PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

S4

VEXABAX Film-coated tablets

Abacavir 600 mg and lamivudine 300 mg

IMPORTANT - HYPERSENSITIVITY REACTION VEXABAX contains abacavir. Patients taking VEXABAX may develop a hypersensitivity reaction (serious allergic reaction). It is essential you read the information on this reaction in the "Take special care with VEXABAX" section of this leaflet. There is also **Alert Information** included on the VEXABAX pack, to remind you and medical staff about VEXABAX hypersensitivity. The text on the pack is shown below.

Patients taking VEXABAX may develop a hypersensitivity reaction (serious allergic reaction) which **can be life-threatening** if treatment with VEXABAX is continued. **CONTACT YOUR DOCTOR IMMEDIATELY for advice on whether you should stop taking VEXABAX 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 ill feeling.

If you have discontinued VEXABAX due to a hypersensitivity reaction, **YOU MUST NEVER TAKE** VEXABAX, or any other medicine containing abacavir again, as

within hours you may experience a life-threatening lowering of your blood pressure or death.

Read all of this leaflet carefully before you start taking VEXABAX.

- Keep this leaflet, you may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- **VEXABAX** 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 VEXABAX IS AND WHAT IT IS USED FOR:

VEXABAX contains both abacavir and lamivudine. VEXABAX belongs to a group of antiretroviral medicines called nucleoside analogue reverse transcriptase inhibitors (NRTIs) and is used in combination with other antiretrovirals to treat Human Immunodeficiency Virus (HIV) infection in adults and adolescents from 12 years of age, weighing at least 40 kg. VEXABAX reduces HIV viral load and keeps it at a low level. It also increases CD4 cell counts. Response to treatment

with VEXABAX varies between patients. Your doctor will be monitoring the effectiveness of your treatment.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE VEXABAX:

Do not take VEXABAX:

- if you are allergic to the active substances abacavir, lamivudine or any of the other ingredients in VEXABAX.
- if you have serious liver disease, VEXABAX may not be suitable for you
- if you are pregnant, intend to become pregnant or if you are breastfeeding your baby.

If you are not sure whether you should be taking VEXABAX, please discuss with your doctor before taking this medicine.

Warnings and precautions:

Take special care with VEXABAX:

Hypersensitivity reaction (serious allergic reaction):

VEXABAX 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. **Who gets these reactions?**

Anyone taking VEXABAX could develop a hypersensitivity reaction to abacavir, which could be life-threatening if they continue to take VEXABAX. Research has found that people with a gene called HLA-B (type 5701) are more likely to have a hypersensitivity reaction to abacavir. 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, be sure to tell your doctor before you take abacavir.**

What are the symptoms?

The most common symptoms of this reaction are:

- high temperature (fever) and a skin rash.

Other frequently observed signs or symptoms include:

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

Other symptoms may include:

- joint or muscle pain, discomfort, swelling of the neck, serious breathing problems and sore throat. Occasionally inflammation of the eye (conjunctivitis), ulcers in the mouth, low blood pressure or tingling or numbness of the hands or feet may occur.

When do these reactions happen?

The symptoms of this allergic reaction can occur at any time during treatment with VEXABAX. However, they usually occur in the first six weeks of treatment and get worse with continued treatment. If you are caring for a child who is being treated with VEXABAX, it is important that you understand the information about this hypersensitivity reaction. If your child gets the symptoms described below **it is essential** that you follow the instructions given.

The hypersensitivity reaction can be life-threatening or fatal if treatment with VEXABAX is continued. You should contact your doctor immediately for advice on whether you should stop taking VEXABAX 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(stomach) pain
- severe tiredness or achiness or generally ill feeling.

Your doctor may advise you to stop taking VEXABAX.

While you are taking VEXABAX, always carry the Alert information which is on the side of the pack.

If you have stopped taking VEXABAX: If you have discontinued VEXABAX due to a hypersensitivity reaction, **YOU MUST NEVER TAKE VEXABAX, or any other medicine containing abacavir** again as **within hours** you may experience a life-threatening lowering of your blood pressure or death.

If you have stopped taking VEXABAX for any reason, particularly because you think you are having side effects or for other illness:

It is important that you inform 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 VEXABAX or any other medicine containing abacavir again.** It is important that you follow this advice.

Reactions have developed in people who start taking abacavir again and had only one symptom on the Alert Information 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 VEXABAX 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 VEXABAX you should return all of your unused VEXABAX to your doctor or pharmacist for proper disposal.

The VEXABAX pack includes Alert Information on the side of the pack, to remind you and medical staff about hypersensitivity reactions. **Keep this Alert information with you at all times.**

Risk of cardiovascular events

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 VEXABAX unless your doctor advises you to do so.

Before you take VEXABAX your doctor needs to know:

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

Talk to your doctor if any of the above applies to you. You may need extra check-ups, including blood tests, while you're taking your medicine. **See Section 4 POSSIBLE SIDE EFFECTS for more information.**

Conditions you need to look out for:

Heart Disease:

There may be an increased risk for heart attacks in patients using VEXABAX.

Tell your doctor if you have heart problems, if you smoke, or have other illnesses that may increase your risk of heart disease such as high blood pressure, or diabetes. Don't stop taking VEXABAX unless your doctor advises you to do so.

Symptoms of 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 *(auto-immune 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 **POSSIBLE SIDE EFFECTS.**

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 **POSSIBLE SIDE EFFECTS.**

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. See *'Conditions you need to look out for'* in Section 4 **POSSIBLE SIDE EFFECTS.**

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). VEXABAX will not stop you passing HIV infection on to other people. To protect other people from becoming infected with HIV:

- **Use a condom** when you have oral or penetrative sex.
- **Do not risk blood transfer** - for example, don't share needles.

Other medicines and VEXABAX:

Always tell your health care professional if you are taking any other medicine. (This includes complementary or traditional medicines.) Abacavir or lamivudine in VEXABAX may interact with certain other medicines.

VEXABAX should not be taken with zalcitabine or emtricitabine, high doses of co-trimoxazole, injections of ganciclovir or foscarnet. If you are taking methadone, your doctor may need to adjust your methadone dose, as abacavir (one of the active substances in VEXABAX) increases the rate at which methadone is cleared from your body. This is unlikely to affect most methadone users.

VEXABAX with food and drink and alcohol:

VEXABAX can be taken with or without food.

Pregnancy, breastfeeding and fertility:

VEXABAX is not recommended for use in pregnant women.

If you are pregnant or planning to become pregnant soon, you must inform your doctor.

You should not breastfeed your baby while taking VEXABAX. Additionally, it is recommended that HIV infected women do not breastfeed their infants under any circumstances in order to avoid transmission of HIV from mother to child.

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking VEXABAX.

Driving and using machines:

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

3. HOW TO TAKE VEXABAX:

Do not share medicines prescribed for you with any other person. Always take VEXABAX exactly as your doctor has instructed. You should check with your doctor or pharmacist if you are unsure.

Take VEXABAX for as long as your doctor recommends. Don’t stop unless your doctor advises you to. Take great care not to miss any doses if at all possible. Swallow the tablet whole with water. The usual dose in adults and adolescents from 12 years of age, who weigh at least 40 kg, is one tablet daily.

If you take more VEXABAX 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.

If you forget to take VEXABAX:

It is important to take VEXABAX as prescribed to ensure you get maximum benefit. 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. It is important to take VEXABAX regularly because irregular intake may increase the risk of hypersensitivity reactions.

If you stop taking VEXABAX:

If you have stopped taking VEXABAX 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 VEXABAX under direct medical supervision. If your doctor thinks that there is a possibility that your symptoms were related to a hypersensitivity reaction, you may be told never to take VEXABAX or any other medicine containing abacavir again.

4. POSSIBLE SIDE EFFECTS:

VEXABAX can have side effects.

Not all side effects reported for VEXABAX are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking VEXABAX, please consult your doctor, pharmacist or other health care professional for advice.

Conditions you need to look out for:

VEXABAX may cause other conditions to develop during HIV treatment.

Hypersensitivity reaction:

VEXABAX can cause a serious allergic reaction known as a hypersensitivity reaction, see 'Hypersensitivity reaction' in 'Take special care with VEXABAX'. **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 VEXABAX:

➔ **Tell your doctor immediately**. Don't take other medicines for the infection without your doctor's advice.

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.

Lactic acidosis is serious side effect:

Some people taking VEXABAX or other medicines like it (NRTIs), 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:

➔ **See your doctor as soon as possible.**

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.

As VEXABAX contains both abacavir and lamivudine, the side effects reported for each of these have been combined.

Frequent side effects:

- headache
- feeling sick *(nausea)*
- hypersensitivity reaction *(see 'hypersensitivity reactions' section above)*
- being sick *(vomiting)*
- diarrhoea
- stomach pains
- loss of appetite
- tiredness, lack of energy
- high temperature *(fever)*
- general feeling of being unwell
- muscle pain and discomfort
- joint pain
- skin rash
- hair loss

Less frequent side effects:

Side effects that may show up in blood tests are:

- a low red blood cell count *(anaemia)* or low white blood cell count *(neutropenia or leucopenia)*
- an increase in the level of liver enzymes
- a decrease in the number of cells involved in blood clotting *(thrombocytopenia)*
- lactic acidosis (see *'Conditions you need to look out for'*)
- inflammation of the pancreas *(pancreatitis)*
- breakdown of muscle tissue

- increase in an enzyme called amylase

Frequency unknown:

- tingling or numbness of the skin, arms or legs
- 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 on large parts of your body surface *(toxic epidermal necrolysis).*
- **If you notice any of these symptoms contact a doctor urgently.**

Side effects that may show up in blood tests are:

- a failure of the bone marrow to produce new red blood cells (pure red cell aplasia). Symptoms include fatigue, shortness of breath with exertion, rapid or irregular heart rate, pale skin, frequent or prolonged infections, unexplained or easy bruising, nosebleeds and bleeding gums, prolonged bleeding from cuts, skin rash, dizziness and headache.

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

Reporting of side effects:

If you get side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects to SAHPRA via the '6.04 Adverse Drug Reaction Reporting Form', found on-line under SAHPRA'S publications: htpp://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of VEXABAX.

5. HOW TO STORE VEXABAX:

Store all medicines out of reach of children.

Store at or below 25 °C. Protect from moisture.

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 VEXABAX contains: The active substances are abacavir and lamivudine. Each VEXABAX film-coated tablet contains abacavir sulphate equivalent to abacavir 600 mg and lamivudine 300 mg. The other ingredients are cellulose microcrystalline, magnesium stearate, silica colloidal anhydrous, sodium starch glycollate.

The tablets are film-coated with a coating material containing FD&C yellow/sunset yellow FCF aluminum lake, hypromellose, macrogol/PEG 400, polysorbate 80 and titanium dioxide.

Sugar free

What VEXABAX looks like and contents of the pack:

Orange coloured capsule shaped, film coated tablets, debossed with ‘RF 90’ on one side and break line on other side.

VEXABAX tablets are available in an HDPE Bottle pack comprising of a white opaque HDPE bottle having a white polypropylene child resistant closure (with induction seal liner) or screw closure (with induction seal liner).

The bottles contain 28, 30 or 90 film-coated tablets with or without a carton.

Holder of Certificate of Registration:

Ranbaxy Pharmaceuticals (Pty) Ltd

14 Lautre Road, Stormill, Ext.1,

Roodepoort, 1724

South Africa

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Access to the corresponding Professional information:

To follow