APPROVEDED PATIENT INFORMATION LEAFLET

SCHEDULING STATUS **S4**

AURO ABACAVIR/LAMIVUDINE 600/300 mg TABLETS (Tablet)

Abacavir / Lamivudine

Sugar free

Read all of this leaflet carefully before you start taking AURO ABACAVIR/LAMIVUDINE 600/300 mg TABLETS.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- **AURO ABACAVIR/LAMIVUDINE 600/300 mg TABLETS** 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 AURO ABACAVIR/LAMIVUDINE 600/300 mg TABLETS is and what it is used for
2. What you need to know before you take AURO ABACAVIR/LAMIVUDINE 600/300 mg TABLETS
3. How to take AURO ABACAVIR/LAMIVUDINE 600/300 mg TABLETS
4. Possible side effects

5. How to store AURO ABACAVIR/LAMIVUDINE 600/300 mg TABLETS
6. Contents of the pack and other information

1. What AURO ABACAVIR/LAMIVUDINE 600/300 mg TABLETS is and what it is used for

AURO ABACAVIR/LAMIVUDINE 600/300 mg TABLETS is a prescription medicine used in combination with other medicines to treat adults and children from 12 years of age, weighing at least 40 kg, who are infected with HIV (human immunodeficiency virus), the virus that causes AIDS.

2 What you need to know before you take [PRODUCT NAME]

Do not take AURO ABACAVIR/LAMIVUDINE 600/300 mg TABLETS:

- If you are hypersensitive (allergic) to abacavir or lamivudine or any of the other ingredients of **AURO ABACAVIR/LAMIVUDINE 600/300 mg TABLETS** (listed in section 6).
- If you have moderate to severe liver disease.
- If you are pregnant or breastfeeding.
- If you have moderate to severe kidney disease.
- Children < 12 years old.
- Patients who weigh < 40kg.

Warnings and precautions

Take special care with AURO ABACAVIR/LAMIVUDINE 600/300 mg TABLETS:

HYPERSENSITIVITY REACTION (SERIOUS ALLERGIC REACTION):

Since AURO ABACAVIR/LAMIVUDINE 600/300 mg TABLETS contain abacavir some patients

taking AURO ABACAVIR/LAMIVUDINE 600/300 mg TABLETS may develop a hypersensitivity reaction (serious allergic reaction) which can be life-threatening if you continue to take AURO ABACAVIR/LAMIVUDINE 600/300 mg TABLETS. There is also an Alert Card included in AURO ABACAVIR/LAMIVUDINE 600/300 mg TABLETS pack, to remind you and medical staff about abacavir hypersensitivity. This card should be removed from the pack and kept with you at all times.

About 5 % of patients, who are treated with abacavir, develop a hypersensitivity reaction.

The most common symptoms of this reaction are high temperature (fever) and a skin rash. Other frequently observed signs are nausea, vomiting, diarrhoea, abdominal pain and severe tiredness.

Other symptoms may include joint or muscle pain, swelling of the neck, shortness of breath, sore throat, cough and headache. Inflammation of the eye (conjunctivitis), mouth ulcers or low blood pressure may occur.

The symptoms of this allergic reaction can occur at any time during treatment with abacavir. However they usually occur in the first six weeks of treatment.

The symptoms worsen with continued treatment and may be life-threatening if treatment is continued.

CONTACT YOUR DOCTOR IMMEDIATELY for advice on whether you should stop taking AURO ABACAVIR/LAMIVUDINE 600/300 mg TABLETS if:

1) you get a skin rash OR

2) you get one or more symptoms from at least TWO of the following groups

- fever

- shortness of breath, sore throat or cough

- nausea or vomiting or diarrhoea or abdominal pain

- severe tiredness or achiness or generally feeling ill

If you have discontinued AURO ABACAVIR/LAMIVUDINE 600/300 mg TABLETS due to a hypersensitivity (allergic) reaction, YOU MUST NEVER TAKE

AURO ABACAVIR/LAMIVUDINE 600/300 mg TABLETS, or any other medicine containing abacavir again as you may experience a life-threatening lowering of your blood pressure or death.

Research has found that people with a gene called HLA-B type 5701 are more likely to have a hypersensitivity reaction to abacavir. Your doctor may do tests for this gene. However, even if you do not have this gene type, it is still possible for you to get this reaction. If you know you have this gene type, tell your doctor before you take abacavir.

AURO ABACAVIR/LAMIVUDINE 600/300 mg TABLETS will not cure your HIV infection and does not prevent a patient infected with HIV from passing the virus to other people.

If you have stopped taking AURO ABACAVIR/LAMIVUDINE 600/300 mg TABLETS for any reason, particularly because you think you are having side-effects or for other illness, it is important to inform your doctor before re-starting. Your doctor will check

whether any symptoms you had may be related to this hypersensitivity reaction. If your doctor thinks there is a possibility that they were related, you will be instructed never to take AURO ABACAVIR/LAMIVUDINE 600/300 mg TABLETS or any other abacavir containing medicine again. It is important that you follow this advice.

Life-threatening hypersensitivity reactions have occurred when abacavir was restarted in patients who reported only one of the symptoms on the Alert Card before stopping.

Hypersensitivity has also been reported when abacavir was restarted in patients who had no symptoms of hypersensitivity before stopping.

If you are hypersensitive (allergic) to abacavir you should return all your unused AURO ABACAVIR/LAMIVUDINE 600/300 mg TABLETS for disposal. Ask your doctor or pharmacist for advice.

- **AURO ABACAVIR/LAMIVUDINE 600/300 mg TABLETS** can cause a condition called lactic acidosis (excess of lactic acid in your blood), together with an enlarged liver. Lactic acidosis can be fatal. Call your doctor at once if you have any of the following symptoms: nausea, vomiting, abdominal pain, shortness of breath, feeling very weak and tired, or weight loss.
- **AURO ABACAVIR/LAMIVUDINE 600/300 mg TABLETS** can cause severe effects on the liver. Call your doctor at once if you have any of these liver symptoms while taking **AURO ABACAVIR/LAMIVUDINE 600/300 mg TABLETS**: nausea, stomach pain, loss of appetite, low fever, dark urine, clay-coloured stools, jaundice (yellowing of the skin or eyes).
- You may need extra check–ups, including blood tests, while you are taking **AURO ABACAVIR/LAMIVUDINE 600/300 mg TABLETS**

- Tell your doctor if you have liver disease (including hepatitis B or C). If you have hepatitis B infection, you should not stop taking **AURO ABACAVIR/LAMIVUDINE 600/300 mg TABLETS** without instructions from your doctor, as this may cause a recurrence of your hepatitis. This may occur due to you suddenly stopping lamivudine.
- Tell your doctor if you have kidney disease as you should not take **AURO ABACAVIR/LAMIVUDINE 600/300 mg TABLETS** if your kidney disease becomes worse.
- **AURO ABACAVIR/LAMIVUDINE 600/300 mg TABLETS** can also cause a dangerous inflammation of the pancreas. Tell your doctor right away if you develop abdominal pain, nausea or vomiting. Tell your doctor if you have had pancreatitis in the past.
- Even while taking **AURO ABACAVIR/LAMIVUDINE 600/300 mg TABLETS,** you may continue to have HIV-related illnesses, including infections caused by other disease-producing organisms. Continue to see your doctor regularly and report any medical problems that occur.
- Fever, headache, stomach pain and/or difficulty breathing may be symptoms of flare-up of old or existing infections or autoimmune disease. Tell your doctor should you have any symptoms of a possible infection.
- **AURO ABACAVIR/LAMIVUDINE 600/300 mg TABLETS** does not prevent a patient infected with HIV from passing the virus to other people. To protect others, you must continue to practice safe sex, safe injection and take precautions to prevent others from coming into contact with your blood and other contaminated body fluids.
- **AURO ABACAVIR/LAMIVUDINE 600/300 mg TABLETS** may increase the risk for heart attacks in patients using **AURO ABACAVIR/LAMIVUDINE 600/300 mg TABLETS**. You should therefore tell your doctor of any heart related problems, high blood pressure, smoking or diabetes.

Children and adolescents

AURO ABACAVIR/LAMIVUDINE 600/300 mg TABLETS is not recommended for the treatment of children as the necessary dose adjustment cannot be made. Medical practitioners should refer to the individual package insert for lamivudine and abacavir.

Taking AURO ABACAVIR/LAMIVUDINE 600/300 mg TABLETS with food and drink:

AURO ABACAVIR/LAMIVUDINE 600/300 mg TABLETS can be taken with or without food.

Pregnancy and Breastfeeding:

- **AURO ABACAVIR/LAMIVUDINE 600/300 mg TABLETS** should not be taken during pregnancy and if you are breastfeeding.
- Tell your doctor if you are pregnant, planning to become pregnant or breastfeeding.

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before you take **AURO ABACAVIR/LAMIVUDINE 600/300 mg TABLETS.**

Driving and using machinery:

AURO ABACAVIR/LAMIVUDINE 600/300 mg TABLETS may cause dizziness. Do not drive or operate machinery while taking **AURO ABACAVIR/LAMIVUDINE 600/300 mg TABLETS** until you know how it affects you.

It is not always possible to predict to what extent **AURO ABACAVIR/LAMIVUDINE 600/300 mg TABLETS** may interfere with the daily activities of a patient. Patients should ensure that

they do not engage in the above activities until they are aware of the measure to which AURO ABACAVIR/LAMIVUDINE 600/300 mg TABLETS affects them.

AURO ABACAVIR/LAMIVUDINE 600/300 mg TABLETS contains Sodium starch glycolate

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium free'.

Taking other medicines with AURO ABACAVIR/LAMIVUDINE 600/300 mg TABLETS:

Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines).

- Alcohol does increase the amount of abacavir in your blood.
- **AURO ABACAVIR/LAMIVUDINE 600/300 mg TABLETS** should not be taken with zalcitabine.
- Tell your doctor if you are using any of the following medicines: antibiotics such as trimethoprim or co-trimoxazole, medicines used to treat acne such as isotretinoin, antiretroviral medicines such as zalcitabine, emtricitabine and the medicine used to treat certain drug addictions or for pain such as methadone. If you are taking any of these medicines, your doctor may need to monitor your therapy more closely, or you may not be able to use **AURO ABACAVIR/LAMIVUDINE 600/300 mg TABLETS.**

3. How to take AURO ABACAVIR/LAMIVUDINE 600/300 mg TABLETS

Do not share medicines prescribed for you with any other person.

Always take **AURO ABACAVIR/LAMIVUDINE 600/300 mg TABLETS** exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure. If you have the impression that the effect of **AURO ABACAVIR/LAMIVUDINE 600/300 mg TABLETS** is too strong or too weak, talk to your doctor or pharmacist.

- The usual dose in adults and adolescents is one tablet once a day. Do not skip doses.
- **AURO ABACAVIR/LAMIVUDINE 600/300 mg TABLETS** should not be given to children less than 12 years old or people weighing less than 40 kg.

If you take more AURO ABACAVIR/LAMIVUDINE 600/300 mg TABLETS than you should:

- Seek emergency medical attention if you think you have used too much of this medicine.

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you forget to take AURO-ABACAVIR/LAMIVUDINE 600/300 mg TABLETS:

If you forget to take a dose, take it as soon as you remember, and then continue as before. Do not take a double dose to make up for forgotten individual doses.

If you have stopped **AURO ABACAVIR/LAMIVUDINE 600/300 mg TABLETS** for any reason, particularly because you think you are having side effects or other illness, it is important that you inform your doctor before restarting (see Boxed Warning on abacavir hypersensitivity).

4. POSSIBLE SIDE EFFECTS

AURO ABACAVIR/LAMIVUDINE 600/300 mg TABLETS can have side effects

Not all side effects reported for **AURO ABACAVIR/LAMIVUDINE 600/300 mg TABLETS** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking **AURO ABACAVIR/LAMIVUDINE 600/300 mg TABLETS**, please consult your doctor, pharmacist or other healthcare professional for advice.

If any of the following happens, stop taking **AURO ABACAVIR/LAMIVUDINE 600/300 mg TABLETS** and tell your doctor immediately or go to the casualty department at your nearest hospital:

- hives, difficulty breathing, swelling of your face, lips, tongue, or throat or any of the serious signs or symptoms described in the **Boxed warnings** of abacavir hypersensitivity.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to **AURO ABACAVIR/LAMIVUDINE 600/300 mg TABLETS**. 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:

- Lactic acidosis (severe increase of lactic acid in the blood) - Inform your doctor immediately if you experience any of the following symptoms of lactic acidosis: nausea, vomiting, stomach pain, deep rapid difficult breathing, feeling very weak and tired, or weight loss.
- Severe liver enlargement.
- Peripheral neuropathy- tingling, numbness, and pain in the hands and feet.
- Pancreatitis (inflammation of the pancreas) - stomach pain, nausea or vomiting.
- skin rash, serious skin reactions.

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

Tell your doctor if you notice any of the following:

The following side effects occur frequently:

- abdominal pain, diarrhoea, nausea, vomiting, headache, fever, inability to sleep, lack of well-being, lethargy, fatigue, cough, nasal symptoms (irritation, runny nose), loss of appetite,

The following side effects occur less frequently:

- anaemia (decreased number of red blood cells), too few white blood cells, too few blood platelets, loss of hair,
- numbness, tingling, joint pain, muscle disorders, increase in enzymes produced by the liver, raised sugar in the blood, increased fats in the blood, changing of body shape due to changes in fat distribution

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 Med Safety APP (Medsafety X SAHPRA) and eReporting platform (whoumc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of **AURO ABACAVIR/LAMIVUDINE 600/300 mg TABLETS.**

5. How to store AURO ABACAVIR/LAMIVUDINE 600/300 mg TABLETS

Store at or below 30 °C (room temperature). Keep the container tightly closed.

Store all medicines out of the reach and sight of children.

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 AURO ABACAVIR/LAMIVUDINE 600/300 mg TABLETS CONTAIN

The active substances are abacavir and lamivudine.

Each film-coated tablet contains abacavir sulfate equivalent to abacavir 600 mg and lamivudine 300 mg.

The other ingredients are FD & C yellow # 6/sunset yellow FCF aluminium lake (C.I. No: 15985), hypromellose, macrogol/PEG 400, magnesium stearate, microcrystalline cellulose, polysorbate 80, sodium starch glycolate and titanium dioxide (C.I. No: 77891).

Sugar free.

What AURO-ABACAVIR/LAMIVUDINE 600/300 mg TABLETS looks like and contents of the pack

Tablets are packed in white HDPE containers with a white closure with an induction sealing wad. Each container contains 30 tablets.

AURO ABACAVIR/LAMIVUDINE 600/300 mg TABLETS are orange coloured, modified capsule shaped film-coated tablets, debossed with ‘H’ on one side and ‘27’ on other side.

Holder of Certificate of Registration

Aurobindo Pharma (Pty) Ltd

Woodhill Office Park, Building 1,

53 Phillip Engelbrecht Avenue

Meyersdal, Ext. 12, 1448

Johannesburg

South Africa

Telephone no.: +27 11 867 9100

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