APPROVED INFORMATION LEAFLET

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

SCHEDULING STATUS: S4

PROPRIETARY NAME AND DOSAGE FORM:

DUMIVA film-coated tablets

Abacavir/lamivudine

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 **DUMIVA** film-coated tablets which contain abacavir and lamivudine may develop a hypersensitivity reaction (serious allergic reaction) which can be life-threatening and can cause death, if treatment with **DUMIVA** is continued. It is essential that you read the information on this reaction in this leaflet under the heading "Take special care with **DUMIVA"**. There is also an alert card included in the **DUMIVA** pack to remind you and medical staff about **DUMIVA'**s hypersensitivity. 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 **DUMIVA** may develop a hypersensitivity reaction (serious allergic reaction) which can be life-threatening if treatment with **DUMIVA** is continued.
CONTACT YOUR DOCTOR IMMEDIATELY for advice on whether you should stop taking **DUMIVA** if:

- you get a skin rash OR
- you get one or more symptoms from at least TWO of the following groups:
  - shortness of breath, sore throat or cough
  - nausea and vomiting or diarrhoea or abdominal pain
  - severe tiredness or achiness or general ill feeling

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

1. WHAT DUMIVA CONTAINS:

DUMIVA consists of abacavir and lamivudine in one film-coated tablet.

Each film-coated tablet contains:
Abacavir sulfate equivalent to abacavir 600 mg
Lamivudine 300 mg
Sugar free

The other ingredients are:

Microcrystalline cellulose, colloidal silicon dioxide, magnesium stearate, sodium starch glycolate,

Opadry yellow

2. WHAT DUMIVA IS USED FOR:

DUMIVA 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. **DUMIVA** is used in combination with other antiretroviral medicines for the treatment of HIV infection in adults and adolescents from 12 years of age. **DUMIVA** is always used with other anti-HIV-1 medicines.

3. BEFORE TAKING DUMIVA:

Do not take DUMIVA:

- If you have previously suffered an allergic reaction to any of the active ingredients abacavir or lamivudin or any other constituent of **DUMIVA**
- If you have liver disease
- If you have kidney disease
- If you are taking emtricitabine (a medicine to treat HIV infection)

Before starting DUMIVA, 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**
- **you are pregnant, planning to become pregnant or breast-feeding**
- **you have heart problems, smoke or suffer from diseases that increase your 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 DUMIVA:

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 **DUMIVA**. 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 **DUMIVA** it

is important you understand the information about this hypersensitivity reaction. If your 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 DUMIVA is continued. You should contact your doctor immediately for advice on whether you should stop taking DUMIVA if:**

- **you get a skin rash OR**
- **you get one or more symptom 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 general ill feeling

If you have discontinued **DUMIVA** because of a hypersensitivity reaction YOU MUST NEVER TAKE **DUMIVA** or any other medicine containing abacavir again as within hours, you may experience a life-threatening lowering of your blood pressure or death. Occasionally life-threatening hypersensitivity reactions have occurred when **DUMIVA** was restarted in patients who got only one of the symptoms on the alert card before stopping.

If you are hypersensitive to **DUMIVA** you should return all unused tablets to your doctor or pharmacist for proper disposal.

DUMIVA can cause a condition called lactic acidosis, together with an enlarged liver. This rare but serious side-effect occurs more often in women. If you have liver disease you may also be more at risk of getting this condition while you are being treated with **DUMIVA**. Your doctor will monitor you for any signs that you may be developing lactic acidosis.

- If you have ever had liver disease, including hepatitis B or C (if you have hepatitis B infection, do not stop taking **DUMIVA** without your doctor's advise, as your hepatitis may come back)
- If you are very overweight (especially if you are a woman)
- Your body shape may change. If you are taking combination antiretroviral therapy for HIV you may find that your body shape changes, because of changes in fat distribution

- You must contact your doctor if you experience joint aches and pain, joint stiffness or difficulty in movement
- **DUMIVA** helps to control your condition but is not a cure for HIV infection. You will need to take it everyday. Do not stop **DUMIVA** without first talking to your doctor. If you are concerned that you may be developing symptoms of a hypersensitivity reaction (see above), call your doctor immediately who will advise you whether you need to stop taking **DUMIVA**
- 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 **DUMIVA**
- Treatment with **DUMIVA** has not been shown to decrease the risk of passing HIV infection on to others by sexual contact or by blood transfer. You should continue to use appropriate precautions to prevent this

  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, do not share needles

Taking DUMIVA with food and drink:

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

Pregnancy and breast-feeding:

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

Pregnancy: The safe use of this medicine in human pregnancy has not been established. Your doctor will advise whether you should continue to take **DUMIVA**.

Breast-feeding: After taking **DUMIVA** it is likely to be found in human breast milk. You are therefore advised not to breast-feed while taking **DUMIVA**.

Driving and using machinery:

DUMIVA is unlikely to affect your ability to operate machinery or drive.

However, do not operate machines or drive unless you are feeling well.

If you have any concerns, tell your doctor.

Taking DUMIVA with other medicines:

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

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

Interactions relevant to **DUMIVA**:

- Rifampicin (used to treat TB)
- Phenobarbital (used to treat epilepsy)
- Phenytoin (used to treat epilepsy)
- Methadone (medicine used to prevent withdrawal symptoms in people who are addicted to opioid substances such as heroin)
- Trimethoprim + sulfamethoxazole (co-trimoxazole) (two antibiotics which can also be given together to treat some types of infections)
- Ganciclovir (antiviral medicine used to treat infections caused by a virus called cytomegalovirus)
- Foscarnet (belongs to a group of medicines called anti-viral medicines.
- Zalcitabine (used in combination with other medicines for HIV infection)

4. HOW TO TAKE DUMIVA:

Your doctor will decide on the dosage which is right for you. Always take **DUMIVA** 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 this medicine is too strong or too weak, talk to your doctor or pharmacist.

Treatment should be prescribed and initiated by a medical practitioner experienced in the management of HIV infection.

DUMIVA Tablets can be taken with or without food.

If you forget to take the DUMIVA Tablets:

If you forget to take a dose of **DUMIVA** Tablets, 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 **DUMIVA** for any reason, especially if you think you are having side effects, or for other illness, it is important that you contact your doctor before restarting. In some cases you doctor will ask you to restart **DUMIVA** 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 hypersensitivity reaction, you may be told never to take **DUMIVA** or any other medicine containing abacavir again.

Do not share medicines prescribed for you with others.

If you take more DUMIVA than you should:

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

5. POSSIBLE SIDE-EFFECTS:

DUMIVA can cause side-effects.

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

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

Some patients treated with DUMIVA and 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 DUMIVA is continued. You should contact your doctor immediately for advice on whether you should stop taking DUMIVA if:

- **you get a skin rash OR**
- **you get one or more symptom 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 your doctor at once if you have any of these serious side-effects:

- swelling of the eye
- mouth ulcers
- low blood pressure
- headache

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)
- lactic acidosis (is more likely to develop in people who have liver disease or in very overweight people, especially women). It can be life-threatening, causing failure of internal organs.
- 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 more than 30 % of the body surface (toxic epidermal necrolysis)

- inflammation of the pancreas (pancreatitis)

- breakdown of muscle tissue

6. STORAGE AND DISPOSAL INFORMATION:

KEEP ALL MEDICINES OUT OF REACH AND SIGHT OF CHILDREN.

Store at or below 30 ^{0}C. Protect from light.

Store the tablets in the original container.

Keep the blisters in the outer carton until required for use.

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 DUMIVA:

DUMIVA is presented in the following:

High Density Polyethylene (HDPE) bottle pack (marketable pack) comprising of a round wide mouth white HDPE bottle with white opaque polypropylene (PP) screw cap with aluminium induction sealing wad with a package insert in an outer carton. Pack size of 28's or 30.

High Density Polyethylene (HDPE) bottle pack (marketable pack) comprising of a blue wide mouth blue opaque HDPE bottle with blue opaque polypropylene screw cap with aluminium induction sealing liner wad with a package insert in an outer carton. Pack size of 28's or 30.

PVC/Aclar blister pack (marketable pack) comprises of clear, transparent, PVC film coated with Aclar on one side (i.e. PVC/Aclar) and hard tempered aluminium foil (coated with VMCH heat seal lacquer) on other side with a package insert in an outer carton. Pack size of 28's or 30.

8. IDENTIFICATION OF DUMIVA:

Yellow coloured, biconvex, film-coated tablet, debossed with "M157" on one side and plain on the other side.

9. REGISTRATION NUMBER/REFERENCE NUMBER:

46/20.2.8/0012

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

Viatris Healthcare (Pty) Ltd

4 Brewery Street

Isando,

Gauteng, 1609

11. DATE OF PUBLICATION OF THE PATIENT INFORMATION LEAFLET:

26 October 2012

For Alert Card – see next page

(Front of Alert Card):

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

Patients taking **DUMIVA** may develop a hypersensitivity reaction (serious allergic reaction) that can be life-threatening if treatment with **DUMIVA** is continued. CONTACT YOUR DOCTOR IMMEDIATELY for advice on whether you should stop taking **DUMIVA** 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 stomachache
   - severe tiredness or aches or general ill feeling

If you have discontinued **DUMIVA** due to this reaction, YOU MUST NEVER take **DUMIVA** 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)

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(Back of Alert Card):

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

Doctor:_____ **Tel:** _____

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