if you are being treated with any of these.

Pregnancy
If you are pregnant, if you become pregnant, or are planning to become pregnant, talk to your doctor about the risks and benefits to you and your baby of taking [Nationally completed name].

[Nationally completed name] and similar medicines may cause side effects in unborn babies. If you have taken [Nationally completed name] during your pregnancy, your doctor may request regular blood tests and other diagnostic tests to monitor the development of your child. In children whose mothers took NRTIs during pregnancy, the benefit from the protection against HIV outweighed the risk of side effects.

Breast-feeding
Breast-feeding is **not recommended** in women living with HIV because HIV infection can be passed on to the baby in breast milk.

A small amount of the ingredients in [Nationally completed name] can also pass into your breast milk.

If you are breast-feeding, or thinking about breast-feeding, you should **discuss it with your doctor as soon as possible**.

Driving and using machines
[Nationally completed name] is unlikely to affect your ability to drive or use machines.

[Nationally completed name] contains isomalt
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

3 How to take [Nationally completed name]

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

Swallow the tablets, with some water. [Nationally completed name] can be taken with or without food.

The tablet can be divided into equal doses.

If you cannot swallow the tablets whole, you may crush and combine them with a small amount of food or drink, and take all the dose immediately.

Stay in regular contact with your doctor

[Nationally completed name] helps to control your condition. You need to keep taking it 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 do not stop taking [Nationally completed name] without your doctor's advice.

How much to take

Adults, adolescents and children who weigh at least 25 kg:
The usual dose of [Nationally completed name] is 300 mg a day. This can be taken as either one 150 mg tablet twice a day (leaving approximately 12 hours between each dose), or two 150 mg tablets once a day as advised by your doctor.

Children weighing at least 20 kg and less than 25 kg:

The usual dose of [Nationally completed name] is 225 mg a day. This can be given as 75 mg (half a 150 mg tablet) in the morning and 150 mg (one whole 150 mg tablet) in the evening, or 225 mg (one and a half 150 mg tablets) once a day as advised by your doctor.

Children weighing at least 14 kg and less than 20 kg:

The usual dose of [Nationally completed name] is 150 mg a day. This can be given as 75 mg (half a 150 mg tablet) twice a day (leaving approximately 12 hours between each dose), or 150 mg (one 150 mg tablet) once a day as advised by your doctor.
An oral solution is also available for the treatment of children over 3 months of age, or for people who need a lower dose than usual, or who cannot take tablets.

If you or your child has a kidney problem, your dose may be altered.
Talk to your doctor if this applies to you or your child.

If you take more [Nationally completed name] than you should

If you take too much [Nationally completed name], tell your doctor or your pharmacist, or contact your nearest hospital emergency department for further advice. If possible, show them the [Nationally completed name] pack.

If you forget to take [Nationally completed name]
If you forget to take a dose, take it as soon as you remember. Then continue your treatment as before. Do not take a double dose to make up for a forgotten dose.

4 Possible side effects

During HIV therapy there may be an increase in weight and in levels of blood lipids and glucose. This is partly linked to restored health and life style, and in the case of blood lipids sometimes to the HIV medicines themselves. Your doctor will test for these changes.

Like all medicines, this medicine can cause side effects, but not everyone gets them.

When you are being treated for HIV, it can be hard to tell whether a symptom is a side effect of [Nationally completed name] 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 for [Nationally completed name], other conditions can develop during combination therapy for HIV.

It is important to read the information later in this section under 'Other possible side effects of combination therapy for HIV'.

Common side effects
These may affect up to **1 in 10** people:
- headache
- feeling sick (*nausea*)
- being sick (*vomiting*)
- diarrhoea
- stomach pains
- tiredness, lack of energy
- fever (high temperature)
- general feeling of being unwell
- muscle pain and discomfort
- joint pain
- difficulty in sleeping (*insomnia*)
- cough
- irritated or runny nose
- rash
- hair loss (*alopecia*).

Uncommon side effects
These may affect **up to 1 in 100** people:

Uncommon side effects that may show up in blood tests are:
- a decrease in the number of cells involved in blood clotting (*thrombocytopenia*)
- a low red blood cell count (*anaemia*) or low white blood cell count (*neutropenia*)
- an increase in the level of liver enzymes.

Rare side effects
These may affect **up to 1 in 1000** people:

- serious allergic reaction causing swelling of the face, tongue or throat which may cause difficulty in swallowing or breathing
- inflammation of the pancreas (*pancreatitis*)
- breakdown of muscle tissue
- inflammation (*hepatitis*).

A rare side effect that may show up in blood tests is:
- an increase in an enzyme called amylase.

Very rare side effects
These may affect **up to 1 in 10,000** people:
- Lactic acidosis (excess lactic acid in the blood)
- tingling or numbness of the arms, legs, hands or feet.

A very rare side effect that may show up in blood tests is:
- a failure of the bone marrow to produce new red blood cells (*pure red cell aplasia*).

If you get side effects
Tell your doctor or pharmacist if any of the side effects gets severe or troublesome, or if you notice any side effects not listed in this leaflet.

Other possible side effects of combination therapy for HIV

Combination therapy including [Nationally completed name] 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.

In addition to the opportunistic infections, autoimmune disorders (a condition that occurs when the immune system attacks healthy body tissue) may also occur after you start taking medicines for the treatment of your HIV infection. Autoimmune disorders may occur many months after the start of treatment. If you notice any symptoms of infection or other symptoms such as muscle weakness, weakness beginning in the hands and feet and moving up towards the trunk of the body, palpitations, tremor or hyperactivity, please inform your doctor immediately to seek necessary treatment.

If you get any symptoms of infection while you are taking [Nationally completed name]:
Tell your doctor immediately. Do not take other medicines for the infection without your doctor's advice.

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. People may be more likely to get this condition:
- if they have been taking combination therapy for a long time
- if they are also taking anti-inflammatory medicines called corticosteroids
- if they drink alcohol
- if their immune systems are very weak
- if they are overweight.

Signs of osteonecrosis include:
- stiffness in the joints
- aches and pains (especially in the hip, knee or shoulder)
- difficulty moving.

If you notice any of these symptoms:
Tell your doctor.

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed in Appendix V. By reporting side effects, you can help provide more information on the safety of this medicine.

5 How to store [Nationally completed name]

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the blister and carton or label after "EXP". The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

Shelf life after first opening of the bottle:
3 months

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6 Contents of the pack and other information

What [Nationally completed name] contains

The active substance is lamivudine. Each tablet contains 150 mg of lamivudine.
The other ingredients are isomalt (E 953), crospovidone Type A, magnesium stearate (E 572), hypromellose 3cp (E 464), hypromellose 6cp (E 464), titanium dioxide (E 171), macrogol 400, polysorbate 80 (E 433).

What [Nationally completed name] looks like and the contents of the pack

White capsule shaped, biconvex scored film coated tablets with a dimension of 15 x 6.5 mm, debossed with J on one side and 16 on the other side, 1 and 6 separated by a score line.

The film-coated tablets are packed in Alu/OPA/Alu/PVC blisters which are inserted in a carton box or in HDPE container with child resistant polypropylene cap.

Pack sizes:
Blister: 14, 28, 30, 56, 60, 84, 90 and 120 film-coated tablets
HDPE container: 30, 60, 90 film-coated tablets

Not all pack sizes may be marketed.

Houder van de vergunning voor het in de handel brengen

Sandoz B.V., Hospitaaldreef 29, 1315 RC Almere, Nederland

Fabrikanten
Lek Pharmaceuticals d.d.
Verovškova 57
1526 Ljubljana
Slovenië

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Polen

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Otto-von-Guericke Allee 1
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Duitsland

S.C. Sandoz, S.R.L.
Str. Livezeni nr. 7A
RO-540472 Targu-Mures
Roemenië

In het register ingeschreven onder
RVG 111999

Dit geneesmiddel is geregistreerd in lidstaten van de EEA onder de volgende namen

Nederland	Lamivudine Sandoz 150 mg, filmomhulde tabletten
Oostenrijk	Lamivudin Sandoz 150 mg – Filmtabletten
Denemarken	Lamivudine Sandoz
Frankrijk	LAMIVUDINE SANDOZ 150 mg, comprimé pelliculé
Duitsland	Lamivudin HEXAL 150 mg Filmtabletten

Deze bijsluiter is voor het laatst goedgekeurd in februari 2024