

<i>Applicant/PHCR:</i>	Macleods Pharmaceuticals SA (Pty) Ltd
<i>Product Name:</i>	Abacavir 600 mg and Lamivudine 300 mg Tablets
<i>Active Ingredient:</i>	Abacavir sulphate and Lamivudine
<i>Dosage Form:</i>	Film-coated tablet
<i>Date:</i>	06 th April 2022

CLEAN AMENDED PROPOSED PATIENT INFORMATION LEAFLET

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SCHEDULING STATUS: **S4**

VIRULATE 600 / 300 (Film-coated tablet)

Abacavir 600 mg and lamivudine 300 mg

Sugar-free

IMPORTANT - HYPERSENSITIVITY REACTION

VIRULATE contains abacavir. Patients taking **VIRULATE** may develop a hypersensitivity reaction (serious allergic reaction). It is essential you read the information on this reaction in the "Take special care with **VIRULATE**" section of this leaflet. There is also an **Alert Card** included in the **VIRULATE** pack, to remind you and medical staff about **VIRULATE** 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 **VIRULATE** may develop a hypersensitivity reaction (serious allergic reaction) which **can be life-threatening** if treatment with **VIRULATE** is continued.

CONTACT YOUR DOCTOR IMMEDIATELY for advice on whether you should stop taking VIRULATE 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 **VIRULATE** due to a hypersensitivity reaction, **YOU MUST NEVER TAKE VIRULATE**, or any other medicine containing abacavir again, as **within hours** you may experience a life-threatening lowering of your blood pressure or death.

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Read all of this leaflet carefully before you start taking VIRULATE

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, ~~or your~~ pharmacist, nurse or other healthcare provider.
- **VIRULATE** 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 **VIRULATE** is and what it is used for
2. What you need to know before you take **VIRULATE**
3. How to take **VIRULATE**
4. Possible side effects
5. How to store **VIRULATE**
6. Contents of the pack and other information

1. What **VIRULATE** is and what it is used for

VIRULATE contains both abacavir and lamivudine. **VIRULATE** 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.

2. What you need to know before you take **VIRULATE**

Do not take **VIRULATE**:

- If you are hypersensitive (allergic) to the active substances abacavir, lamivudine or any of the other ingredients in **VIRULATE**.
- If you have serious liver disease, **VIRULATE** may not be suitable for you.
- If you are below 12 years of age and or weigh less than 40 kg.
- If you are pregnant, intend to become pregnant or if you are breastfeeding your baby.

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- If you are taking the following medicines:
 - cladribine (for hairy cell leukemia),
 - zalcitabine or emtricitabine (for HIV infection)

Warnings and precautions

Tell your doctor or healthcare professional before you take **VIRULATE**:

Take special care with **VIRULATE**:

Hypersensitivity reaction (serious allergic reaction):

VIRULATE 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 **VIRULATE** could develop a hypersensitivity reaction to abacavir, which could be life-threatening if they continue to take **VIRULATE**.

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

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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 **VIRULATE**. 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 **VIRULATE**, 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 VIRULATE is continued. You should contact your doctor immediately for advice on whether you should stop taking VIRULATE 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 **VIRULATE**.

Always carry your Alert Card while you are taking VIRULATE.

If you have stopped taking VIRULATE:

If you have discontinued **VIRULATE** due to a hypersensitivity reaction, **YOU MUST NEVER TAKE VIRULATE, 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 **VIRULATE** 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

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thinks there is a possibility that they were related, **you may be told never to take VIRULATE 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 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 **VIRULATE** 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 **VIRULATE** you should return all of your unused **VIRULATE** to your doctor or pharmacist for proper disposal.

The **VIRULATE** pack includes an Alert Card, to remind you and medical staff about hypersensitivity reactions. **Detach this card and keep it with you at all times**.

- Long term use of **VIRULATE** may lead to an increase of acid in your body, and includes signs such as nausea, vomiting, stomach pain and cramps, weight loss, shortness of breath or fast breathing and fatigue. You may have a condition known as "lactic acidosis". Stop taking **VIRULATE** and consult your doctor immediately.
- **VIRULATE** may cause mitochondrial dysfunction which leads to poor growth, developmental delays and muscle weakness in infants exposed to **VIRULATE**. Take your child, to your doctor immediately if your child appears pale, weak, sleepy all the time, is breathing faster, the heart is beating faster, the child does not appear to be putting on weight, is vomiting, has fever, sore throat, mouth ulcers, appears stiff, has convulsions (fits) or behaving abnormally. Your doctor will perform additional medical and laboratory tests on your child.
- **VIRULATE** may cause inflammation of the pancreas. Inform your doctor if you experience severe upper stomach pain with nausea (feeling sick) and vomiting.
- **VIRULATE** may change your body shape, by changing the way body fat is distributed. You may lose fat from your legs, arms and face and/or gain fat around the abdomen (tummy) and internal

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organs; get larger breasts or fatty lumps on the back of the neck (buffalo hump). If you notice changes in your body shape, tell your doctor.

- If you are with advanced HIV infection (AIDS), you have a weak immune system and are more likely to develop serious infections (opportunistic infections). When you 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).

If you notice signs of inflammation or infection, or deterioration thereof, tell your doctor at once.

- Some patients taking combination antiretroviral therapy may develop a bone disease called osteonecrosis (death of bone tissue caused by loss of blood supply to the bone). Signs of osteonecrosis are joint stiffness, aches and pains (especially of the hip, knee and shoulder) and difficulty in movement. If you notice any of these symptoms inform your doctor.
- If you have ever had liver disease, including hepatitis B or C then talk to your doctor. You may need extra check-ups, including blood tests, while taking your medication.
- There may be an increased risk for heart attacks in patients using **VIRULATE**. 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 **VIRULATE** unless your doctor advises you to do so.
- You will need to take **VIRULATE** every day. **VIRULATE** helps to control your condition and delay disease progression, but it is not a cure for HIV infection. You may continue to develop other infections and other illnesses associated with HIV disease. You should keep in regular contact with your doctor. Do not stop taking your medicine without first talking to your doctor.
- **VIRULATE** 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.

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- **VIRULATE** may increase weight, blood cholesterol, triglyceride, lactic acid, sugar levels and cause insulin resistance. Your doctor will perform blood tests at regular intervals to monitor cholesterol, triglyceride, lactic acid and sugar levels.

Other medicines and VIRULATE:

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

- **VIRULATE** should not be taken with cladribine (for hairy cell leukemia), zalcitabine, emtricitabine (for HIV infection), high doses of co-trimoxazole (antibiotic)
- Tell your doctor if you are taking methadone (used to treat addiction), as your doctor may need to change your methadone dose.
- Tell your doctor if you are taking phenytoin (for epilepsy). Your doctor may need to monitor you while you are taking **VIRULATE**.
- Medicines (usually liquids) containing sorbitol and other sugar alcohols (such as xylitol, mannitol, lactitol or maltitol), if taken regularly.

VIRULATE with food and drink and alcohol

VIRULATE can be taken with or without food.

Pregnancy, breastfeeding and fertility:

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

You should not take VIRULATE if you are pregnant.

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You should not breastfeed your baby while taking **VIRULATE**. 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.

Driving and using machinery:

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

How to take VIRULATE:

- Do not share medicines prescribed for you with any other person.
- Always take **VIRULATE** exactly as your doctor has instructed. You should check with your doctor or pharmacist if you are unsure.
- Take **VIRULATE** for as long as your doctor recommends. Do not 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 VIRULATE than you should:

In the event of overdosage consult your doctor or pharmacist. If neither is available contact the nearest hospital or poison control center.

If you forget to take VIRULATE:

It is important to take **VIRULATE** 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 **VIRULATE** regularly because irregular intake may increase the risk of hypersensitivity reactions.

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If you stop taking VIRULATE:

If you have stopped taking **VIRULATE** 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 **VIRULATE** 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 **VIRULATE** or any other medicine containing abacavir again.

3. Possible side effects:

VIRULATE can have side effects.

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

If any of the following happens, stop taking **VIRULATE** and tell your doctor immediately or go to the casualty department at your nearest hospital:

- A serious allergic reaction known as a hypersensitivity reaction, see 'Hypersensitivity reaction' in 'Take special care with **VIRULATE**'. It is important that you read and understand the information about this serious reaction.
- Hives; swelling of the face, lips, mouth, tongue or throat which may cause difficulty in swallowing or breathing.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to **VIRULATE**. You may need urgent medical attention or hospitalization.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- Adult respiratory distress syndrome (ARDS) occurs when fluid builds up in the tiny, elastic air sacs (alveoli) in your lungs. The fluid keeps your lungs from filling with enough air, which means less oxygen reaches your bloodstream. This deprives your organs of the oxygen they need to function.

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- Respiratory failure (a condition in which your blood doesn't have enough oxygen or has too much carbon dioxide) with symptoms of shortness of breath and confusion.
- 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.
- Swelling under the skin of face, throat, limbs and genitals (angioedema) with difficulty in breathing.
- Lactic acidosis characterised by nausea (feeling sick), vomiting, diarrhoea, abdominal (stomach) pain, difficulty or abnormality in breathing, fatigue and weight loss.
- Liver damage – nausea; stomach pain; low fever; loss of appetite; dark urine; clay-coloured stools; jaundice (yellowing of the skin or eyes).
- Kidney damage – little or no urination, swelling in the ankles and feet, shortness of breath, nausea and vomiting, metallic taste in the mouth.
- Fever, chills, sore throat, cough, or other signs of infection.
- 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).
- Inflammation of the pancreas - severe upper stomach pain with nausea (feeling sick) and vomiting.
- Changes in body shape because of changes in fat distribution.
- Stiffness in the joints, aches and pains (especially in the hip, knee or shoulder), difficulty moving as these are signs of osteonecrosis (see Take special care with **VIRULATE**).
- Breakdown of muscle tissue that releases a damaging protein into the blood (rhabdomyolysis) characterised by dark, reddish urine, decreased amount of urine, weakness and muscle pain.

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These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects

- Unwarranted fear of being overweight (anorexia)
- Headache and difficulty falling or staying asleep
- Cough, nasal symptoms.
- Deep, rapid, difficult breathing
- Nausea, abdominal pain, vomiting, diarrhoea
- Joint pain and muscle disorders
- Fever, lack of energy and tiredness, general feeling of being unwell.

Less frequent side effects:

- Weakness, numbness and pain from nerve damage, usually in the hands and feet (peripheral neuropathy)
- Rashes, hair loss.
- Mouth ulceration
- Sore throat
- Swollen ankles, feet and legs, swollen lymph glands, low blood pressure, eye infection (conjunctivitis)
- Tingling or numbness of the skin, arms or legs (paraesthesia)
- Breakdown of muscle tissue.

Side effects that may show up in blood tests are:

- Low red blood cell count (anaemia), low white blood cell count (neutropenia, or leucopenia),
- Decrease in the number of cells involved in blood clotting (thrombocytopenia)
- An increase in an enzyme called amylase

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- An increase in the level of liver enzymes
- Elevated creatine phosphokinase
- Elevated creatinine
- Increased weight and 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 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: <http://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of **VIRULATE**.

4. How to store VIRULATE:

Store at or below 30 °C.

Protect from light and moisture.

Keep in original packaging until required for use.

Keep the container tightly closed and in the carton until required for use.

Keep blisters in the carton until required for use.

Store all medicines out of the reach of children.

Do not take the medicine after the expiry date stated on the bottle or blister and carton.

Return all unused medicine to your pharmacist.

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

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5. Contents of the pack and other information:

What VIRULATE contains:

- The active substances are abacavir 300 mg and lamivudine 300 mg.
- The other ingredients are colloidal silicon dioxide, low-substituted hydroxypropyl cellulose, magnesium stearate, microcrystalline cellulose, povidone. The tablets are coated with coating made up of hydroxypropyl methylcellulose, polyethylene glycol, polysorbate, titanium dioxide and FD & C yellow no. 6 aluminium lake.

What VIRULATE looks like and contents of the pack:

Orange coloured, modified capsule shaped, biconvex, film coated tablets debossed with "1 60" on one side and plain on other side.

HDPE container

Tablets are packed in a 75 ml round white HDPE container with 38 mm neck finish, closed with a white 38 mm child resistant closure with HS 123 white printed liner, packed in an outer carton. Each HDPE container contains a 1 g silica gel sachet.

Pack sizes include 28 or 30 tablets.

Not all packs and pack sizes are necessarily marketed.

Blister pack

Tablets are packed in a blister containing cold form laminate 25 µm OPA/45 µm aluminium foil/60 µm PVC as the forming material and plain 25 µm aluminium foil with 6-8 gsm heat seal lacquered as the lidding material, packed in a pre-printed carton.

Pack sizes include 28 or 30 tablets.

Not all packs and pack sizes are necessarily marketed.

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Office block 1, Bassonia Estate Office Park (East),
1 Cussonia Drive, Bassonia Rock, Ext. 12,
Alberton, South Africa.

This leaflet was last revised in

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