Front Side

335 mm

360 mm

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

VIRATEN TABLETS (Film-coated tablet)
50 mg Dolutegravir, 300 mg Lamivudine and 300 mg Tenofovir disoproxil fumarate
Contains sugar (120,0 mg mannitol).

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

1. What VIRATEN TABLETS is and what it is used for

VIRATEN TABLETS is used to treat Human Immunodeficiency Virus (HIV) infection in adults aged 18 years and older.

2. What you need to know before you take VIRATEN TABLETS

Do not take VIRATEN TABLETS:
- If you are hypersensitive (allergic) to dolutegravir, lamivudine and tenofovir disoproxil fumarate, or any of the other ingredients of **VIRATEN TABLETS**. If you have uncontrolled kidney failure.
- If you are currently taking any of the following medicines:
  - adefovir dipivoxil and didanosine (used for HIV infection)
  - dofetilide or pilsicainide (to treat heart conditions).
  - metformin (to treat diabetes).
- If you suffer from moderate or severe liver disease.

Warnings and precautions
Take special care with **VIRATEN TABLETS:**
- Safety and efficacy of the individual active ingredients in various combination medicines for HIV treatment with similar dosages as contained in **VIRATEN TABLETS** have been established in clinical studies of HIV patients. However, safety and efficacy of the medicine combination as in **VIRATEN TABLETS** for the treatment of HIV have not been established in clinical studies. Please consult with your doctor or pharmacist for further information regarding use of **VIRATEN TABLETS**.
- **VIRATEN TABLETS** may increase 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.
- **VIRATEN TABLETS** 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 organs; get larger breasts or fatty lumps on the back of the neck (buffalo hump).
- If you have advanced HIV infection (AIDS) and have any infection, you may develop acute symptoms of the infection or inflammation and a worsening of the symptoms of an existing infection once treatment with **VIRATEN TABLETS** is started. 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.
- You will need to take **VIRATEN TABLETS** every day. **VIRATEN TABLETS** 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.
- Treatment with **VIRATEN TABLETS** has not been shown to reduce the risk of passing HIV infection on to others by unprotected sexual contact or by blood transfer (for example, blood transfusions or sharing needles). You should continue to use appropriate precautions to prevent this.
- Long term use of **VIRATEN TABLETS** 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 **VIRATEN TABLETS** and consult your doctor immediately.
- 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.
- **VIRATEN TABLETS** may cause inflammation of the pancreas. Inform your doctor if you experience severe upper stomach pain with nausea (feeling sick) and vomiting.
- Tell your doctor if you have had kidney disease, or if tests have shown problems with your kidneys. **VIRATEN TABLETS** may affect your kidneys. **VIRATEN TABLETS** is not usually taken with other medicines that can damage your kidneys. If this is unavoidable, your doctor will monitor your kidney function.
- Inform your doctor if you have had any liver disease (including hepatitis B or C), as treatment with **VIRATEN TABLETS** in patients with liver disease could cause severe side effects affecting the liver including death. Your doctor will monitor your liver function by performing blood tests on a regular basis.
- If you have an ongoing hepatitis B infection, do not stop **VIRATEN TABLETS** without your doctor's advice, as your hepatitis may come back. The hepatitis may be more severe if you also have a serious liver disease.
- Your doctor will let you know if you have a genetic mutation known as a K65R mutation. If you have this mutation, your doctor will avoid prescribing **VIRATEN TABLETS** to you.
- **VIRATEN TABLETS** decreases bone mineral density which could result in fractures. Your doctor may prescribe calcium and vitamin D supplements while taking **VIRATEN TABLETS**.
- **VIRATEN TABLETS** is not recommended for the elderly who are more than 65 years of age.

Other medicines and VIRATEN TABLETS
Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines).

- Tell your doctor if you are taking, or have recently taken any other medicines.
- Tell your doctor if you are taking dofetilide or pilsicainide, to treat heart conditions.
- Tell your doctor if you are taking metformin, to treat diabetes.
- Tell your doctor if you are taking abacavir, adefovir dipivoxil, etravirine, efavirenz, nevirapine, atazanavir/ritonavir, tipranavir/ritonavir, fosamprenavir/ritonavir, tenofovir or lamivudine (for HIV infection).
- Tell your doctor if you are taking atazanavir and/or duranavir/ritonavir, lopinavir/ritonavir (for HIV infection). If you are taking any of these medicines, your doctor may need to monitor your therapy more closely or you may not be able to use **VIRATEN TABLETS**.
- Tell your doctor if you are taking other medicines containing didanosine (for HIV infection). Taking **VIRATEN TABLETS** with other antiviral medicines that contain didanosine can raise the levels of didanosine in your blood. Inflammation of the pancreas and neuropathy (disorders with the nerves) can occur. Your doctor will carefully consider whether to treat you with combinations of tenofovir and didanosine.
- 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 other medicines that may reduce your kidney function. Some examples include
  - Aminoglycosides (for bacterial infection)
  - Adefovir dipivoxil (for viral infection)
  - Cidofovir (for viral infection)
  - Acyclovir(for viral infection)
  - Valacyclovir(for viral infection)
  - Ganciclovir(for viral infection)
  - Valganciclovir(for viral infection)
  - Amphotericin B (for fungal infection)
  - Foscarnet (for viral infection)
  - Pentamidine (for infections)
  - Interleukin-2 (to treat cancer)
  - Vancomycin (for bacterial infection)

Some medicines can affect how **VIRATEN TABLETS** works, or make it more likely that you will have side effects, or make side effects worse. These include:
- Rifampicin, to treat tuberculosis.
- Medicines called antacids, to treat indigestion and heartburn. Do not take an antacid during the 6 hours before you take **VIRATEN TABLETS**, or for at least 2 hours after you take it.
- Calcium and iron supplements. Do not take a calcium or iron supplement during the 6 hours before you take **VIRATEN TABLETS**, or for at least 2 hours after you take it.
- Phenytoin and phenobarbitone, to treat epilepsy.
- Oxcarbamazepine and carbamazepine, to treat epilepsy and bipolar disorder.
- St. John's wort (*Hypericum perforatum*), a herbal remedy used for depression.
- Zalcitabine in combination with trimethoprim or co-trimoxazole should not be taken with **VIRATEN TABLETS**.
- Tell your doctor or pharmacist if you are taking any of these. Your doctor may decide to adjust your dose or you may need additional checkups.

VIRATEN TABLETS with food and drink and alcohol
VIRATEN TABLETS can be taken with or without food.
Alcohol should be avoided.

Pregnancy, breastfeeding and fertility
IMPORTANT INFORMATION FOR WOMEN OF CHILD-BEARING AGE:
If you are a woman of child-bearing age who has been prescribed or are taking a dolutegravir (DTG) or DTG containing medicines such as **VIRATEN TABLETS** and if you wish to become pregnant, please note the following:
1. DTG or DTG containing medicines such as **VIRATEN TABLETS** may cause birth defects of the skull, brain, spine, or spinal cord when used at the time of conception or during the first three months of pregnancy. If your healthcare provider has prescribed a DTG or DTG containing medicines such as **VIRATEN TABLETS** for you, you must use effective birth control. Please discuss alternative treatment and contraceptive options with your healthcare provider.
2. Your healthcare provider will perform a pregnancy test, and your pregnancy test must be negative before you can start treatment with a DTG or DTG containing medicines such as **VIRATEN TABLETS**. Your healthcare provider will frequently perform a pregnancy test during your treatment with DTG or DTG containing medicines such as **VIRATEN TABLETS**. If you suspect that you are pregnant, you must go to your healthcare provider without any delay to do a pregnancy test to confirm whether you are pregnant or not.
3. If you are planning to become pregnant and are taking a DTG or DTG containing medicines such as **VIRATEN TABLETS**, it is important that you continue taking your medicine as well as your regular contraception, until your healthcare provider has discussed alternative treatment options with you, to enable you to make an informed choice about the treatment option that is most appropriate or suitable for you.
4. Should you unexpectedly fall pregnant or suspect that you are pregnant while taking a DTG or DTG containing medicines such as **VIRATEN TABLETS**, you need to contact your healthcare provider without any delay. The risk of birth defects is highest when you take DTG or DTG containing medicines such as **VIRATEN TABLETS** at the time of conception and during the first trimester (3 months) of your pregnancy. Your healthcare provider will discuss alternative treatment options with you and provide you with a pregnancy management plan, which will include frequent monitoring of your unborn baby and regular follow-up visits during your pregnancy.
5. If you become pregnant while taking a DTG or DTG containing medicines such as **VIRATEN TABLETS**, your healthcare provider will encourage you to register on a pregnancy registry. This registry collects information of antiretroviral medicines used during pregnancy and the outcomes of babies born to mothers who have been treated with ARV medicines during pregnancy, in order to identify how ARV medicines are affecting mothers and their babies. Your healthcare provider will register you on the registry programme and you will not be required to complete any forms. Your name and address will not be entered in the registry and no one will be able to trace any information stored in the registry back to you or your baby. Your identity and information will remain confidential. It is best that your healthcare provider registers you as soon as your pregnancy has been confirmed and even before the outcome of the pregnancy is known.
6. You should not breastfeed your baby while taking DTG or DTG containing medicines such as **VIRATEN TABLETS**, as these medicines may appear in your breastmilk and cause harm to your baby. Please discuss alternative feeding options with your healthcare provider.

Driving and using machines
VIRATEN TABLETS may affect the ability to drive and use machines. Do not engage in driving or using machines until you know how **VIRATEN TABLETS** affects you.

VIRATEN TABLETS contains
VIRATEN TABLETS contains mannitol and may have a laxative effect.

3. How to take VIRATEN TABLETS

- Do not share medicines prescribed for you with any other person.
- Always take **VIRATEN TABLETS** exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.
- If you have the impression that the effect of **VIRATEN TABLETS** is too strong or too weak, tell your doctor or pharmacist.
- Stay under a healthcare provider's care when taking **VIRATEN TABLETS**. Do not change your treatment or stop treatment without first talking with your healthcare provider.
- The usual dose of **VIRATEN TABLETS** is one tablet, swallowed with water, once a day, taken with or without food.
- Tell your doctor if you are taking rifampicin (for TB) as your doctor may prescribe an additional dose of dolutegravir 50 mg.
- Tell your doctor if you are taking isoniazid (for TB).

If you take more VIRATEN TABLETS than you should:
- Seek emergency medical attention if you think you have taken too much of **VIRATEN TABLETS**.
- 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 VIRATEN TABLETS:
It is important to take your **VIRATEN TABLETS** regularly at the same time each day. 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.

If you stop taking VIRATEN TABLETS:
Take **VIRATEN TABLETS** for as long as your doctor recommends. Do not stop taking **VIRATEN TABLETS** unless your doctor tells you to.

4. Possible side effects

VIRATEN TABLETS can have side effects.
Not all side effects reported for **VIRATEN TABLETS** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking **VIRATEN TABLETS**, please consult your doctor, pharmacist or other healthcare professional for advice.
If any of the following happens, stop taking VIRATEN TABLETS and tell your doctor immediately or go to the casualty department at your nearest hospital:
- Skin rash
- A high temperature (fever)
- Lack of energy (fatigue)
- Muscle or joint aches.
- 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 **VIRATEN TABLETS**. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:
- Lactic acidosis (severe increase of lactic acid in the blood, a serious side effect that can be fatal) – The following side effects may be signs of lactic acidosis: deep rapid breathing, drowsiness, feeling sick (nausea), being sick (vomiting) and stomach pain.
- 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.
- 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 VIRATEN TABLETS**)
- Psychiatric symptoms including severe depression or suicidal thoughts.

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:
- Headache, dizziness, difficulty falling asleep, abnormal dreams
- Depression
- Runny or blocked nose
- Cough
- Feeling sick (nausea), vomiting, stomach cramps or pain, diarrhoea, flatulence
- Hair loss (alopecia)
- Rashes (including red spots or blotches sometimes with blistering and swelling of the skin), which may be allergic reactions, itching, changes in skin colour including darkening of the skin in patches
- Fatigue, tiredness, lack of energy
- Joint pain, muscle pain and discomfort, back pain or chest pain
- Fever
- General feeling of being unwell
- Feeling depressed or anxious
- Problems with nerves; numbness, tingling, pins and needles
- Weight loss, loss of appetite, lack of appetite

Less frequent side effects:
- Difficulty breathing
- Heartburn and feeling bloated (dyspepsia)
- Breakdown of muscle tissue
- Feeling depressed
- Inflammation of the liver
- Swelling of the skin
- Damage to neurons
- Sweating
- Excessive pain in the bones

Frequent side effects that may show up in laboratory tests are:
- Increased levels of alanine and aspartate aminotransferase enzymes which indicate problems with the liver.
- Increased levels of creatine phosphokinase in the blood that may result in muscle pain and weakness.
- A low red blood cell count (anaemia) or low white blood cell count (neutropenia)
- A decrease in the number of cells involved in blood clotting (thrombocytopenia).

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 online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of **VIRATEN TABLETS**.

5. How to store VIRATEN TABLETS

Store at or below 25 °C. (Room temperature)
Protect from light and moisture.
Keep the HDPE containers tightly closed.
KEEP ALL MEDICINES OUT OF REACH OF CHILDREN.
Do not store in a bathroom.
Do not use after the expiry date stated on the label / carton / bottle.
Return all unused medicine to your pharmacist.
Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of pack and other information

What VIRATEN TABLETS contain
Each film-coated tablet contains: Dolutegravir sodium equivalent to dolutegravir 50 mg, Lamivudine 300 mg and Tenofovir disoproxil fumarate 300 mg.
Contains sugar (120,0 mg mannitol).
The other ingredients are microcrystalline cellulose, sodium starch glycolate, povidone, sodium stearyl fumarate, ferric oxide yellow, pregelatinized starch, croscarmellose sodium, isopropyl alcohol, magnesium stearate and coating agent containing hypromellose, triacetin and titanium dioxide (C.I. No. 77891).

What VIRATEN TABLETS looks like and contents of the pack
White to off white, capsule shaped, film-coated tablets, debossed with 'F67' on one side and plain on the other side.

HDPE container pack of 28 or 30 tablets:
Tablets are packed in a 100 ml (28 tablets) or 120 ml (30 tablets) round white HDPE bottle with 38-400 neck finish closed with 38 mm white, continuous thread polypropylene closure with pulp and heat seal liner. Each HDPE container contains a 3 g silica gel sachet. The labelled HDPE container is packed in a pre-printed unit carton.

HDPE container pack of 84 or 90 tablets:
Tablets are packed in a 200 ml, round white HDPE bottle with 38 neck finish closed with 38 mm white, continuous thread polypropylene closure with pulp and heat seal 123 white printed liner. Each HDPE container contains a 3 g silica gel sachet. The labelled HDPE container is packed in a preprinted unit carton.

HDPE container pack of 100 tablets:
Tablets are packed in a 250 ml, round white HDPE bottle with 53-400 neck finish closed with 53 mm white, continuous thread polypropylene closure with pulp and heat seal liner. Each HDPE container contains a 3 g silica gel sachet. The labelled HDPE container is packed in a preprinted unit carton.

HDPE container pack of 180 tablets:
Tablets are packed in a 400 ml, round white HDPE bottle with 53-400 neck finish closed with 53 mm white, continuous thread polypropylene closure with pulp and heat seal liner. Each HDPE container contains a 3 g silica gel sachet. The labelled HDPE container is packed in a pre-printed unit carton.

Holder of Certificate of Registration and Manufacturer
MACLEODS PHARMACEUTICALS SA (PTY) LTD
Office block 1, Bassonia Estate Office Park (East),
1 Cussonia Drive, Bassonia Rock, Ext. 12,
Alberton, South Africa.

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Access to the corresponding Professional Information
The corresponding professional information can be accessed at https://www.macleodspharma.com or email macleodsrsa@macleodspharma.com or contact 011 682 1169

VIRATEN TABLETS
PM03481704

Back Side

335 mm

360 mm

PASIËNTINLIGTINGSTUK

SKEDULERINGSTATUS S4

VIRATEN TABLETS (filmbedekte tablet)
50 mg Dolutegravir, 300 mg lamivudien en
300 mg tenofovirdisoproksielfumaraat
Bevat suiker (120,0 mg mannitol)

Lees die volledige inligtingsblad voordat u begin om VIRATEN TABLETS te neem

- Hou hierdie inligtingsblad. U mag die moontlik weer wil lees.
- Indien u enige verdere vrae het, moet u asseblief u dokter of apteker raadpleeg.
- **VIRATEN TABLETS** is vir u persoonlik voorgeskryf en u behoort dit nie met ander te deel nie. Dit mag hulle skade aandoen, alhoewel hulle dieselfde simptome mag toon.

Wat is in hierdie inligtingsblad

1. Wat **VIRATEN TABLETS** is en waarvoor dit gebruik word.
2. Wat u behoort te weet voordat u **VIRATEN TABLETS** neem.
3. Hoe om **VIRATEN TABLETS** te neem.
4. Moontlike newe-effekte.
5. Hoe om **VIRATEN TABLETS** op te berg.
6. Inhoud van die verpakking en ander inligting.

1. Wat VIRATEN TABLETS is en waarvoor dit gebruik word

VIRATEN TABLETS word gebruik om die Menslike Immuuntekortvirus (MIV) infeksie in volwassenes ouer as 18 jaar oud en ouer te behandel.

2. Wat u behoort te weet voordat u VIRATEN TABLETS neem

Moenie VIRATEN TABLETS neem nie

- As u hipersensitief (allergies) teen dolutegravir, lamivudien en tenofovirdisoproksielfumaraat, of enige ander van die komponente van **VIRATEN TABLETS** is. As u ongekontroleerde nierversaking het.
- As u tans enige van die volgende medisyne neem.
  - adefovirdipivoksiel en didanosien (gebruik vir MIV infeksie).
  - Dofetilied of pilsikaïenied (vir die behandeling van hartkondisies).
  - Metformien (vir die behandeling van diabetes)
- As u aan matige of erge lewersiekte ly

Waarskuwings en voorsorgsmaatreëls

Neem spesiale sorg met **VIRATEN TABLETS**:

- Die veiligheid en effektiwiteit van die individuele aktiewe bestanddele in verskillende kombinasiemedisyne vir die behandeling van MIV met soortgelyke dosisse soos wat in **VIRATEN TABLETS** voorkom is in kliniese studies van MIV-pasiënte bestudeer. Die veiligheid en effektiwiteit van die kombinasie soos in **VIRATEN TABLETS** is nie in kliniese studies vasgestel nie. Raadpleeg asseblief u dokter of apteker vir verdere inligting ten opsigte van die gebruik van **VIRATEN TABLETS**.
- **VIRATEN TABLETS** mag bloedcholesterol, trigliseriede, melksuur, suikervlakke verhoog en insulienweerstand veroorsaak. U dokter sal gereeld bloedtoetse uitvoer om cholesterol, trigliseriede, melksuur en suikervlakke te monitor.
- **VIRATEN TABLETS** mag u liggaamsvorm verander deur die manier waarop vet in die liggaam versprei word, te verander. U mag vet van u bene, arms en gesig verloor en/of vet om die buik en interne organe aansit en groter borste of vetknoppe agter op die nek (buffelskof) ontwikkel.
- As u aan gevorderde MIV-infeksie (VIGS) ly en 'n ander infeksie ook het, mag u akute simptome of inflammasie en 'n agteruitgang van die simptome van die reeds bestaande infeksie ontwikkel wanneer u die behandeling met **VIRATEN TABLETS** begin. Indien u enige tekens van inflammasie of 'n agteruitgang van die infeksie ondervind, moet u onmiddellik u dokter daarvan in kennis stel.
- Sommige pasiënte wat kombinasie anti-retrovirusterapie neem mag 'n beensiekte wat osteonekrose (afsterwing van beenweefsel weens 'n tekort aan bloedtoevoer aan die been) genoem word, ontwikkel . Tekens van osteonekrose is gewrigsstyfheid, -pyn, algemene pyn (veral van die heup, knie en skouer) en moeite met beweging. As u enige van hierdie tekens ondervind, moet u, u dokter in kennis stel.
- U sal **VIRATEN TABLETS** elke dag moet neem. **VIRATEN TABLETS** help om u kondisie onder beheer te hou en mag die vordering van die siekte vertraag. Dit sal egter nie die MIV-infeksie genees nie. U mag aanhou om ander infeksies en ander siektes wat met MIV-siekte verband hou, te ontwikkel U behoort gereeld met u dokter in kontak te bly. Moenie ophou om u medisyne te neem sonder om eers u dokter te raadpleeg nie.
- Daar is nie aangetoon dat die behandeling met **VIRATEN TABLETS** die risiko van oordraging van MIV-siekte deur onbeskermde seksuele kontak of bloedoordraging (bv. bloedoortapping of die medegebruik van naalde) verminder nie. U behoort aan te hou om die nodige voorsorgsmaatreëls te tref om dit te voorkom.
- Die langtermyn gebruik van **VIRATEN TABLETS** mag tot 'n toename van suur in u liggaam lei en sluit tekens van naarheid, braking, maagpyn, en -krampe, massaverlies, kortasemheid of vinnige asemhaling en moegheid in. U mag aan 'n kondisie wat melksuurasidose genoem word, ly. Staak die gebruik van **VIRATEN TABLETS** en raadpleeg onmiddellik u dokter.
- Neem u kind onmiddellik dokter toe as hy/sy:

  - bleek of swak is
  - die heeltyd slaperig is
  - vinniger asemhaal
  - 'n vinniger hartklop het
  - nie gewig optel nie
  - braak
  - koors kry
  - 'n seer keel het
  - mondulkusse kry
  - styfheid toon
  - stuiptrekkings of abnormale gedrag toon

U dokter sal addisionele mediese- en laboratoriumtoetse op u kind doen.

- **VIRATEN TABLETS** mag inflammasie van die pankreas veroorsaak. Stel u dokter in kennis indien u erge boonste buikpyn met naarheid en braking ondervind
- Stel u dokter in kennis as u aan 'n niersiekte gely het of as toetse aangedui het dat daar probleme met u niere is. **VIRATEN TABLETS** mag u niere affekteer. **VIRATEN TABLETS** word gewoonlik nie saam met ander medisyne wat u niere mag beskadig, geneem nie. As dit egter onvermydelik is, sal u dokter u nierfunksie gereeld monitor.
- Stel u dokter in kennis indien u enige lewersiekte (insluitende hepatitis B of C) gehad het, aangesien die behandeling met **VIRATEN TABLETS** by pasiënte met 'n lewersiekte, ernstige newe-effekte kan veroorsaak wat die lewer aantas, (insluitende die dood). U dokter sal u lewerfunksie monitor deur gereelde bloedtoetse uit te voer.
- As u aan 'n aanhoudende hepatitis B infeksie ly, moet u nie ophou om **VIRATEN TABLETS** te gebruik, sonder u dokter se advies nie, aangesien u hepatitis kan terugkeer. Die hepatitis mag erger wees as u ook aan 'n ernstige lewersiekte ly.
- U dokter sal u in kennis stel as u 'n genetiese mutasie, bekend as K65R-mutasie huisves. As u hierdie mutasie huisves, sal u dokter 'n voorskrif vir **VIRATEN TABLETS** vermy.
- **VIRATEN TABLETS** verlaag die beenmineraaldigtheid wat tot frakture mag lei. U dokter mag kalsium en vitamien D aanvullings voorskryf terwyl u **VIRATEN TABLETS** neem.
- **VIRATEN TABLETS** word nie vir die gebruik in bejaardes, ouer as 65 jaar oud, aanbeveel nie.

Ander medisyne en VIRATEN TABLETS

Stel altyd u professionele gesondheidswerker in kennis as u ander medisyne gebruik (dit sluit komplementêre en tradisionele medisyne in)

- Stel u dokter in kennis as u ander medisyne gebruik of onlangs gebruik het.
- Stel u dokter in kennis as u dofetilied en pilsikaïenied, om hartkondisies te behandel, neem
- Stel u dokter in kennis as u metformien neem om diabetes te behandel.
- Stel u dokter in kennis as u abakavir, adefovirdipivoksiel, etravirien, efavirens, nevirapien, atasanavir/ritonavir, tipranavir/ritonavir, fosamprenavir/ritonavir, tenofovir of lamivudien (vir MIV-infeksie) neem.
- Stel u dokter in kennis as u atasanavir en/of duranavir/ritonavir, lopinavir/ritonavir (vir MIV-infeksie) neem. As u enige van hierdie medisyne neem mag dit nodig wees dat u dokter u terapie meer noukeurig sal monitor, of u sal moontlik nie **VIRATEN TABLETS** kan gebruik nie.
- Stel u dokter in kennis as u enige medisyne wat didanosien bevat (vir MIV-infeksie). Deur **VIRATEN TABLETS** met ander anti-virusmedisyne wat didanosien bevat te neem, kan die bloedvlakke van didanosien in u bloed verhoog. Inflammasie van die pankreas en neuropatie (senuwee-afwykings) mag voorkom. U dokter sal noukeurige oorweging daaraan skenk om u met kombinasies van tenofovir en didanosien te behandel.
- Stel u dokter in kennis as u metadoon (om verslawing te behandel) neem, aangesien dit moontlik nodig mag wees om u metadoondosis te verander.
- Stel u dokter in kennis as u ander medisyne neem wat u nierfunksie mag verlaag. Sommige voorbeelde sluit die volgende in:

  - Aminoglikosiedes (vir bakteriese infeksies)
  - Adefovirdipivoksiel (vir virusinfeksies)
  - Sidofovir (vir virusinfeksies)
  - Asiklovir (vir virusinfeksies)
  - Valasiklovir (vir virusinfeksies)
  - Gansiklovir (vir virusinfeksies)
  - Valgansiklovir (vir virusinfeksies)
  - Amfoterisien B (vir swaminfeksies)
  - Foskarnet (vir virusinfeksies)
  - Pentamidien (vir infeksies)
  - Interleukien-2 (om kanker te behandel)
  - Vankomisien (vir bakteriese infeksies)

Sommige medisyne kan die manier waarop **VIRATEN TABLETS** werk, affekteer, of die waarskynlikheid dat u newe-effekte ontwikkel of dat die newe-effekte erger word, verhoog. Dit sluit die volgende in:

- Rifampisien, om tuberkulose te behandel
- Teensuurmiddels om slegte spysvertering en sooibrand te behandel. Moenie 'n teensuurmiddel neem gedurende die 6 ure voordat u **VIRATEN TABLETS** neem nie, of vir ten minste 2 uur nadat u dit geneem het nie.
- Kalsium- en ysteraanvullings. Moenie kalsium- en ysteraanvullings neem gedurende die 6 ure voordat u **VIRATEN TABLETS** neem nie, of vir ten minste 2 uur nadat u dit geneem het nie.
- Fenitoïen of fenobarbitoon om epilepsie te behandel
- Okskarbamasepien en karbamasepien om epilepsie en bipolêre afwyking te behandel
- St. John se kruid (*Hypericum perforatum*), 'n kruiemedisyne om depressie te behandel
- Salsitabien in kombinasie met trimetopriem of ko-trimoksasool behoort nie saam met **VIRATEN TABLETS** geneem te word nie
- Stel u dokter of apteker in kennis as u enige van hierdie medisyne neem. U dokter mag besluit om u dosis aan te pas of dit mag addisionele opvolgbesoeke vereis.

VIRATEN TABLETS met voedsel, vloeistof en alkohol

VIRATEN TABLETS kan met of sonder voedsel geneem word.

Alkohol behoort vermy te word.

Swangerskap, borsvoeding en vrugbaarheid

BELANGRIKE INLIGTING VIR VROUE WAT SWANGER MAG RAAK:

As u 'n vrou is wat swanger mag raak en u neem dolutegravir (DTG) of DTG bevattende medisyne (soos **VIRATEN TABLETS**), of dit is aan u voorgeskryf, en u wil graag swanger word, moet u asseblief die volgende in gedagte hou:

1. DTG of DTG bevattende medisyne soos **VIRATEN TABLETS** mag geboortedefekte van die skedel, brein, ruggraat of rugmurg veroorsaak, indien dit geneem word teen die tyd van konsepsie of gedurende die eerste drie maande van swangerskap. As u professionele gesondheidswerker DTG of DTG bevattende medisyne soos **VIRATEN TABLETS** aan u voorgeskryf het, moet u 'n betroubare metode van voorbehoeding gebruik. Bespreek asseblief alternatiewe behandeling en voorbehoedingsopsies met u professionele gesondheidswerker.
2. U professionele gesondheidswerker sal 'n swangerskapstoets uitvoer en die toets moet negatief wees voordat u met die behandeling met DTG of 'n DTG bevattende middels, soos **VIRATEN TABLETS**, kan begin. U professionele gesondheidswerker sal gereeld 'n swangerskapstoets gedurende u behandeling met DTG of 'n DTG bevattende medisyne, soos **VIRATEN TABLETS**, uitvoer. As u vermoed dat u swanger is moet u onmiddellik u professionele gesondheidswerker besoek om 'n swangerskapstoets uit te voer om te bevestig of u swanger is of nie.
3. As u beplan om swanger te raak en u neem DTG of DTG bevattende medisyne soos **VIRATEN TABLETS**, is dit belangrik dat u voortgaan om u medisyne te neem en effektiewe voorbehoeding toe te pas, totdat u professionele gesondheidswerker alternatiewe behandelingsopsies met u bespreek het, om u in staat te stel om 'n ingeligte keuse oor die mees geskikte behandelingsopsie vir u, te kan maak.
4. As u onverwags swanger raak of vermoed dat u swanger is terwyl u DTG of DTG bevattende medisyne soos **VIRATEN TABLETS** neem, behoort u onmiddellik u professionele gesondheidswerker in kennis te stel. Die risiko van geboortedefekte is die hoogste wanneer u DTG of DTG bevattende medisyne soos **VIRATEN TABLETS** gedurende die tyd van konsepsie, of binne die eerste trimester (3 maande) van u swangerskap, neem. U professionele gesondheidswerker sal alternatiewe behandelingsopsies met u bespreek en u van 'n swangerskap bestuursplan voorsien wat gereelde monitering van u ongebore baba, asook gereelde opvolgbesoeke gedurende u swangerskap, sal insluit
5. As u swanger raak terwyl u DTG of DTG bevattende medisyne soos **VIRATEN TABLETS** neem, sal u professionele gesondheidswerker u aanmoedig om op 'n swangerskapregister te registreer. Hierdie register versamel inligting oor antiretrovirale medisyne wat gedurende swangerskap gebruik word en die uitkomste van die babas wat gebore is by moeders wat gedurende swangerskap met ARV-medisyne behandel is, om vas te stel hoe ARV-middels moeders en hul babas affekteer. U professionele gesondheidswerker sal u op die swangerskapsregister registreer en dit sal nie vir u nodig wees om enige vorms in te vul nie. U naam en adres sal nie in die register ingevul word nie en niemand sal in staat wees om enige inligting wat in die register voorkom, terug na u of u baba te verwys nie. U identiteit en inligting sal konfidensieel gehou word. Dit sal die beste wees as u professionele gesondheidswerker register hou die dag wat u swangerskap bevestig is en selfs voor die uitkoms van die swangerskap bekend is.
6. U behoort nie u baba te borsvoed terwyl u DTG of DTG bevattende medisyne soos **VIRATEN TABLETS** neem nie, aangesien hierdie medisyne in die borsmelk mag voorkom en u baba skade kan aandoen. Bespreek asseblief alternatiewe voedingsopsies met u professionele gesondheidswerker.

Bestuur en die gebruik van masjinerie

VIRATEN TABLETS mag die vermoë om te bestuur en met masjinerie te werk, affekteer. Moenie bestuur of met masjinerie werk voordat u nie weet hoe **VIRATEN TABLETS** u affekteer nie.

VIRATEN TABLETS bevat:
VIRATEN TABLETS bevat mannitol en dit mag 'n lakserende effek hê.

3. Hoe om VIRATEN TABLETS te neem

- Moenie medisyne wat aan u voorgeskryf is met ander persone deel nie.
- Gebruik **VIRATEN TABLETS** presies soos deur u dokter of apteker voorgeskryf. Raadpleeg u dokter of apteker as u onseker is.
- As u onder die indruk is dat **VIRATEN TABLETS** te sterk of te swak is, moet u u dokter of apteker raadpleeg.
- Bly onder die sorg van u professionele gesondheidswerker wanneer u **VIRATEN TABLETS** neem. Moenie u behandeling verander of staak sonder om eers u professionele gesondheidswerker te raadpleeg nie.
- Die normale dosis van **VIRATEN TABLETS** is een tablet, geneem met water, een keer per dag, met, of sonder voedsel.
- Stel u dokter in kennis as u rifampisien (vir TB) neem, aangesien u dokter 'n addisionele dosis dolutegravir 50 mg mag voorskryf.
- Stel u dokter in kennis as u isoniasied (vir TB) neem.

As u te veel VIRATEN TABLETS neem:

- Kry nood mediese aandag as u dink dat u te veel **VIRATEN TABLETS** geneem het.
- In die geval van oordosering moet u u dokter of apteker raadpleeg. Indien hulle nie beskikbaar is nie, moet u na u naaste hospitaal of gifbeheersentrum gaan.

As u vergeet het om VIRATEN TABLETS te neem:

Dit is belangrik dat u u **VIRATEN TABLETS** gereeld op die dieselfde tyd elke dag neem. As u vergeet het om 'n dosis te neem, neem dit wanneer u daarvan onthou, en gaan dan voort soos voorheen. Moenie 'n dubbel dosis neem om vir 'n oorgeslaande dosis op te maak nie.

As u ophou om VIRATEN TABLETS te neem:

Neem **VIRATEN TABLETS** vir solank as wat u dokter dit aanbeveel. Moenie ophou om **VIRATEN TABLETS** te neem tensy u u dokter geraadpleeg het nie.

4. Moontlike newe-effekte

VIRATEN TABLETS kan newe-effekte hê.

Nie al die newe-effekte wat vir **VIRATEN TABLETS** aangemeld is, word in hierdie inligtingsblad genoem nie. Indien u algemene gesondheid agteruitgaan of u ondervind enige ongewenste effekte terwyl u **VIRATEN TABLETS** neem, moet u asseblief u dokter, apteker of ander professionele gesondheidswerker vir advies raadpleeg.
Indien enige van die volgende voorkom, moet u ophou om VIRATEN TABLETS te neem en onmiddellik u dokter raadpleeg, of gaan na die ongevalle afdeling van u naaste hospitaal:

- Veluitslag
- Hoë temperatuur (koors)
- Tekort aan energie (moegheid)
- Spier- of gewrigspyn
- Urtikarie; swelling van die gesig, lippe, mond, tong of keel mag moeite met sluk en asemhaling veroorsaak

Hierdie is almal ernstige newe-effekte. As u hierdie newe-effekte ondervind, het u moontlik 'n ernstige allergiese reaksie teen **VIRATEN TABLETS**. U mag moontlik dringende mediese hulp of hospitalisering benodig

Stel u dokter in kennis of gaan na die ongevalle afdeling van u naaste hospitaal as u enige van die volgende ondervind:

- Melksuurasidose (erge toename in melksuur in die bloed, 'n ernstige newe-effek wat fataal mag wees) - Die volgende newe-effekte mag tekens van melksuurasidose wees: diep, vinnige asemhaling, lomerigheid, naarheid, braking en maagpyn.
- Lewerbeskadiging - naarheid, buikpyn, lae koors, verlies aan eetlus, donkerkleurige uriene, kleigekleurde stoelgang, geelsug (vergeling van die vel of oë)
- Nierbeskadiging- min of geen urinering, swelling van die enkels en voete, kortasemheid, naarheid en braking, metaalsmaak in die mond.
- Koors, koue koors, seer keel, hoes of ander tekens van infeksie.
- Inflammasie van die pankreas - erge boonste buikpyn met naarheid en braking.
- Veranderinge in liggaamsvorm weens veranderinge in vetverspreiding.
- Styfheid in die gewrigte, pyn (veral in die heup, knie of skouer), moeite met beweging aangesien dit tekens van osteonekrose is (sien **Neem spesiale sorg met VIRATEN TABLETS**)
- Psigiatriese simptome, insluitende erge depressie of selfmoordgedagtes.

Hierdie is almal ernstige newe-effekte. U het moontlik dringend mediese hulp nodig.

Stel u dokter in kennis as u enige van die volgende waarneem:

Gereelde newe-effekte:
- Hoofpyn, duiseligheid, moeite om aan die slaap te raak, abnormale drome.
- Depressie.
- Loperige of verstopte neus.
- Hoes.
- Naarheid, braking, maagkrampe of -pyn, diarree, winderigheid.
- Haarverlies
- Uitslag (insluitende rooi kolle of vlekke, soms met blaasvorming en swelling van die vel) wat allergiese reaksies mag wees, jeuk, verandering in velkleur, insluitende verdonkering van die vel in kolle.
- Vermoeidheid, moegheid, tekort aan energie.
- Gewrigspyn, spierpyn en ongemak, rug- of borspyn.
- Koors.
- Algemene gevoel van ongesteldheid.
- Depressie of angs.
- Senuweeprobleme: gevoelloosheid, prikkeling, spelde en naalde.
- Massaverlies, verlies of tekort aan eetlus.

Minder gereelde newe-effekte:

- Moeite met asemhaling.
- Sooibrand en opgeblaas voel (dispepsie).
- Afbraak van spierweefsel.
- Depressie.
- Inflammasie van die lewer.
- Swelling van die vel.
- Neuronbeskadiging.
- Sweet.
- Oormatige beenpyn.

Gereelde newe-effekte wat in laboratoriumtoetse mag opduik:

- Verhoogde vlakke van alanien en aspartaataminotransferase ensieme dui op lewerprobleme.
- Verhoogde vlakke van kreatienfosfokinase in die bloed wat tot spierpyn en -swakheid mag lei.
- 'n Lae rooibloedseltelling (anemie) of 'n lae witbloedseltelling (neutropenie).
- 'n Afname in die aantal selle wat by bloedklonting betrokke is (trombositopenie)

As u enige newe-effekte ondervind wat nie in hierdie inligtingsblad genoem is nie, moet u asseblief u dokter of apteker raadpleeg.

Aanmelding van newe-effekte
As u newe-effekte ondervind, raadpleeg u dokter, apteker of verpleegster. Dit sluit enige moontlike newe-effekte in wat nie in hierdie inligtingsblad genoem word nie. U kan ook newe-effekte aan SAHPRA via die " **6.04 Adverse Drug Reaction Reporting Form**" aanmeld wat aan lyn onder SAHPRA se publikasies: https://www.sahpra.org.za/Publications/Index/8 gevind kan word. U kan help om meer inligting oor die veiligheid van **VIRATEN TABLETS** te verskaf.

5. Hoe om VIRATEN TABLETS op te berg

Bewaar by of benede 25 °C. (Kamertemperatuur)
Beskerm teen lig en vogtigheid.
Hou die HDPE houers dig toe
HOU ALLE MEDISYNE BUITE BEREIK VAN KINDERS
Moenie in die badkamer bewaar nie.
Moenie na die vervaldatum op die etiket, karton of houer gebruik nie.
Neem alle ongebruikte medisyne terug na u apteker.
Moenie van ongebruikte medisyne in die drein of rioolsisteem (bv. toilet) ontslae raak nie.

6. Inhoud van die houer en ander inligting

Wat VIRATEN TABLETS bevat.

Elke filmbedekte tablet bevat: Natriumdolutegravir gelykstaande aan dolutegravir 50 mg, Lamivudien 300 mg en Tenofovir disoproksielfumaraat 300 mg.

Bevat suiker (120,0 mg mannitol)

Die ander bestanddele is mikrokristallyne sellulose, natriumstyselglikolaat, povidoon, natriumstearielfumaraat, geel ysteroksied, gepregelatiniseerde stysel, kruiskarmellosenatrium, isopropielalkohol, magnesiumstearaat en 'n dekmateriaal wat hipromellose, trisetien en titaandioksied (C.I. Nr. 77891) bevat.

Hoe VIRATEN TABLETS lyk en inhoud van die verpakking

Wit tot byna-wit kapsuulvormige filmbedekte tablette met 'F67' op die een kant gedruk en glad aan die ander kant.

HDPE houerpak met 28 of 30 tablette:
Tablette word in 100 ml (28 tablette) of 120 ml (30 tablette), ronde wit HDPE-botteltjies met 38-400 nekafwerking afgelsuit met 38 mm wit, deurlopende skroefdraad-polipropileen-deksel met pulp en hitte-seëlvoering verpak. Elke HDPE houer bevat 'n 3 g silikajelsakkie. Die geëtiketteerde houer word in 'n voorafgedrukte kartonhouer verpak.

HDPE houerpak met 84 of 90 tablette:
Tablette word in 200 ml, ronde wit HDPE-botteltjies met 38 nekafwerking afgelsuit met 38 mm wit, deurlopende skroefdraad-polipropileen-deksel met pulp en hitte-seëlvoering verpak. Elke HDPE houer bevat 'n 3 g silicagelsakkie. Die geëtiketteerde houer word in 'n voorafgedrukte kartonhouer verpak.

HDPE houerpak met 100 tablette:
Tablette word in 250 ml, ronde wit HDPE-botteltjies met 53-400 nekafwerking afgelsuit met 53 mm wit, deurlopende skroefdraad-polipropileen-deksel met pulp en hitte-seëlvoering verpak. Elke HDPE houer bevat 'n 3 g silikagelsakkie. Die geëtiketteerde houer word in 'n voorafgedrukte kartonhouer verpak.

HDPE houerpak met 180 tablette:
Tablette word in 400 ml, ronde wit HDPE-botteltjies met 53-400 nekafwerking afgelsuit met 53 mm wit, deurlopende skroefdraad-polipropileen-deksel met pulp en hitte-seëlvoering verpak. Elke HDPE houer bevat 'n 3 g silikajelsakkie. Die geëtiketteerde houer word in 'n voorafgedrukte kartonhouer verpak.

HOUER VAN DIE SERTIFIKAAT VAN REGISTRASIE
Macleods Pharmaceuticals SA (Edms.) Bpk
Kantoorblok 1
Bassonia Estate Office Park (Oos)
Cussoniarylaan, Bassonia Rock Uitbr 12,
Alberton, Suid Afrika.

Hierdie inligtingsblad is laas hersien
02 Mei 2023

REGISTRASIENOMMER
52/20.2.8/0770

Toegang tot die o oreenstemmende Professionele Inligting
Die ooreenstemmende professionele in ligting kan verkry word by https://www.macleodspharma.com of e-pos macleodsrsa@macleodspharma.com of kontak 011 682 1169.

PACKAGING RESEARCH & DEVELOPMENT

Restricted Circulation

(Front Page)

ARTWORK / PRINTPROOF APPROVAL FORM

Note : Exclusion of PI, text update, and dimension change.

1. Product: VIRATEN TABLETS (Dolutegravir sodium 50 mg, Lamivudine 300 mg and Tenofovir disoproxil fumarate 300 mg Tablets)	
2. Country: South Africa	**3. Packaging component: Patient Information Leaflet**
4. No. of Colours: 1 Colour	**5. Pantone Shade No.: Black**
6. Specification: 40 gsm bible paper	
7. Machine Layout No.: NA	**8. Dimensions: 360 (L) x 335 (W) mm**
9. Design / Style: Booklet	**10. Item code No.: PM03481704**
11. Artwork has been made: Actual Size	**12. Pharma code No.: 34137 mini**
13. Barcode/NDC no: NA	**14. Supersedes Item code No: PM03481703**
15. Revision no: 03	**16. File Name : Z:\Dolute, Lami, Teno\Viraten\01\Viraten PI-PIL PM03481704.cdr**
Approved By:	**17. Location: Baddi**

PRD	M.A. HOLDER	MEDICAL/RAD	QC	PRODN	QA
	Vanita Rajool Digitally signed by Vanita Rajool DN: cn=Vanita Rajool, o=Macleods Pharmaceuticals SA (Pty) Ltd., ou=Responsible Pharmacist, email=vanitar@macleodspharma.com, c=ZA Date: 2024.08.12 14:49:30 +02'00'				

Note: 1. To follow overleaf checklist for approval of Artwork / Print proof.

Instructions to Vendor :

1. Before processing, please ensure First pull out / Commercial supply should match with approved Artwork with respect to Design, Size, Fonts & Text.
2. Print proof to represent full printing area with Station Numbers.

FRM/CQA/021/04-01

Reason for revision :	Item code	Artwork Release Date	Artwork Implementation Date
1) New Artwork for South Africa	PM03481701	19/01/21	Not implemented
2) Change in text matter, format and dimensions	PM03481702	01/03/21	Not implemented
3) Label claim changed	PM03481703	15/03/21	20/09/22
3) Exclusion of PI, text update, and dimension change.	PM03481704		