Front Top

280 mm

335 mm

Patient Information Leaflet

SCHEDULING STATUS: S4

EMTROC TABLETS (Film-coated tablet)
Emtricitabine 200 mg and tenofovir disoproxil fumarate 300 mg
Contains sugar (88,0 mg lactose monohydrate)

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

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

Treatment for HIV infection
EMTROC TABLETS is used to treat Human Immunodeficiency Virus (HIV) infection in adults. **EMTROC TABLETS** is always used in combination with other anti-HIV medicines to treat patients with HIV-1 infection.
Treatment for Pre-Exposure Prophylaxis (PrEP)
To reduce the risk of getting HIV-1 in adults, **EMTROC TABLETS**, when taken daily together with safer sex practices.

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

Do not take EMTROC TABLETS:
- If you are hypersensitive (allergic) to emtricitabine and tenofovir disoproxil fumarate, or any of the other ingredients of **EMTROC TABLETS**.
- If you have kidney problems.
- If you are pregnant or breastfeeding.
- If you are already taking any other emtricitabine, tenofovir or lamivudine containing medicines because these medicines contain the same or similar active ingredients.
- If you are HIV positive or if your HIV status is not known, when using **EMTROC TABLETS** to prevent HIV infection.
- If you are not fully committed to use **EMTROC TABLETS** every day for Pre-Exposure Prophylaxis.

Warnings and precautions
Take special care with EMTROC TABLETS.

EMTROC TABLETS may lead to serious problems with your liver or cause too much acid in your blood. If left untreated, this may cause death. The safety and efficacy of EMTROC TABLETS in patients who are infected with both human immunodeficiency virus (HIV) and hepatitis B virus (HBV) have not been established. EMTROC TABLETS should not be used for treatment of chronic HBV infection. You should be closely monitored by your doctor for several months if you are infected with HBV and discontinue the use of EMTROC TABLETS.

- **EMTROC TABLETS** may cause lactic acidosis, together with an enlarged liver, which can be fatal. Deep, rapid breathing, drowsiness, and symptoms such as nausea, vomiting and stomach pain, might indicate the development of lactic acidosis. Lactic acidosis occurs more often in women. Patients who are overweight are more at risk.
- **EMTROC TABLETS** may cause inflammation of the pancreas. Inform your doctor if you experience severe upper stomach pain with nausea (feeling sick) and vomiting.
- Inform your doctor if you have had any liver disease including hepatitis B or C, as treatment with **EMTROC TABLETS** in patients with liver disease could cause severe side effects affecting the liver including death in case of concomitant antiviral therapy for hepatitis B or C.
- If your child was exposed to **EMTROC TABLETS** during pregnancy and 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, has fever, sore throat, mouth ulcers, appears stiff, has convulsions (fits) or behaving abnormally, take your child to the doctor. Your doctor will perform medical and laboratory tests on your child.
- Tell your doctor if you have had kidney disease, or if tests have shown problems with your kidneys. **EMTROC TABLETS** may affect your kidneys.
- Your doctor may monitor your kidney function.
- Tell your doctor if you are taking any other medicines, as **EMTROC TABLETS** may interact with these medicines (see **Other medicines and EMTROC TABLETS** below).
- **EMTROC TABLETS** decreases bone mineral density which could result in fractures. Your doctor may prescribe calcium and vitamin D supplements while taking **EMTROC TABLETS**.
- 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.
- **EMTROC 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, gal bladder 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 **EMTROC TABLETS** is started. If you notice signs of inflammation or infection, or deterioration thereof, tell your doctor at once.
- You will need to take **EMTROC TABLETS** every day. **EMTROC 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 **EMTROC 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.

Information before taking EMTROC TABLETS to help prevent you from getting HIV
- You must get tested to be sure you are HIV-negative. It is important that you also get tested at least every 3 months as recommended by your healthcare provider while taking **EMTROC TABLETS**. Ask your partner to get tested. Know the HIV status of your partner.
- **EMTROC TABLETS** may not always keep you from getting HIV.
- You must still practice safe sex at all times. Do not have any kind of sex without protection. Always practice safe sex by using a latex or polyurethane condom to lower the chance of sexual contact with semen, vaginal secretions, or blood.
- Get information and support to help reduce risky sexual behaviour.
- Have fewer sex partners.
- Do not miss any doses of **EMTROC TABLETS**. Missing doses increases your risk of exposure and getting HIV.
- Tell your healthcare provider if you have any of the following symptoms in the last month before you start taking **EMTROC TABLETS** or at any time while taking **EMTROC TABLETS**:
  - tiredness
  - fever
  - sweating a lot (especially at night)
  - rash
  - vomiting
  - diarrhoea
  - joint or muscle aches
  - headache
  - sore throat
  - enlarged lymph nodes in the neck or groin.

These may be signs of HIV infection and you may need to have another test to diagnose HIV. Also, tell your healthcare provider if you think you were recently exposed to the HIV virus. If you are already taking **EMTROC TABLETS** to prevent HIV-1 infection, your healthcare provider may tell you to stop taking **EMTROC TABLETS** until an HIV test confirms that you do not have HIV-1 infection.

Other important information:
Avoid doing things that can increase your risk of spreading HIV infection to other people if you are HIV-infected, or increase your risk of acquiring HIV if you are taking **EMTROC TABLETS** for prevention. These include:
- Do not share or re-use needles or other injection equipment.
- Do not share personal items that can have blood or body fluids on them, like toothbrushes and razor blades.
- Do not have any kind of sex without protection. Always practice safe sex by using a latex or polyurethane condom to lower the chance of sexual contact with semen, vaginal secretions or blood.

Children and adolescents
- The safety and effectiveness of **EMTROC TABLETS** in children and patients younger than 18 years has not been determined.

Other medicines and EMTROC 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 abacavir, emtricitabine, indinavir, lamivudine, atazanavir and/or lopinavir/ritonavir (for HIV infection).
- Tell your doctor if you are taking other medicines containing didanosine (for HIV infection). Taking **EMTROC 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.
- Ledipasvir and sofosbuvir or sofosbuvir and velpatasvir, or sofosbuvir / velpatasvir/voxilaprevir co-formulation or adefovir dipivoxil. These medicines used for a liver disease called hepatitis B or C may increase the amount of tenofovir DF (a component of **EMTROC TABLETS**) in your blood, which could result in more side effects.
- 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)
- Valganaclovir (for viral infection)

EMTROC TABLETS with food and drink and alcohol
EMTROC TABLETS 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 **EMTROC TABLETS**.
- You must not take **EMTROC TABLETS** during pregnancy.
- Do not breastfeed during treatment with **EMTROC TABLETS**. It is not known whether the active substance in **EMTROC TABLETS** passes into human breast milk.

Driving and using machines
EMTROC TABLETS can cause dizziness. If you feel dizzy while taking **EMTROC TABLETS** do not drive and do not use any tools or machines.

EMTROC TABLETS contains
EMTROC TABLETS contains sugar (lactose monohydrate).
EMTROC TABLETS contains lactose. Patients with the rare hereditary conditions of lactose or galactose intolerance should not take **EMTROC TABLETS**.

3. How to take EMTROC TABLETS

Do not share medicines prescribed for you with any other person.
Always take **EMTROC TABLETS** exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure. Your doctor will tell you how long your treatment with **EMTROC TABLETS** will last. Do not stop treatment early. If you have the impression that the effect of **EMTROC TABLETS** is too strong or too weak, talk to your doctor or pharmacist.

- Stay under a healthcare provider's care when taking **EMTROC TABLETS**. Do not change your treatment or stop treatment without first talking with your healthcare provider.
- Always take **EMTROC TABLETS** in combination with other anti-HIV medicines.
- The usual dose of **EMTROC TABLETS** is one tablet once a day, taken with or without food.
- Take **EMTROC TABLETS** at the same time each day.
- *Treatment of HIV*
  If you take **EMTROC TABLETS** for the treatment of HIV infection, it should be used in combination with other anti-HIV medicines.
- *Prevention of HIV*
  If you take **EMTROC TABLETS** to reduce the risk of getting HIV-1, you must also use other methods to reduce your risk of getting HIV. See "Take special care with **EMTROC TABLETS**".

If you take more EMTROC TABLETS than you should
In the event of overdosage consult your doctor or pharmacist. If neither is available contact the nearest hospital or poison control centre.
- Seek emergency medical attention if you think you have taken too much of **EMTROC TABLETS**.

If you forget to take EMTROC TABLETS
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 EMTROC TABLETS
You should not stop treatment unless your doctor instructs you to. When your **EMTROC TABLETS** supply starts to run low, get more from your healthcare provider or pharmacy. This is very important because the amount of virus in your blood will increase if the medicine is stopped for even a short time. The virus may develop resistance to **EMTROC TABLETS** and become difficult to treat.

4. Possible side effects

EMTROC TABLETS can have side effects.
Not all the side effects reported for **EMTROC TABLETS** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking **EMTROC TABLETS** please consult your doctor, pharmacist or healthcare professional for advice.

If any of the following happens, stop taking **EMTROC TABLETS** and tell your doctor immediately or go to the casualty department at your nearest hospital:
- Hives; difficulty breathing; swelling of your face, lips, tongue, or throat.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to **EMTROC 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).
- Fever, chills, sore throat, cough, or other signs of infection.

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

Tell your doctor if you notice any of the following side effects and they worry you or if any of these symptoms are severe or do not go away:

Frequent side effects
Sleep problems (inability to sleep, abnormal dreams), headache, dizziness, nausea (feeling sick), being sick (vomiting), diarrhoea, indigestion, inflammation of the pancreas, pain in the abdomen (tummy), excessive gas in the stomach or bowel, skin rashes, skin discolouration (especially on the palms and or soles), pain, unusual tiredness or weakness, lack of appetite, fever, sweating, weight loss.
Laboratory blood tests may show lack of white blood cells, high cholesterol levels, high sugar levels, raised liver enzymes, increased levels of bilirubin (due to liver damage), increased creatine kinase levels (due to muscle damage), low phosphate levels, low potassium levels.

Less frequent side effects:
Lack of energy, depression, anxiety, problems with nerves, numbness, tingling, pins and needles, increased cough, runny or blocked nose, joint pain, muscle pain, muscle weakness, breakdown of muscle, muscle pain or weakness which may occur due to damage to the kidney tubule cells, inflammation of the liver, fatty liver, shortness of breath, lung infection, pain, back pain; chest pain; kidney problems, changes to your urine, changes in body fat, including an increased amount of fat in the upper back and neck, breast and around the trunk, loss of fat from the legs, arms and face may also happen.
Laboratory blood tests may show low red blood cells or decrease in haemoglobin levels blood in the urine.

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 **EMTROC TABLETS**.

5. How to store EMTROC TABLETS

Store all medicines out of reach of children.
Store at or below 25 °C. (room temperature).
Keep the blister in the carton until required for use.
Keep the containers tightly closed.
Protect from light.
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 EMTROC TABLETS contains
- The active substances are 200 mg emtricitabine and 300 mg of tenofovir disoproxil fumarate.
- The other ingredients are colloidal silicon dioxide, croscarmellose sodium, lactose monohydrate, magnesium stearate, microcrystalline cellulose, pre-gelatinized starch, coating containing hydroxypropyl methylcellulose, lactose monohydrate, titanium dioxide (Colour Index No. 77891), triacetin, FD&C Blue No.2 (Colour Index No. 73015).

What EMTROC TABLETS looks like and contents of the pack
Blue coloured capsule shaped, biconvex, film coated tablets debossed "L 24" on one side of the tablet and plain on other surface.

1. HDPE Container. Pack of 28 or 30 tablets.
75 ml white, heavy weight, round white HDPE bottle with 38-400 neck finish with a 38 mm white closure with pulp and heat seal liner containing a 3 g silica gel sachet.
2. Alu-Alu blister pack (10 X 10) tablets
Cold form laminate 25 micron OPA/45 micron Aluminium foil/60 micron PVC and plain 25 micron aluminium foil with 6-8 GSM HSL.

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.

Registration Number/Reference Number
47/20.2.8/0188.

This leaflet was last revised in
Date of registration: 7 December 2012
Revision date: 7 November 2019

TO ACCESS THE PROFESSIONAL INFORMATION:
Please visit https://acdvo.co.za/downloads/pi/Emtroc-PI.pdf or scan the QR code below.

Scan for PI

EMTROC TABLETS
(Film-coated tablet)
PM03229502

Back Top

280 mm

335 mm

INLIGTINGSBLAD VIR PASIËNTE

SKEDULERINGSTATUS : S4

EMTROC TABLETS (filmbedekte tablet)
Emtrisitabien 200 mg en tenofovirdisoproksielfumaraat 300 mg
Bevat suiker (88,0 mg laktosemonohidraat)

- Lees die hele brosjure sorgvuldig voordat u begin om **EMTROC TABLETS** te neem.
- Hou hierdie blaadjie. U mag dit moontlik weer wil lees.
- Indien u enige vrae het, moet u asseblief u dokter of apteker raadpleeg.
- **EMTROC TABLETS** is vir u persoonlik voorgeskryf en u behoort nie u medisyne met ander mense te deel nie. Dit mag hulle skade aandoen, ookal toon hulle dieselfde simptome as u.

Wat is in hierdie inligtingsblad
1. Wat **EMTROC TABLETS** is en waarvoor dit gebruik word.
2. Wat u moet weet voordat u **EMTROC TABLETS** neem.
3. Hoe om **EMTROC TABLETS** te neem.
4. Moontlike newe-effekte.
5. Hoe om **EMTROC TABLETS** op te berg.
6. Inhoud van die pak en ander inligting.

1. Wat EMTROC TABLETS is en waarvoor dit gebruik word

Behandeling van MIV-infeksie
EMTROC TABLETS word gebruik om die Menslike Immuniteitsvirus (MIV) infeksie in volwassenes te behandel.
EMTROC TABLETS word altyd in kombinasie met ander anti-MIV medisyne gebruik om pasiënte met MIV-1 infeksie te behandel.

Behandeling van Voorblootstellingsprofilakse (PePR)
Om die risiko van verkryging van MIV-1 in volwassenes te verminder, word **EMTROC TABLETS** saam met veiliger sekspraktyke voorgeskryf.

2. Wat u moet weet voordat u EMTROC TABLETS neem

Moenie EMTROC TABLETS neem nie:
- As u hipersensitief (allergies) teen emtrisitabien en tenofovirdisoproksielfumaraat of enige van die ander bestanddele van **EMTROC TABLETS** is.
- As u aan nierprobleme ly.
- As u swanger is of borsvoed.
- As u reeds enige ander emtrisitabien-, tenofovir- of lamivudienbevattende medisyne gebruik, aangesien hierdie medisyne dieselfde of soortgelyke aktiewe bestanddele bevat.
- As u MIV-positief is of as u MIV-status onbekend is, wanneer u **EMTROC TABLETS** gebruik om MIV-infeksie te voorkom.
- As u nie ten volle toegewyd is om **EMTROC TABLETS** elke dag vir voorblootstellingsprofilakse te gebruik nie.

Waarskuwings en voorbehoedsmaatreëls
Neem spesiale sorg met **EMTROC TABLETS**

EMTROC TABLETS kan tot ernstige probleme met u lewer of te veel suur in u bloed lei. As dit onbehandel bly, kan dit tot die dood lei. Die veiligheid en effektiwiteit van EMTROC TABLETS in pasiënte wat met beide menslike immuniteitvirus (MIV) en hepatitis B virus (HBV) besmet is, is nie vasgestel nie. EMTROC TABLETS behoort nie vir die behandeling van chroniese HBV infeksie gebruik te word nie. U behoort vir ertlike maande noukeurig deur u dokter gemonitor te word as u met HBV besmet is en met die gebruik van EMTROC TABLETS staak.

- **EMTROC TABLETS** kan melksuurasidose met 'n vergroote lewer veroorsaak, wat fataal mag wees. Diep, vinnige asemhaling en simptome soos naarheid, braking en maagpyn mag op die ontwikkeling van melksuurasidose dui. Melksuurasidose kom meer dikwels in vroue voor. Pasiënte wat oorgewig is loop 'n groter risiko.
- **EMTROC TABLETS** mag inflammasie van die pankreas veroorsaak. Stel u dokter in kennis as u erge boonste buikpyn met naarheid en braking ondervind.
- Stel u dokter in kennis as u aan enige lewersiekte, insluitende hepatitis B of C gely het, aangesien die behandeling met **EMTROC TABLETS** in pasiënte met lewersiekte erge newe-effekte wat die lewer affekteer, kan veroorsaak. Insluitende die dood in die geval van meegaande antiviroterapie vir hepatitis B of C.
- As u kind gedurende swangerskap aan **EMTROC TABLETS** blootgestel is en hyfsy bleek of swak is, hestyd slapend voel, vinniger asemhaal en die hart vinniger klop, nie massa aansit nie, braak, koorsig is, seer keel of mondblase het, styf lyk, stuipsamevalle kry of abnormaal optree, moet u die kind dokter toe neem. U dokter sal mediese en laboratoriumtoetse op u kind uitvoer.
- Stel u dokter in kennis as u 'n niersiekte gehad het of as toetse probleme met u niere aangetoon het. **EMTROC TABLETS** mag u niere affekteer.
- U dokter mag moontlik u nierfunksie monitor.
- Stel u dokter in kennis as u enige ander medisyne neem aangesien **EMTROC TABLETS** 'n waseliwerking met hierdie medisyne mag hê. (sien Ander medisyne en **EMTROC TABLETS** hieronder.)
- **EMTROC TABLETS** laat die beenmineraaldigtheid afneem wat tot fraktuur kan lei. U dokter mag moontlik kalsium en vitamien D suplemente voorskryf terwyl u **EMTROC TABLETS** neem.
- Sommige pasiënt met kombinasie antiretrowirusterapie ontwikkel osteonekrose, 'n verlies aan beenweefsel wat veroorsaak word deur verminderde bloedtoevoer na die been. Tekens van osteonekrose is gewrigsstyfheid, pyn (veral in die heup, knie en skouer) en moeite met beweging. As u enige van hierdie simptome ondervind, moet u dokter daarvan in kennis stel.
- **EMTROC TABLETS** mag die vorm van u liggaam verander deur die manier waarop die liggaamsvet verspreid word, te verander. U mag vet van u bene, arms en gesig verloor en/of vet om die buik en interne organe aansit; groter borste of vetbulte op die agterkant van die nek (buffelhoof) ontwikkel.
- As u aan gevorderde MIV-infeksie (VIGS) ly en enige ander infeksie opdoen, kan u akute simptome van die infeksie of inflammasie en 'n agteruitgang van die simptome van 'n reeds bestaande infeksie ontwikkel wanneer die behandeling met **EMTROC TABLETS** begin. Indien u enige tekens van inflammasie of infeksie of agteruitgang daarvan waarneem, moet u onmiddellik u dokter daarvan in kennis stel.
- U sal **EMTROC TABLETS** elke dag moet neem. **EMTROC TABLETS** help om die konsentrasie te behoer en vertraag die vordering van die siekte. U mag aanhou om ander infeksies en siektes wat met MIV-siekte geassosieer word, te ontwikkel. U behoort in gereelde kontak met u dokter te bly. Moenie ophou om die medisyne te neem sonder om vooraf met u dokter te praat nie.
- Daar is nie aangetoon dat die behandeling met **EMTROC TABLETS** die risiko van oordraging van MIV-siekte na ander deur onbeskermde seksuele kontak of deur bloedkontaminasie (byvoorbeeld bloedoorlopings of die deel van naalde) verminder nie. U behoort aan te hou om die gepaste voorsorgmaatreëls te tref om dit te voorkom.

Inligting voordat u begin om EMTROC TABLETS te neem om te voorkom dat u MIV opdoen.
- U moet getoets word om te verseker dat u MIV-negatief is. Dit is belangrik dat u ook elke 3 maande getoets word. Soos aanbeveel deur gesondheidsorgverskaffer, terwyl u **EMTROC TABLETS** gebruik. Vra u seksmaat om ook getoets te word. Ken die MIV-status van u seksmaat.
- **EMTROC TABLETS** mag u moontlik nie altyd beskerm teen die opdoen van MIV nie.
- **U moet nog steeds veilige sekspraktyke beoefen. Moenie enige soort seks sonder beskerming beoefen nie.** Oefen altyd veilige seks uit deur die gebruik van 'n lateks of poliëruretaan kondoom om die kans van seksuele kontak met semen, vaginale afskeidings of bloed te verminder.
- Kry inligting en ondersteuning om te help om die risiko van riskante seksuele gedrag te verminder.
- Beperk die aantal seksmaats.
- Moenie enige dosisse **EMTROC TABLETS** oorslaan nie. Oorgeslaande dosisse verhoog die risiko van blootstelling en die opdoen van MIV.
- Stel u gesondheidsorgverskaffer in kennis as u enige van die volgende simptome gehad het binne 'n maand voordat begin om **EMTROC TABLETS** te neem, of enige tyd terwyl u **EMTROC TABLETS** gebruik.
  - Moegheid
  - Koors
  - Uitermalige sweet (veralsnags)
  - Uitslag
  - Braking
  - Diarree
  - Gewrigs- of spierpyn
  - Hoofpyn
  - Seer keel
  - Vergrootte limfkliere in die nek of lies

Die bogenoemde mag tekens van MIV-infeksie wees en u mag moontlik weer getoets moet word om MIV te diagnoseer. Stel u gesondheidsorgverskaffer ook in kennis as u dink dat u onlangs aan die MIV-virus blootgestel is. As u reeds **EMTROC TABLETS** neem om MIV-1 infeksie te voorkom, maag u gesondheidsorgverskaffer u moontlik inlig om met die gebruik van **EMTROC TABLETS** te staak totdat 'n MIV-toets bevestig dat u nie MIV-positief is nie.

Ander belangrike inligting:
Vermy dinge wat u risiko vir die verspreiding van MIV-infeksie na ander mense vergroot as u MIV-positief is, of die risiko vir die opdoen van MIV as u **EMTROC TABLETS** vir voorkoming neem. Dit sluit die volgende in:
- Moenie naalde of ander inspuitingtoerusting deel of hergebruik nie.
- Moenie persoonlike items wat bloed of liggaamsvloeistowwe bevat, soos tandestorsels of skeermesleminetjies deel nie.
- Moenie enige soort seks sonder beskerming beoefen nie. **Beoefen altyd veilige seks deur 'n lateks of poliëruretaan kondoom te gebruik om die kans van seksuele kontak met semen, vaginale afskeidsel of bloed te verminder.**

Kinders en adolessente
- Die veiligheid en effektiwiteit van **EMTROC TABLETS** in kinders en pasiënte jonger as 18 jaar oud is nie vasgestel nie.

Ander medisyne en EMTROC TABLETS
Stel altyd u gesondheidsorgverskaffer in kennis as u enige ander medisyne gebruik (dit sluit komplementêre en tradisionele medisyne in).
- Stel u dokter in kennis as u tans ander medisyne neem of onlangs geneem het.
- Stel u dokter in kennis as u efavirenz, emtrisitabien, indinavir, lamivudien, atasanavir en/of lopinavir/ritonavir (vir MIV-infeksie) neem.
- Stel u dokter in kennis as u ander medisyne neem wat didanosien (vir MIV-infeksie) bevat. Die neem van **EMTROC TABLETS** wat didanosien bevat mag die vlakke van didanosien in u bloed verhoog. Inflammasie van die pankreas en neuropatie (afwykings van die senuwees) kan voorkom. U dokter sal met sorg oorweeg of hyfsy u met kombinasies van tenofovir en didanosien moet behandel.
- Ledipasvir en sofosbuvir, of sofosbuvir en valpatasvir, of sofosbuvir/velpatasvir/ voksilaprevir bo-formulasie of adefovir-dipivoksiel. Hierdie medisyne wat vir lewersiektes nl. hepatitis B of C gebruik word mag die hoeveelheid tenofovir DF (n komponent van **EMTROC TABLETS**) in u bloed verhoog, wat tot meer newe-effekte kan lei.
- Stel u dokter in kennis as u ander medisyne neem wat u nierfunksie mag laat afneem. Sommige voorbeelde sluit die volgende in:
  - Aminoglikosiede (bakteriese infeksie)
  - Adefovirdipivoksiel (vir virusinfeksie)
  - Sidofovir (vir virusinfeksie)
  - Asiklovir (vir virusinfeksie)
  - Valasiklovir (vir virusinfeksie)
  - Gansiklovir (vir virusinfeksie)
  - Valgansiklovir (vir virusinfeksie)

EMTROC TABLETS met voedsel, vloeistof en alkohol
EMTROC TABLETS kan met of sonder voedsel geneem word.

Swangerskap, borsvoeding en vrugbaarheid
As u swanger is of u baba borsvoed moet u asseblief u dokter, apteker of ander gesondheidsorgverskaffer vir advies raadpleeg voordat u **EMTROC TABLETS** neem.
- Moenie **EMTROC TABLETS** gedurende swangerskap gebruik nie.
- Moenie gedurende behandeling met **EMTROC TABLETS** borsvoed nie. Dit is nie bekend of die aktiewe bestanddeel van **EMTROC TABLETS** na menslike borsmelk versprei nie.

Bestuur en die gebruik van masjinerie
EMTROC TABLETS kan duiseligheid veroorsaak. As u duiseligheid voel terwyl u **EMTROC TABLETS** neem, moet u nie bestuur of met enige masjinerie of gereedskap werk nie.

EMTROC TABLETS bevat suiker (laktosemonohidraat)
EMTROC TABLETS bevat laktose. Pasiënte met die selde voorkomende oorerflike kondisies van laktose- of galaktosieintoleransie behoort nie **EMTROC TABLETS** te neem nie.

3. Hoe om EMTROC TABLETS te neem

Moenie medisyne wat aan u voorgeskryf is met enige ander persoon deel nie.
Neem altyd **EMTROC TABLETS** presies soos deur u dokter voorgeskryf. Raadpleeg u dokter of apteker as u onseker is. U dokter sal u in kennis stel oor hoe lank die behandeling met **EMTROC TABLETS** sal duur. Moenie die behandeling vroeg staak nie. As u onder die indruk is dat die effek van **EMTROC TABLETS** te sterk of te swak is, moet u u dokter of apteker raadpleeg.
- Bly onder gesondheidsorgverskaffer se toesig wanneer u **EMTROC TABLETS** neem. Moenie u behandeling verander of daarmee staak sonder om eers met u gesondheidsorgverskaffer te gesels nie.
- Neem altyd **EMTROC TABLETS** in kombinasie met ander antiretrovirusmiddels.
- Die normale dosis van **EMTROC TABLETS** is een tablet per dag, met of sonder voedsel.
- Neem **EMTROC TABLETS** elke dag op dieselfde tyd.

Behandeling van MIV
As u **EMTROC TABLETS** neem om die risiko van opdoen van MIV-1 te verminder, moet u ook ander metodes gebruik om die risiko van die opdoen van MIV te verminder (Sien "Neem spesiale sorg met **EMTROC TABLETS**").

As u te veel EMTROC TABLETS geneem het
In die geval van oordosering moet u u dokter of apteker raadpleeg. As nulle nie beskikbaar is nie, kontak u naaste gifbeheersentrum.
- Kry noodmediese hulp as u dink dat u te veel **EMTROC TABLETS** geneem het.

As u vergeet om EMTROC TABLETS te neem
As u vergeet het om u **EMTROC TABLETS** te neem, moet u dit neem sodra u daarvan onthou en gaan dan met die normale skedule voort.
Moenie die dosis verdubbel om vir 'n oorgeslaande dosis op te maak nie.

As u ophou hom EMTROC TABLETS te neem
U moet nie met die behandeling staak tensy u dokter dit aanbeveel nie. Wanneer u aantal **EMTROC TABLETS** inpk raak, moet u meer by u gesondheidsorgverskaffer of apteek kry. Dit is baie belangrik aangesien die hoeveelheid virus in u bloed sal vermeerder as u met die behandeling staak, selfs net vir 'n kort tydjie. Die virus mag weerstand teen **EMTROC TABLETS** ontwikkel en moeilik raak om te behandel.

4. Moontlike newe-effekte

EMTROC TABLETS kan newe-effekte hê.
Nie al die newe-effekte wat vir **EMTROC TABLETS** aangemeld is word in hierdie inligtingsblad ingesluit nie. Indien u algemene gesondheid agteruitgaan of as u enige ongewone effekte ondervind terwyl u **EMTROC TABLETS** neem, moet u u dokter, apteker of gesondheidsorgverskaffer raadpleeg.

Indien enige van die volgende gebeur moet u **met EMTROC TABLETS** staak en onmiddellik u dokter raadpleeg of gaan na die ongevalle afdeling van u naaste hospitaal.
- Urtikaria; moeite met asemhaling; swelling van u gesig, lippe, long of keel.

Hierdie is almal baie ernstige newe-effekte. As nulle voorkom mag u dalk 'n allergiese reaksie teen **EMTROC TABLETS** ontwikkel het. U mag moontlik dringende mediese sorg of hospitalisering benodig.

Stel onmiddellik u dokter in kennis of gaan na die ongevalle afdeling van u naaste hospitaal as u enige van die volgende waarneem:
- Melksuurseldose (erge toename van melksuur in die bloed, 'n ernstige newe-effek wat fataal mag wees)
- Die volgende newe-effekte mag tekens van melksuurseldose wees: diep, vinnige asemhaling, lomerigheid, naarheid, braking en maagpyn.
- Lewerbeskadiging - naarheid, maagpyn, effense koors, verlies aan eetlus, donker urien, kleigekleurde stoelgang, geelsug (geel verkleuring van die vel of oë)
- Koors, kouekoors, seer keel, hoes of ander tekens van infeksie.

Hierdie is almal ernstige newe-effekte. U het moontlik dringende mediese sorg nodig.

Stel u dokter in kennis as u enige van die volgende newe-effekte waarneem en hulle kommer wek, of as enige van hierdie simptome erg is of nie verdwyn nie.

Slaapprobleme (onvermoë om te slaap, abnormale drome), hoofpyn, duiseligheid, braking, diarree, indigestie, inflammasie van die pankreas, buikpyn, ormatige gas in die maag of derm kanaal, veluitslag, velverkleuring (veral van die handpalms en voetsole), pyn, ongewone moegheid of swakheid, verlies aan eetlus, koors, sweet massaverlies.
Laboratorium bloedtoetse mag 'n tekort aan witbloedselle, hoë cholesterolvlakke, hoë suikervlakke, verhoogde lewerenssieme, 'n toename in bilirubiemvlakke (weens lewerbeskadiging), 'n toename in kreatien-kinasevlakke, lae fosfaatvlakke en lae kalium lekke aandui.

Minder dikwels voorkomende newe-effekte.
Tekort aan energie, depressie, angs, senuweeprobleme, gevoelloosheid, prikkeling, spekte en naalde, toename in hoes, koorsige of vroulyke neus, gewrigspyn, spierpyn, spierswakheid, allergiese reaksie, spierpyn of -swakheid as gevolg van beskadiging van die nierbuisselle, inflammasie van die lewer, vetrige lewer, hortadembeid, longinfeksie, pyn, rugpyn, borspyn; nierprobleme, veranderinge in urien, veranderinge in liggaamsvet, insluitende 'n toename en die hoeveelheid vet op die boonste gedeelte van die rug en nek, bors en om die buikruse terwyl 'n verlies aan vet van die bene, arms en gesig ook mag voorkom.
Laboratoriumtoetse mag 'n afname in rooibloedselle of 'n afname in hemoglobienvlakke en bloed in die urien aandui.

Aanmelding van newe-effekte
As u newe-effekte waarneem, moet in u dokter, apteker of verpleër in kennis stel. Dit sluit enige moontlike newe-effekte wat nie in hierdie inligtingblad genoem word nie. U kan ook newe-effekte aan SAHPRA via die **"6.0 Nadelige Middelreaksie Aanmeldingsvorm"** aanmeld. Dit kan aanlyn gevind word onder SAHPRA se publikasies: https://sahpra.org.za/Publications/Index/8. Deur newe-effekte aan te meld kan u help om meer inligting oor die veiligheid van **EMTROC TABLETS** te verskaf.

5. Hoe om EMTROC TABLETS te bewaar

Bewaar alle medisyne buite bereik van kinders.
Bewaar teen of benede 25 °C (kamertemperatuur).
Hou die blaarverpakking in die karton tot voor gebruik.
Hou die bottel stewig toe
Beskerm teen lig.
Moenie in die badkamer bewaar nie.
Moenie na die vervaldatum op die etiket/karton/bottel gebruik gebruik nie.
Neem alle ongebruikte medisyne na u apteker terug.
Moenie ongebruikte medisyne in die drein of rioleringsisteem (bv toilette) wegdoen nie.

6. Inhoud van die verpakking en ander inligting

- Die aktiewe bestanddeels is 200 mg emtrisitabien en 300 mg tenofovirdisoproksielfumarsaat.
- Die ander bestanddele is kolloïdale silikondioksied, kroskarmellose natrium, laktosemonohidraat, magnesiumstearaat, mikrokristallyne sellulose, voorafgelatiniseerde stysel. Die bedekking bevat hidroksipropielmetielsellulose, laktosemonohidraat, titandioksied (Kleurindeks Nr. 77891) triasetien, FD&C Blou Nr.2 (Kleurindeks No. 73015).

Hoe EMTROC TABLETS lyk en die inhoud van die verpakking
HDPE bottel. Pak van 28 of 30 tablette.
- 75 ml, swaardiens, ronde wit HDPE bottel 38 - 400 nek en 'n 36 mm deksel met pulp en hitteseël -voering wat 'n 3 g silikagelsakkie bevat.

Alu-Alu stolpverpakking (10 X 10) tablette:
- Kouevormlaminaat 25 mikron PA/45 aluminiumfoelie /60 mikron PVC en gewone 25 mikron aluminiumfoelie met 8-8 GSM HSL.

Houer van die registrasiesertifikaat en vervaardiger:
Macleods Pharmaceuticals SA (Edms) Bpk.
Kantoorblok, Bassonia Estate Office Park (Ooe)
Cussoniarylaan 1, Bassonia Rock ulbr. 17
Alberton Suid Afrika

Registrasienommer/Verwysingsnommer
4/26.2.5/0185

Die laaste hersiening van hierdie inligtingsblad was:
Datum van registrasie
7 Desember 2012

Datum van hersiening
7 November 2019

MASTER COPY

MACLEODS

PACKAGING RESEARCH & DEVELOPMENT

Restricted Circulation

(Front Page)

ARTWORK / PRINTPROOF APPROVAL FORM

Note : Excluded the PI (English and Afrikaans lanuguage), Removed child resistant, Included QR codes and website URL and dimension change in PIL.

1. Product: EMTROC TABLETS (Emtricitabine 200 mg and Tenofovir disoproxil fumarate 300 mg Tablets)	
2. Country: South Africa (Activo)	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: 335(L) x 280 (H) mm
9. Design / Style: Booklet	10. Item code No.: PM03229502
11. Artwork has been made: Actual Size	12. Pharma code No.: 33000 mini
13. Barcode/NDC no: NA	14. Supersedes Item code No: PM03229501
15. Revision no: 01	16. File Name :X:\EMTRICITABINE AND TENOFOVIR\04\EMTROC TABLETS PIL- PM03229502.cdr
Approved By:	17. Location: Baddi

PRD	M.A. HOLDER	MEDICAL/RAD	QC	PRODN	QA
15/06/23	Vanita Rajool	16/06/23	20/06/23	21/6/23	22/06/23

QA Tanko 22/06/23

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	PM03229501	27/12/19	07/09/2020
2) Excluded the PI (English and Afrikaans lanuguage), Removed child resistant, Included QR codes and website URL and dimension change in PIL.	PM03229502		

UNCONTROLLED COPY