

Applicant: Ranbaxy Pharmaceuticals (Pty) Ltd
Product name: Sonke Lamivudine 150 tablets
Dosage form: Film- coated Tablets
Strength: Lamivudine 150 mg/tablet

APPROVED PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: **S4**

SONKE LAMIVUDINE 150 Tablets

Lamivudine

Sugar-free

Read all of this leaflet carefully before you start taking SONKE LAMIVUDINE 150

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- **SONKE LAMIVUDINE 150** has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What **SONKE LAMIVUDINE 150** is and what it is used for
2. What you need to know before you take **SONKE LAMIVUDINE 150**
3. How to take **SONKE LAMIVUDINE 150**
4. Possible side effects
5. How to store **SONKE LAMIVUDINE 150**
6. Contents of the pack and other information

1. What SONKE LAMIVUDINE 150 is and what it is used for

SONKE LAMIVUDINE 150 tablets are used as part of the combination treatment of HIV infection in adults and children above the age of 12 years old.

2. What you need to know before you take SONKE LAMIVUDINE 150

Do not take SONKE LAMIVUDINE 150 tablets if

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- You have previously had an allergic reaction to lamivudine or to any of **SONKE LAMIVUDINE 150** ingredients listed above. (An allergic reaction may include rash, itching, swelling of the face, lips, tongue or hands/feet or breathing difficulties) (listed in section 6).
- You have blood disorders
- You are pregnant or breastfeeding

Warnings and precautions

Take special care with SONKE LAMIVUDINE 150:

- If you have a history of liver disease, including chronic active hepatitis. Patients with liver disease including chronic hepatitis B or C, who are treated with combination antiretrovirals, have a higher risk of severe and potentially life-threatening liver problems. Your doctor may conduct blood tests in order to check how well your liver is working or may switch you to another medicine. If you have severe liver disease, do not take SONKE LAMIVUDINE 150.
- If you have hepatitis B infection, your doctor will carefully consider the best treatment regimen for you. Symptoms of your hepatitis may become worse after discontinuation of SONKE LAMIVUDINE 150.
- If you develop stomach pain, nausea or vomiting. Check with your doctor, as these could be signs of an inflamed pancreas or a condition called lactic acidosis. If you are feeling unwell, consult your doctor.
- Liver disease has been known to occur.
- If you have kidney disease.
- If you have lipodystrophy (a problem with the way your body uses and stores fat). This condition is characterised by being overweight (obesity), build-up of fat on the back of the neck between the shoulders (buffalo hump), loss of fat under the skin (making the face look thin), breast enlargement and high levels of fat and glucose (sugar) in the blood. If you have any of these signs, you should be thoroughly examined by your doctor.
- In rare cases, as your immune system becomes stronger, it can also attack healthy body tissue (autoimmune disorders). The symptoms of autoimmune disorders may develop many months after you start taking medicine to treat your HIV infection.

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- If you notice any of the symptoms of osteonecrosis (where parts of the bone tissue die, because of reduced blood supply to the bone): joint aches and pain, joint stiffness or difficulty in movement, tell your doctor.
- You may still develop infections and other complications of HIV infection while using **SONKE LAMIVUDINE 150**.
- You are still at a risk of transmission of HIV to other people through sexual contact or blood contamination, while taking **SONKE-LAMIVUDINE 150**.
- You should stop **SONKE-LAMIVUDINE 150** tablets immediately if you develop abdominal (intestinal) pain, nausea or vomiting, shortness of breath, tiredness and weight loss and you should contact your doctor.

SONKE-LAMIVUDINE 150 must be used with caution in patients with liver and kidney disorders as well as in the elderly.

Other medicines and SONKE-LAMIVUDINE 150

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines).

If you are taking other medicines on a regular basis, including complimentary or traditional medicines, concomitant use of SONKE-LAMIVUDINE 150 with these medicines may cause undesirable interactions. Please consult your doctor, pharmacist or other health care professional for advice.

Care is needed if you are taking the following medicines along with **SONKE LAMIVUDINE 150**:

- Trimethoprim/sulphamethoxazole (a medicine to treat infections)
- Zalcitabine
- Emtricitabine (used to treat HIV infection).
- Cladribine (used to treat a certain type of cancer).
- Medicines (usually liquids) containing sorbitol and other sugar alcohols (such as xylitol,)

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SONKE-LAMIVUDINE 150 with food or drink

SONKE LAMIVUDINE 150 can be taken with or without food.

Pregnancy and breastfeeding

You must not use SONKE LAMIVUDINE 150 when pregnant or breastfeeding your infant.

If you are pregnant or breastfeeding your baby while taking this medicine, please consult your doctor, pharmacist or other health care professional for advice.

Driving and using machines

SONKE LAMIVUDINE 150 may cause dizziness or tiredness in some patients. Do not drive or operate any tools or machines until you know how **SONKE LAMIVUDINE 150** affects you because your concentration may be affected.

3. How to take SONKE-LAMIVUDINE 150

Do not share medicines prescribed for you with other persons.

Always take SONKE LAMIVUDINE TABLETS exactly as your doctor or pharmacist has told you. You should check with your doctor or pharmacist if you are unsure.

Adults and adolescents: Take two tablets once a day or one tablet twice daily in combination with zidovudine.

Children weighing between 14 kg to 20 kg:

Take one tablet once a day.

Children weighing at least 25 kg:

Take one tablet twice a day or take two tablets once a day.

If you have liver and kidney problems, your doctor may adjust the doses accordingly.

To help you remember to take **SONKE LAMIVUDINE 150**, try to get into the habit of taking it at the same time each day.

Take **SONKE LAMIVUDINE 150** as directed and for as long as directed; do not stop them, even if you feel better, as the symptoms may return.

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*If you have the impression that the effect of **SONKE LAMIVUDINE 150** tablets is too strong or too weak, talk to your doctor or pharmacist.*

If you have taken more SONKE LAMIVUDINE 150 than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, rush the patient to the nearest hospital or poison centre. Take this leaflet or some tablets with you so your doctor will know what you have taken.

If you forget to take SONKE LAMIVUDINE 150 tablets

Take them as soon as you remember. However, if it is almost time for your next dose, skip the missed dose and go back to your regular dosing schedule. Do not take a double dose to make up for forgotten individual doses.

4. Possible side effects

SONKE LAMIVUDINE 150 can have side effects.

Not all side-effects reported for **SONKE LAMIVUDINE 150** are included in this leaflet. Should your general health worsen while taking **SONKE LAMIVUDINE 150**, please consult your doctor, pharmacist or other health care professional for advice.

If any of the following happens, stop taking **SONKE LAMIVUDINE 150** and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Rashes, hives, itching, chest constriction, shortness of breath or swelling of the face, lips, tongue, hands/ feet, fainting, high temperature (fever)

These are all very serious side effects. If you have them, you may have had a serious reaction to **SONKE LAMIVUDINE 150**. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- A breakdown of muscle tissue that releases a damaging protein into the blood (rhabdomyolysis); symptoms include: dark, reddish urine, a decreased amount of urine, weakness and muscle aches.

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- Excess lactic acid in the blood (lactic acidosis); symptoms include: rapid breathing, excessive sweating, cool and clammy skin, sweet-smelling breath, stomach pain, nausea or vomiting, confusion and tiredness.
- Inflammation of the pancreas (pancreatitis); symptoms include severe stomach pain with nausea and vomiting and fever.
- Inflammation of the liver (hepatitis); symptoms include: yellow skin or eyes (jaundice), nausea, fatigue and fever.

These are all serious side effects. You may need urgent medical attention

Tell your doctor if you notice any of the following side effects:

Frequent side effects:

- Nausea, vomiting, stomach pain or cramps, diarrhoea
- Unusual weakness or tiredness
- Fever, general feeling of illness
- Difficulty in sleeping
- Headache, sensation of pins and needles, tingling, burning, numbness
- Muscle pain or cramping
- Joint pain
- Cough, irritated or runny nose

Side effects with frequency unknown:

- Loss of hair

Side effects that may show up in your blood tests:

- A reduction in the number of white blood cells (neutropenia)
- A reduction in the number of platelets (cells that make the blood clot) (thrombocytopenia)
- A reduction in the number of red blood cells (anaemia)
- A failure of the bone marrow to produce new red blood cells (pure red cell aplasia)
- An increase in liver enzymes

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- An increase in the level of an enzyme called amylase in the blood

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the “**6.04 Adverse Drug Reaction Reporting Form**”, found online under SAHPRA’s publications: <https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of **SONKE LAMIVUDINE 150**

5. How to store SONKE LAMIVUDINE 150

Store all medicines out of reach of children.

- Store at or below 25 °C.
- Store in the original package.
- Keep the blister in the outer carton.

- Protected from light/moisture.
- Do not store in a bathroom.
- Do not use after the expiry date stated on the label.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains or sewerage systems e.g. toilets.

6. Contents of the pack and other information

What SONKE LAMIVUDINE 150 contains

Each SONKE LAMIVUDINE 150 tablet contains 150 mg lamivudine. (active substance).

The other ingredients are:

Tablet core: Magnesium stearate, microcrystalline cellulose; sodium starch glycollate

Flim coat: Hypromellose; titanium dioxide; propylene glycol.

What SONKE LAMIVUDINE 150 looks like and contents of the pack

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White to off-white, oval shaped, biconvex, film-coated tablets with 'RX919' debossed on one side and a score line on the other side.

10 tablets are packed in blister strips of clear, transparent, PVC film with an aluminium foil backing.

Cartons contain 10, 30 or 60 tablets.

56 or 60 Tablets packed in securitainers or in white opaque HDPE bottles.

Holder of Certificate of Registration

RANBAXY PHARMACEUTICALS (PTY) LTD

a Sun Pharma company

14 Lautre Road, Stormill Ext 1

Roodepoort, 1724

South Africa

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Marketed by Sonke Pharmaceuticals (Pty) Ltd

This product is for use only in the territories of South Africa, Namibia, Botswana, Lesotho and Swaziland, is not for resale and any other use is not authorised.

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