PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

SONKE ABACAVIR 300 Tablets

Abacavir 300 mg

Contains no sugar

Read all of this leaflet carefully before you start taking SONKE ABACAVIR 300.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.
- **SONKE ABACAVIR 300** 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.

HYPERSENSITIVITY REACTION

Hypersensitivity reactions (serious allergic reaction):

SONKE ABACAVIR 300 contains abacavir.

Abacavir can cause a serious allergic reaction known as a hypersensitivity reaction, which can be life-threatening if treatment with abacavir-containing products is not stopped.

The SONKE ABACAVIR 300 pack includes an **Alert Card**, to remind you and medical staff about abacavir hypersensitivity. **Detach this card and always carry your Alert Card while you are taking SONKE ABACAVIR 300**.

Who gets these reactions?

Anyone taking **SONKE ABACAVIR 300** could develop a hypersensitivity reaction, which could be life-threatening if they continue to take **SONKE ABACAVIR 300**.

You are more likely to develop such a reaction if you have a gene called **HLA-B*5701** (but you can get a reaction even if you don't have this gene). You may have been tested for this gene before SONKE ABACAVIR 300 was prescribed for you. **If you know you have this gene, tell your doctor before you take SONKE ABACAVIR 300.**

What are the symptoms of a hypersensitivity reaction (serious allergic reaction)?

The most common symptoms are:

- **fever** (high temperature) and **skin rash.**

Other common symptoms are:

- nausea (feeling sick), vomiting (being sick), diarrhoea, abdominal (stomach) pain, severe tiredness, shortness of breath, cough, headache, muscle pain and discomfort.

Other less common symptoms can include:

- pains in the joints, swelling of the neck, serious breathing problems, sore throat
- occasionally, inflammation of the eye (conjunctivitis), mouth ulcers, low blood pressure, tingling or numbness of the hands or feet.

When do these reactions happen?

Hypersensitivity reactions can start at any time during treatment with **SONKE ABACAVIR 300** but are more likely during the first 6 weeks of treatment.

Contact your doctor immediately:

1) if you get a skin rash OR

2) if you get symptoms from at least 2 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 ill feeling.

Your doctor may advise you to stop taking **SONKE ABACAVIR 300**.

If you have stopped taking **SONKE ABACAVIR 300:**

If you have stopped taking **SONKE ABACAVIR 300** because of a hypersensitivity reaction, **you must NEVER AGAIN take SONKE ABACAVIR 300, or any other medicine containing abacavir**. If you do, within hours, your blood pressure could fall dangerously low which could result in death.

If you have stopped taking **SONKE ABACAVIR 300** for any reason, particularly because you think you are having side effects or for other illness, it is important that you contact your doctor

before restarting. Your doctor will check whether any symptoms you had before stopping may be related to this hypersensitivity reaction. If your doctor thinks there is a possibility that they were related, you may be told never to take **SONKE ABACAVIR 300** or any other medicine containing abacavir again. It is important that you follow this advice.

Occasionally, reactions have developed in people who start taking abacavir again and had only one symptom on the Alert Card before they stopped taking it.

Reactions have developed in people who start taking abacavir again, but who had no symptoms before they stopped taking it.

If your doctor advises that you can start taking SONKE ABACAVIR 300 again, you may be asked to take your first doses in a place where you will have ready access to medical care if you need it.

If you are hypersensitive to **SONKE ABACAVIR 300** you should return all of your unused **SONKE ABACAVIR 300** to your doctor or pharmacist for proper disposal.

1. What SONKE ABACAVIR 300 is and what it is used for

Abacavir belongs to a group of medicines called nucleoside analogue reverse transcriptase inhibitors (NRTIs). NRTIs are used to treat the human immunodeficiency virus (HIV) infection. **SONKE ABACAVIR 300** is used in combination with other antiretroviral medicines for the treatment of HIV infected adults and children.

2. What you need to know before you take SONKE ABACAVIR 300

Do not take SONKE ABACAVIR 300 if:

- You are hypersensitive (allergic) to abacavir (or any other medicine containing abacavir) or any of the other ingredients of SONKE ABACAVIR 300 (listed in section 6).
  Carefully read all the information about hypersensitivity in the BOXED WARNING and section 4.
- You have moderate or severe liver disease.
- You are pregnant or breastfeeding.
- **SONKE ABACAVIR 300** should not be used in children under 3 months of age.

If you think any of the above applies to you, don't take **SONKE ABACAVIR 300** until you have checked with your doctor.

Warnings and precautions:

Take special care with **SONKE ABACAVIR 300**:

Before you take **SONKE ABACAVIR 300** your doctor needs to know:

- if you have ever had liver disease, including hepatitis B or C.

Conditions you need to look out for:

Hypersensitivity reactions:

SONKE ABACAVIR 300 contains abacavir. Abacavir can cause a serious allergic reaction known as a hypersensitivity reaction, which can be life-threatening if treatment with abacavir containing products is not stopped.

Carefully read all the information about hypersensitivity reactions in the BOXED WARNING.

Lactic acidosis:

A condition that is caused by build-up of lactic acid in the body. It is more likely to develop in people who have liver disease, especially in women. It can be life-threatening, causing failure of internal organs. See 'Conditions you need to look out for' in section 4.

Change in body shape:

People taking combination therapy for HIV may find that their body shape changes, because of changes in fat distribution. See 'Conditions you need to look out for' in section 4.

Infection and inflammation:

People with advanced HIV infection (AIDS) have weak immune systems and are more likely to develop serious infections (opportunistic infections). When they start treatment, the immune system becomes stronger, so the body starts to fight infections. Symptoms of infection and inflammation may develop, caused by either:

- old, hidden infections flaring up again as the body fights them
- the immune system attacking healthy body tissue (autoimmune disorders).

The symptoms of auto-immune disorders may develop many months after you start taking medicine to treat your HIV infection.

See 'Conditions you need to look out for' in section 4.

Heart disease:

Abacavir may increase your risk of heart attack. If you have heart problems, smoke or suffer from diseases that increase your risk of heart disease such as high blood pressure and diabetes, tell your doctor. Do not stop taking **SONKE ABACAVIR 300** unless you are advised to do so by your doctor.

Protect other people:

HIV infection is spread by sexual contact with someone who has the infection, or by transfer of infected blood (for example, by sharing injection needles). 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 need regular blood tests:

For as long as you are taking **SONKE ABACAVIR 300**, your doctor will arrange regular blood tests to check for side effects. There is more information about these side effects in this leaflet. See section 4.

Risk of cardiovascular events (Heart problems)

It cannot be excluded that abacavir may increase the risk of having cardiovascular events. **Tell your doctor** if you have cardiovascular problems, if you smoke, or have other illnesses that may increase your risk of cardiovascular diseases such as high blood pressure, or diabetes. Do not stop taking **Sonke Abacavir 300** unless your doctor advises you to do so.

Other medicines and SONKE ABACAVIR 300.

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

Care is needed if you are taking the following along with **SONKE ABACAVIR 300**:

- Alcohol
- Methadone (medicine used as pain killer or replacement therapy for drug abuse).
- Retinoids such as isotretinoin.
- Riociguat

Pregnancy and breastfeeding

If you are pregnant or breast feeding your baby while taking this medicine, please consult your doctor, pharmacist or other healthcare professional for advice before taking this medicine.

Pregnancy:

SONKE ABACAVIR 300 should not be used during pregnancy as the safe use of **SONKE ABACAVIR 300** in human pregnancy has not been established. (see section 2, **'Do not take SONKE ABACAVIR 300'**).

Breastfeeding:

SONKE ABACAVIR 300 should not be used in lactation (see section 2, **'Do not take SONKE-ABACAVIR 300'**). Mothers who are HIV-positive should not breastfeed. This is because HIV infection can be passed on to the baby in breast milk. If formula feeding is not possible, you should get advice from your doctor.

Driving and using machines

SONKE ABACAVIR 300 is unlikely to affect your ability to drive or operate machinery. If you have any concerns consult your doctor.

3. How to take SONKE ABACAVIR 300

Do not share medicines prescribed for you with any other person. Take your medicine as directed by your doctor. Do not take more or less than the doctor told you to.

Adults, adolescents and children weighing at least 25 kg:
The recommended dose of **SONKE ABACAVIR 300** is one tablet twice daily. This may be taken as either 300 mg (one tablet) twice daily or 600 mg (two tablets) once daily, with or without food.

SONKE ABACAVIR 300 should be swallowed whole with water. For patients who are unable to swallow tablets, the tablets may be crushed and added to a small amount of semi-solid food or liquid, all of which should be consumed immediately.
Your doctor will tell you how long the treatment with **SONKE ABACAVIR 300** will last.
If you have the impression that the effect of **SONKE ABACAVIR 300** is too strong or too weak, talk to your doctor or pharmacist.

If you have taken more **SONKE ABACAVIR 300** than you should
In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

Take this leaflet or some tablets with you so your doctor will know what you have taken.

If you forget to take SONKE ABACAVIR 300

If you forget to take SONKE ABACAVIR 300 at the right time, take it as soon as you remember, and then follow your usual schedule. 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.

If you stop taking SONKE ABACAVIR 300:

If you have stopped taking SONKE ABACAVIR 300 for any reason, particularly because you think you are having side effects or for other illness, it is important that you contact your doctor before restarting. In some cases, your doctor will ask you to restart SONKE ABACAVIR 300 under direct medical supervision or where medical care can be readily accessed by yourself or others.
If you have hepatitis B infection, don't stop SONKE ABACAVIR 300 without your doctor's advice, as your hepatitis may come back.

4. Possible side effects

Not all side-effects reported for SONKE ABACAVIR 300 are included in this leaflet. Should your general health worsen while taking SONKE ABACAVIR 300, please consult your healthcare provider for advice.

Conditions to look out for:

Hypersensitivity reactions:

SONKE ABACAVIR 300 can cause a hypersensitivity reaction (serious allergic reaction) which can be life-threatening. This is described in the BOXED WARNING at the beginning of the leaflet. It is important that you read and understand the information about this serious reaction.

Symptoms of infection and inflammation:

Symptoms of infection and inflammation may develop and include:

- muscle weakness and/or muscle pain
- joint pain or swelling
- weakness beginning in the hands and feet and moving up towards the trunk of the body

- palpitations or tremor
- hyperactivity (excessive restlessness and movement).

If you get any symptoms of infection while you're taking SONKE ABACAVIR 300, tell your doctor immediately. Don't take other medicines for the infection without your doctor's advice.

See "Take special care with SONKE ABACAVIR 300".

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 stomach, or on the breasts or internal organs.
- Fatty lumps (sometimes called buffalo hump) may appear on the back of the neck.

If you notice changes in your body shape, tell your doctor immediately.

Lactic acidosis is a serious side effect:

Some people taking SONKE ABACAVIR 300 develop a condition called lactic acidosis, together with an enlarged liver.

Signs of lactic acidosis include:

- deep, rapid, difficult breathing
- drowsiness
- numbness or weakness in the limbs
- feeling sick (nausea), being sick (vomiting)
- stomach pain.
- During your treatment, your doctor will monitor you for signs of lactic acidosis. If you have any of the symptoms listed above or any other symptoms that worry you, s**ee your doctor immediately**.

Tell your doctor if you notice any of the following:

Frequent side effects:

- hypersensitivity reaction (see BOXED WARNING)
- feeling sick (nausea)
- being sick (vomiting)

- diarrhoea
- headache
- high temperature (fever)
- lack of energy (lethargy)
- fatigue
- loss of appetite
- skin rash (without any other illness).

Less frequently reported side effects:

- inflammation of the pancreas (pancreatitis)
- lactic acidosis (see "Conditions you need to look out for")
- skin rash, which may form blisters and looks like small targets (central dark spots surrounded by a paler area, with a dark ring around the edge) (erythema multiforme)
- a widespread rash with blisters and peeling skin, particularly around the mouth, nose, eyes and genitals (Stevens-Johnson syndrome), and a more severe form causing skin peeling in more than 30 % of the body surface (toxic epidermal necrolysis).

If you notice any of these symptoms contact a doctor urgently.

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.

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 ABACAVIR 300**.

5. How to store SONKE ABACAVIR 300

Store at or below 25 ºC

Store all medicines out of reach of children.

Store in the original package.

Do not use after the expiry date stated on the label.

- 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 SONKEABACAVIR 300 contains

Each tablet contains abacavir sulphate equivalent to abacavir 300 mg as the active ingredient.

The other ingredients are:

Tablet core: Colloidal silicon dioxide; magnesium stearate, microcrystalline cellulose; sodium starch glycollate

Film-coat: Hypromellose; iron oxide red; iron oxide yellow, macrogol/; polyethylene glycol 400; titanium dioxide.

The tablets are sugar free.

What SONKE ABACAVIR 300 looks like and contents of the pack

Peach coloured, capsule shaped, biconvex film coated tablets, debossed with ‘RA72’ on one side and plain on the other side with intact coating.

Cartons containing 10, 30, 60 or 100 tablets packed in PVdC coated PVC blister strips of 10’s with a backing of hard tempered aluminium foil coated with a heat seal lacquer on the inner side.

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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