PATIENT INFORMATION LEAFLET

Note! Please see proposed **Alert Card** on last page

SCHEDULING STATUS: S4

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM:

KAVIMUN Film-coated Tablets

Abacavir 300 mg film-coated tablet

- Read all of this leaflet carefully before you start taking **KAVIMUN**.
- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or pharmacist.
- **KAVIMUN** 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.

WARNING:

If you are a patient taking abacavir, as in **KAVIMUN,** you may develop a serious allergic reaction. It is important that you read the information on this reaction in this leaflet. There is also an Alert Card included in the **KAVIMUN** pack, to remind you and the medical staff about this medicine's serious allergic reaction. This card should be removed from the pack and kept with you at all times. The text on this card is shown below. Patients taking **KAVIMUN** may develop a serious allergic reaction which can be life-threatening if treatment with **KAVIMUN** is continued. **CONTACT A DOCTOR IMMEDIATELY** for advice on whether you should stop taking **KAVIMUN** if:

- You get a skin rash OR
- You get one or more symptoms from at least TWO of the following:
  - ► fever
  - ► shortness of breath, sore throat or a cough
  - ► nausea or vomiting or diarrhoea or abdominal pain
  - ► severe tiredness or aches or just generally feeling ill

If the **KAVIMUN** treatment has been discontinued due to an allergic reaction, **YOU MUST NEVER TAKE KAVIMUN**, or any other medicine that contains abacavir again, as **within hours** you may experience a life-threatening lowering of your blood pressure or death.

1. WHAT KAVIMUN CONTAINS:

Each film-coated tablet contains 300 mg Abacavir as the active substance.

The other ingredients are: cellulose microcrystalline, magnesium stearate, silica colloidal anhydrous, sodium starch glycolate, film-coat {hypromellose, iron oxide yellow, iron oxide red, polyethylene glycol 400, titanium dioxide}.

Sugar free

2. WHAT KAVIMUN IS USED FOR:

KAVIMUN belongs to a group of antiviral medicines, also known as antiretrovirals, called nucleoside analogue reverse transcriptase inhibitors (NRTIs). These are used to treat Human Immunodeficiency Virus (HIV) infection. **KAVIMUN** is used in combination with other antiretroviral medicines for the treatment of HIV infection.

3. BEFORE YOU TAKE KAVIMUN:

Do not take KAVIMUN:

- If you are allergic to the active ingredient abacavir, or any of the other ingredients in **KAVIMUN** tablets.
- If you are pregnant, planning to become pregnant or breast-feeding (see **Pregnancy and breast-feeding).**
- If you have end-stage kidney disease.
- If you have moderate or severe liver function impairment.

Before starting treatment with KAVIMUN, tell your doctor about all of your medical conditions, including:

- **If you have been tested and know whether or not you have a particular gene variation called HLA-B*5701.**

If you are not sure about any of these please consult your doctor.

Take Special Care with KAVIMUN:

Hypersensitivity reaction (serious allergic reaction):

If you have discontinued **KAVIMUN** because of a hypersensitivity reaction YOU MUST NEVER

TAKE **KAVIMUN** again.

Hypersensitivity to abacavir, as in **KAVIMUN**:

The most important symptoms are fever and a skin rash. Other symptoms are nausea, vomiting, diarrhoea, abdominal (stomach) pain, severe tiredness, pains in the joints or muscles, swelling of the neck, shortness of breath, cough, sore throat, headache. Inflammation of the eye, mouth ulcers and low blood pressure can also occur. **If you stopped taking KAVIMUN because of a hypersensitivity reaction, you MUST NOT take KAVIMUN or any other product containing abacavir again, as the symptoms will get worse and may be life-threatening.**

Lactic acidosis:

KAVIMUN can cause a condition called lactic acidosis, together with an enlarged liver. Lactic acidosis is caused by a build-up of lactic acid in the body. It usually develops after a few months of treatment and can be life-threatening. This serious side-effect occurs more often in very overweight people, especially women. If you have a liver disease you may also be more at risk of getting this condition when being treated with **KAVIMUN.** Your doctor will monitor you for any signs that you may be developing lactic acidosis. Signs of lactic acidosis include:

• deep, rapid, difficult breathing
• drowsiness
• numbness or weakness in the limbs
• nausea, vomiting and 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.

- If you are taking combination antiretroviral therapy for HIV you may find that your body shape changes, because of changes in fat distribution.

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

- Patients taking **KAVIMUN** may develop a condition called osteonecrosis. With this condition, parts of the bone tissue die because of reduced blood supply to the bone.

  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.

- Patients with advanced HIV infection (AIDS) have weak immune systems and are more likely to develop serious infections (opportunistic infections). When these patients start taking **KAVIMUN**, 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.

- If you have heart problems, smoke or suffer from diseases that increase your risk of heart disease, such as high blood pressure, high cholesterol or diabetes.

- **KAVIMUN** helps to control your condition but is not a cure for HIV infection. You will need to take it everyday. Do not stop **KAVIMUN** without first talking to your doctor. If you are concerned that you may be developing symptoms of a hypersensitivity reaction, call you doctor immediately who will advise you whether you need to stop taking **KAVIMUN.** You may continue to develop other infections and other illnesses associated with HIV disease. You should therefore keep in regular contact with your doctor while taking **KAVIMUN.**

- Treatment with **KAVIMUN** has not been shown to decrease the risk of passing HIV infection on to others by sexual contact or by blood contamination. You must continue to use appropriate precautions to prevent this

  To protect other people from becoming infected with HIV:

  - **a condom must be used** when someone has oral or penetrative sex
  - **blood transfer should be avoided** – for example, needles must not be shared

Taking KAVIMUN with food and drink:

You can take **KAVIMUN** with or without food.

Pregnancy and breast-feeding:

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

Pregnancy:

The safe use of this **KAVIMUN** in human pregnancy has not been established.

You should therefore not take **KAVIMUN** if you are pregnant.

Breast-feeding:

After taking **KAVIMUN**, the active ingredient abacavir is likely to be found in human breast milk.

You are therefore advised not to breast-feed while taking **KAVIMUN**.

Driving and using machinery:

KAVIMUN is unlikely to affect your ability to operate machinery or drive. If you have any concerns, tell your doctor.

Taking other medicines with KAVIMUN:

If you are taking other medicines on a regular basis, including complementary or traditional medicines, the use of KAVIMUN with these medicines may cause undesirable interactions. Please consult your doctor, pharmacist or other healthcare professional for advice.

If you are taking the following medicines your doctor may want to adjust the dosage of these medicines or of **KAVIMUN:**

- Rifampicin (this is used to treat serious bacterial infections)
- Phenobarbital (this is used to treat epilepsy)
- Phenytoin (this is used to treat epilepsy)
- Methadone (this medicine is used to prevent withdrawal symptoms in people who are addicted to opioid substances such as heroin)

4. HOW TO TAKE KAVIMUN:

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

Always take **KAVIMUN** exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

KAVIMUN can be taken with or without food.

The usual dose in adults and adolescents over 12 years of age is 300 mg (one tablet) twice daily or 600 mg daily.

Take the doses 12 hours apart.

Swallow the tablet whole with water or another drink

Your doctor will tell you how long your treatment with **KAVIMUN** will last.

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

If you take more KAVIMUN than you should:

Accidently taking too much of **KAVIMUN** is unlikely to cause serious side-effects, but tell your doctor or pharmacist or contact your nearest hospital emergency department for further advice.

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

If you forget to take KAVIMUN:

If you forget to take a dose of **KAVIMUN**, take it as soon as you remember and then continue as before.

Do not take a double dose to make up for missed individual doses.

If you have stopped taking **KAVIMUN** for any reason, especially if you think you are having side-effects, or for another illness, it is important that you contact your doctor before restarting. In some cases you doctor will ask you to restart **KAVIMUN** under direct medical supervision or where medical care can be easily accessed by yourself or others. If your doctor thinks that there is a possibility your symptoms were related to a hypersensitivity reaction, you may be told not to take **KAVIMUN** or any other medicine containing abacavir ever again.

5. POSSIBLE SIDE-EFFECTS

KAVIMUN can have side-effects.

Get emergency medical help if you notice any of these signs of an allergic reaction:

• some patients treated with KAVIMUN and who did not have a gene called HLA-B*5701 also developed a serious allergic reaction.

The hypersensitivity reaction can be life-threatening or fatal if treatment with KAVIMUN is continued. You should contact a doctor immediately for advice on whether you should stop taking KAVIMUN if:

• you get a skin rash OR

• 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 aches and pains or generally feeling ill

Call a doctor at once if you notice any of these serious side-effects:

- inflammation of the eye (conjunctivitis)
- mouth ulcers
- low blood pressure
- headache
- lactic acidosis

Signs of lactic acidosis include:

• deep, rapid, difficult breathing

• drowsiness

• numbness or weakness in the limbs

• nausea and vomiting

• stomach pain

Other side-effects include:

Frequent:

- anorexia
- various blood disorders
- irritated or runny nose
- skin rash
- joint pains
- disease of the lymph
- muscle pain and discomfort
- kidney failure

Less frequent:

- sensation of weakness in the limbs
- 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 large areas of the body surface (toxic epidermal necrolysis)
- inflammation of the pancreas (pancreatitis)
- breakdown of muscle tissue

Frequency not known:

- redistribution/accumulation of body fat (fat may be lost from the legs, arms or face; extra fat may build up around the tummy or on the breasts; fatty lumps (sometimes called buffalo hump) may appear on the back of the neck)
- liver disorders, such as jaundice, enlarged liver or fatty liver, lactic acidosis, severe hepatomegaly with steatosis
- excess of triglycerides (fat) in the blood
- increase of sugar in the blood

- hyperlactataemia

Not all side-effects reported for **KAVIMUN** are included in this leaflet. Should your general health worsen while taking **KAVIMUN**, please consult a medical practitioner, pharmacist or other healthcare professional for advice.

6. STORING AND DISPOSING OF KAVIMUN:

KEEP ALL MEDICINES OUT OF REACH AND SIGHT OF CHILDREN.

Store at or below 30 ^{0}C.

Store the tablets in the original container.

Keep the container in the outer container

Keep the container tightly closed.

Do not store in bathrooms.

Do not use after the expiry date stated on the label/carton/bottle.

Return all unused medicines to your pharmacist.

Do not dispose of unused medicines in drains or sewerage systems (e.g. toilets).

7. PRESENTATION OF KAVIMUN:

KAVIMUN is packed in a white coloured HDPE bottle with white opaque polypropylene (PP) screw cap with induction sealing liner, packaged in a carton or **KAVIMUN** is packed in a round blue opaque high density polyethylene (HDPE) bottle with blue opaque polypropylene (PP) screw cap with induction sealing liner, packaged in a carton or **KAVIMUN** is packed in a PVC/PVdC blister pack (marketable pack) comprising of a clear, transparent, PVC film coated with PVdC on one side (i.e., PVC/PVdC) and aluminium foil coated with VMCH heat seal lacquer on other side. Blisters are presented in a carton. Pack size of 56's or 60's.

8. IDENTIFICATION OF KAVIMUN:

Peach coloured, capsule shaped biconvex film-coated tablet, debossed with “M110” on one side and plain on the other.

9. REGISTRATION NUMBER:

46/20.2.8/0979

10. NAME AND ADDRESS OF REGISTRATION HOLDER:

Viatris Healthcare (Pty) Ltd.

4 Brewery Street

Isando, Gauteng,

1601

11. DATE OF PUBLICATION:

06 March 2014

(Front of Alert Card):

IMPORTANT ALERT CARD
KAVIMUN (Film-coated Tablets)
Carry this card with you at all times

Patients taking **KAVIMUN** may develop a hypersensitivity reaction (serious allergic reaction) that can be life-threatening if treatment with **KAVIMUN** is continued. CONTACT YOUR DOCTOR IMMEDIATELY for advice on whether you should stop taking **KAVIMUN** 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, cough or sore throat,
   - nausea, vomiting, diarrhoea or stomach ache
   - severe tiredness or aches or general ill feeling

If you have discontinued **KAVIMUN** due to this reaction, YOU MUST NEVER take **KAVIMUN** again as within hours you may experience a life-threatening lowering of your blood pressure or death.

Your risk of this allergic reaction is much higher if you have a gene variation called HLA-B*5701 than if you do not. Your doctor can determine with a blood test if you have this gene variation.

(see reverse of card)

(Back of Alert Card):

You should contact your Doctor immediately if you think you are having a hypersensitivity reaction to **KAVIMUN**. Write your Doctor's details below:

Doctor:_____ Tel: _____

<u>If your doctor is not available, you must urgently seek alternative medical advice (e.g. the emergency unit of the nearest hospital).</u>