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

Read all of this leaflet carefully before you start giving Kavimun Paed.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- Kavimun Paed has been prescribed for your child and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as the patient's.
- **If any of the side-effects get serious or if you notice any side-effects not listed in this leaflet, please tell your doctor or pharmacist.**

SCHEDULING STATUS

S4

PROPRIETARY NAME AND DOSAGE FORM:

KAVIMUN PAED Film-coated Tablets

Abacavir

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WARNING:
LACTIC ACIDOSIS AND SEVERE HEPATOMEGALY WITH STEATOSIS, INCLUDING FATAL CASES, HAVE BEEN REPORTED WITH THE USE OF NUCLEOSIDE ANALOGUES ALONE OR IN COMBINATION WITH OTHER ANTIRETROVIRALS.

Patients taking **KAVIMUN PAED** may develop a serious allergic reaction. It is important that the parent or a responsible person read the information on this reaction in the **SPECIAL WARNING** section of this leaflet. There is also an Alert Card included in the **KAVIMUN PAED** pack, to remind the parent or responsible person and medical staff about this medicine's serious allergic reaction. This card should be removed from the pack and kept with the patient at all times. The text on this card is shown below. Patients taking **KAVIMUN PAED** may develop a serious allergic reaction which can be life-threatening if treatment with **KAVIMUN PAED** is continued.

CONTACT A DOCTOR IMMEDIATELY for advice on whether you should stop giving **KAVIMUN PAED** if:

- The child gets a skin rash OR
- The child gets 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 PAED** treatment has been discontinued due to an allergic reaction, **THE CHILD MUST NEVER TAKE KAVIMUN PAED**, or any other medicine that contains abacavir again, as **within hours** the child may experience a life-threatening lowering of their blood pressure or death.

1. WHAT KAVIMUN PAED CONTAINS

Each film-coated tablet contains 60 mg abacavir as the active ingredient.

Sugar free

The other ingredients in the tablets are: cellulose microcrystalline, silica colloidal anhydrous, magnesium stearate, sodium starch glycolate: Film-coating: hypromellose, titanium dioxide, polyethylene glycol 400, iron oxide yellow, iron oxide red

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2. WHAT KAVIMUN PAED IS USED FOR:

KAVIMUN PAED 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 PAED** is used in combination with other antiretroviral medicines for the treatment of HIV infection.

3. BEFORE GIVING KAVIMUN PAED:

Do not give KAVIMUN PAED:

- to a child who has an allergy to the active ingredient abacavir, or any of the other ingredients in **KAVIMUN PAED** tablets
- to a child who has or *ever* had liver disease, including hepatitis B or C
- to a child who is pregnant, planning to become pregnant or breast-feeding (see **Pregnancy and breast-feeding)**

Before starting treatment with KAVIMUN PAED, tell your doctor about all of your child's

medical conditions, including if:

- **your child has been tested and know whether or not he/she has a particular gene variation called HLA-B*5701**
- **your child has heart problems, smoke or suffer from diseases that increase the risk of heart disease e.g. high blood pressure, high cholesterol or diabetes**

If you are not sure about any of these please consult your doctor.
Take special care with KAVIMUN PAED:

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Hypersensitivity reaction (serious allergic reaction): The most important symptoms of this reaction are high temperature (fever) and a skin rash. Other frequently seen signs or symptoms are nausea, vomiting, diarrhoea, abdominal pain, shortness of breath, cough, headache, and severe tiredness. Other symptoms may be joint or muscle pain, swelling of the neck and sore throat. Occasionally swelling of the eye, ulcers in the mouth or low blood pressure may occur. The symptoms of this allergic reaction can occur at any time during treatment with **KAVIMUN PAED**. 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 **KAVIMUN PAED** it is important you understand the information about this allergic reaction. If the child gets the symptoms described below, it is essential you follow the instructions given. **The hypersensitivity reaction can be life-threatening or fatal if treatment with KAVIMUN PAED is continued. You should contact your doctor immediately for advice on whether you should stop treatment with KAVIMUN PAED (see boxed WARNING at the start of this text).**

If your child stopped taking **KAVIMUN PAED** because of a hypersensitivity reaction YOUR CHILD MUST NEVER TAKE **KAVIMUN PAED** or any other medicine containing abacavir again as within hours they may experience a life-threatening lowering of their blood pressure or death. Occasionally life-threatening allergic reactions have occurred when **KAVIMUN PAED** was restarted in patients who got only one of the symptoms on the alert card before stopping.

If your child is allergic to **KAVIMUN PAED** you should return all unused tablets to the doctor or pharmacist for proper disposal.

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- **KAVIMUN PAED** can cause a condition called lactic acidosis, together with an enlarged

  liver. This rare but serious side effect occurs more often in overweight people, especially females. If your child has a liver disease the risk of getting this condition when being treated with **KAVIMUN PAED** is increased. The doctor will monitor your child for any signs suggesting the development of lactic acidosis.
- **KAVIMUN PAED** helps to control HIV infection but is not a cure. The child will need to take it everyday. The child must not stop taking **KAVIMUN PAED** without you first talking to the doctor. If you are concerned that the child may be developing symptoms of a hypersensitivity reaction, call the doctor immediately who will advise whether you need to stop giving **KAVIMUN PAED**. The child may continue to develop other infections and other illnesses associated with HIV disease. You should therefore keep in regular contact with the doctor while giving **KAVIMUN PAED** to your child.
- The child's body shape may change. If the child is taking combination antiretroviral therapy for HIV you may find that the body shape changes, because of changes in fat distribution.
- You must contact the doctor if the child experiences joint aches and pain, joint stiffness or difficulty in movement.
- Treatment with **KAVIMUN PAED** has not been shown to decrease the risk of passing HIV infection on to others by sexual contact or by blood transfer. If the child is sexually active the child should 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

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- blood transfer should be avoided – for example, needles must not be shared.

Kavimun Paed with food and drink:

Your child can take **KAVIMUN PAED** with or without food.

Pregnancy and breastfeeding

If the patient is pregnant or breast-feeding a baby while taking Kavimun Paed, please consult the doctor, pharmacist, or other healthcare professional for advice.

Pregnancy:

The safe use of **KAVIMUN PAED** in human pregnancy has not been established. The doctor will advise whether the patient should continue to take **KAVIMUN PAED**.

Breast-feeding:

After receiving **KAVIMUN PAED**, the active ingredient abacavir is likely to be found in human breast milk. The patient is therefore advised not to breast-feed while taking **KAVIMUN PAED**.

Driving and using machinery

KAVIMUN PAED is for use in children and they are unlikely to operate machinery or drive a motor vehicle. If there are any concerns, tell the doctor.

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Taking KAVIMUN PAED with other medicines:

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

It is important to tell the doctor about all the medicines your child is taking or have taken, including those you have bought yourself.

If your child is taking the following medicines your doctor may want to adjust the dosage of these medicines or of **KAVIMUN PAED:**

- 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)
- Trimethoprim + sulfamethoxazole (co-trimoxazole) (these are two antibiotics which can be given together to treat some types of infections)
- Ganciclovir (this is an antiviral medicine used to treat infections caused by a virus called cytomegalovirus)
- Foscarnet (this belongs to a group of medicines called anti-viral medicines. It works by stopping viruses from multiplying in number and is used to treat different infections caused by viruses)

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- Zalcitabine (this is used in combination with other medicines for treatment of HIV infection).

4. HOW TO GIVE KAVIMUN PAED:

Do not share medicines prescribed for the patient with others.

Always give **KAVIMUN PAED** exactly as the doctor has instructed you. You should check with the doctor or pharmacist if you are not sure.

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

KAVIMUN PAED can be given with or without food.

The recommended dose of **KAVIMUN PAED** is based on the child's body weight and will be determined by the doctor. The doctor will also explain how and when the tablets must be taken.

Children younger than three months: KAVIMUN PAED must not be given to children younger than three months.

If you give more KAVIMUN PAED than you should:

If you accidentally give the child too many **KAVIMUN PAED** tablets contact the nearest hospital emergency department for further advice.

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In the event of overdosage, speak to a doctor or pharmacist. If neither is available, go to the nearest hospital or poison control centre for help.

If you forget to give KAVIMUN PAED:

If you forget to give the child a dose of **KAVIMUN PAED,** give it as soon as you remember and then continue as before.

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

If you have stopped giving **KAVIMUN PAED** for any reason, especially if you think the child is having side-effects, or for another illness, it is important that you contact a doctor before again giving **KAVIMUN PAED** to the child. In some cases the doctor will ask you to restart **KAVIMUN PAED** under direct medical supervision or where medical assistance is available.

If your doctor thinks that there is a possibility the symptoms were related to a hypersensitivity reaction, you may be told not to give the child **KAVIMUN PAED** or any other medicine containing abacavir ever again.

5. POSSIBLE SIDE-EFFECTS

KAVIMUN PAED can cause side-effects.

Not all side-effects reported for KAVIMUN PAED are included in this leaflet. Should the child's general health worsen while taking KAVIMUN PAED, please consult a doctor, pharmacist or other healthcare professional for advice.

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

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

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

  - **the child gets a skin rash OR**
  - **the child gets 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

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Other side-effects include:

Frequent:

- anorexia
- difficulty in sleeping
- cough
- irritated or runny nose
- skin rash
- hair loss
- joint pains
- muscle pain and discomfort

Less frequent:

- a low red blood cell count (anaemia) or low white blood cell count (neutropenia)
- 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)
- sensation of weakness in the limbs
- increase in an enzyme called amylase
- liver disorders, such as jaundice, enlarged liver or fatty liver, hepatitis
- 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)

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- breakdown of muscle tissue

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

6. STORAGE AND DISPOSAL OF KAVIMUN PAED:

KEEP ALL MEDICINES OUT OF REACH AND SIGHT OF CHILDREN.

Store at or below 30 °C.

Store the tablets in the original container.

Keep the container in the outer container.

Protect from light.

Do not use if seal over bottle opening is broken or missing.

Do not remove from cs1rton until required for use.

Keep the container tightly closed.

Do not store in bathrooms.

Do not give 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:

KAVIMUN PAED film-coated tablets are supplied as follows:

High Density Polyethylene (HOPE) bottle Pack (marketable pack) comprising of a white coloured HDPE bottle with white opaque polypropylene (PP) screw cap with induction sealing liner, packed in a carton with a package insert in a pack size of 60.

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PVC/PVdC blister pack (marketable pack) comprises of clear, transparent, PVC film coated with PVdC on one side (i.e., PVC/PVdC) and hard tempered aluminium foil coated with VMCH heat seal lacquer on other side packed in a carton with a package insert in a pack size of 60.

8. IDENTIFICATION OF KAVIMUN PAED:

Peach coloured, round biconvex film coated tablet, debossed with "M20" on one side and break line on the other side

9. REGISTRATION NUMBER/REFERENCE NUMBER:

46/20.2.8/0006

10. NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE:

Viatris Healthcare (Pty) Ltd.

4 Brewery Street, Isando,

Gauteng, 1601

11. DATE OF PUBLICATION OF THE PATIENT INFORMATION LEAFLET:

14 September 2012

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(Front of Alert Card):

IMPORTANT ALERT CARD

KAVIMUN PAED (Film-coated Tablets)

The patient must carry this card with them at all times

Patients taking **KAVIMUN PAED** may develop a hypersensitivity reaction (serious allergic reaction) that can be life-threatening if treatment with **KAVIMUN PAED** is continued. YOU MUST CONTACT A DOCTOR IMMEDIATELY for advice on whether you should stop giving **KAVIMUN PAED** if:

1. The patient gets a skin rash OR
2. The patient gets 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 the patient has discontinued **KAVIMUN PAED** due to this reaction, THEY MUST NEVER RECEIVE **KAVIMUN PAED** again as within hours they may experience a life-threatening lowering of their blood pressure or death.

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

(see reverse of card)

(Back of Alert Card):

You should contact the patient's Doctor immediately if you think they are having a

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hypersensitivity reaction to **KAVIMUN PAED.** Write the Doctor's details below:

Doctor:_____ **Tel:**_____

If the doctor is not available, you must urgently seek alternative medical advice for the patient (e.g. the emergency unit of the nearest hospital).