Front Side

335 mm

EMTRITAF 200/25
(film-coated tablet)
PM04340699

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

EMTRITAF 200/25
emtricitabine/tenofovir alafenamide
Sugar Free

WARNING:
TOO MUCH LACTIC ACID IN YOUR BLOOD (LACTIC ACIDOSIS) IS A SERIOUS BUT RARE MEDICAL EMERGENCY THAT CAN LEAD TO DEATH. TELL YOUR HEALTHCARE PROVIDER RIGHT AWAY IF YOU GET THESE SYMPTOMS: WEAKNESS OR BEING TIRED MORE THAN USUAL, UNUSUAL MUSCLE PAIN, BEING SHORT OF BREATH OR FAST BREATHING, STOMACH PAIN WITH NAUSEA AND VOMITING, COLD OR BLUE HANDS AND FEET, FEEL DIZZY OR LIGHTHEADED, OR A FAST OR ABNORMAL HEARTBEAT.
IF YOU HAVE HEPATITIS B INFECTION, YOUR DOCTOR WILL CAREFULLY CONSIDER THE BEST TREATMENT REGIMEN FOR YOU. IF YOU HAVE HEPATITIS B INFECTION, LIVER PROBLEMS MAY BECOME WORSE AFTER YOU STOP TAKING EMTRITAF 200/25. IT IS IMPORTANT NOT TO STOP TAKING EMTRITAF 200/25 WITHOUT TALKING TO YOUR DOCTOR. YOU MUST REMAIN UNDER THE CARE OF YOUR DOCTOR WHILE TAKING EMTRITAF 200/25.

Read all of this leaflet carefully before you start taking EMTRITAF 200/25
- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- **EMTRITAF 200/25** 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 **EMTRITAF 200/25** is and what it is used for
2. What you need to know before you take **EMTRITAF 200/25**
3. How to take **EMTRITAF 200/25**
4. Possible side effects
5. How to store **EMTRITAF 200/25**
6. Contents of the pack and other information

1. What EMTRITAF 200/25 is and what it is used for

EMTRITAF 200/25 contains two active substances:
- emtricitabine, an antiretroviral medicine of a type known as a nucleoside reverse transcriptase inhibitor (NRTI)
- tenofovir alafenamide, an antiretroviral medicine of a type known as a nucleotide reverse transcriptase inhibitor (NtRTI)

EMTRITAF 200/25 blocks the action of the reverse transcriptase enzyme, which is essential for the virus to multiply. **EMTRITAF 200/25** therefore reduces the amount of HIV in your body.
EMTRITAF 200/25 in combination with other medicines is for the treatment of human immunodeficiency virus 1 (HIV-1) infection in adults and adolescents 12 years of age and older, who weigh at least 35 kg.

2. What you need to know before you take EMTRITAF 200/25

Do not take EMTRITAF 200/25:
If you are allergic to emtricitabine, tenofovir alafenamide or any of the other ingredients of this medicine (listed in section 6 of this leaflet).

Warnings and precautions
Too much lactic acid blood (lactic in your acidosis) is a serious but rare medical emergency that can lead to death. Tell your healthcare provider right away if you get these symptoms: weakness or being more tired than usual, unusual muscle pain, being short of breath or fast breathing, stomach pain with nausea and vomiting, cold or blue hands and feet, feel dizzy or lightheaded, or a fast or abnormal heartbeat.

If you have hepatitis B infection, your doctor will carefully consider the best treatment regimen for you. If you have hepatitis B infection, liver problems may become worse after you stop taking **EMTRITAF 200/25.** It is important not to stop taking **EMTRITAF 200/25** without talking to your doctor.
You must remain under the care of your doctor while taking **EMTRITAF 200/25**.
You can still pass on HIV when taking **EMTRITAF 200/25**. Discuss with your doctor the precautions needed to avoid infecting other people. **EMTRITAF 200/25** is not a cure for HIV infection. While taking **EMTRITAF 200/25** you may still develop infections or other illnesses associated with HIV infection.
During HIV therapy such as with **EMTRITAF 200/25** there may be an increase in weight and in levels of blood lipids and glucose. This is partly linked to restored health and life style, and in the case of blood lipids sometimes to the HIV medicines themselves. Your doctor will test for these changes.
Autoimmune disorders (the immune system attacks healthy body tissue), may also occur after you start taking medicines for HIV infection such as **EMTRITAF 200/25**. Autoimmune disorders may occur many months after the start of treatment. Look out for any symptoms of infection or other symptoms such as:
- Muscle weakness
- Weakness beginning in the hands and feet and moving up towards the trunk of the body
- Palpitations, tremor or hyperactivity

Talk to your doctor before taking EMTRITAF 200/25:
If you have liver problems or have suffered liver disease, including hepatitis.
- Patients with liver disease including chronic hepatitis B or C, who are treated with antiretrovirals, have a higher risk of severe and potentially fatal liver complications. If you have hepatitis B infection, your doctor will carefully consider the best treatment regimen for you.
- If you have hepatitis B liver problems it may become worse after you stop taking **EMTRITAF 200/25**. Do not stop taking **EMTRITAF 200/25** without talking to your doctor: see section 3, Do not stop taking **EMTRITAF 200/25**.
- Your doctor may not prescribe **EMTRITAF 200/25** to you if the virus has a K65R mutation.

Once you start taking **EMTRITAF 200/25**, look out for:
- Signs of inflammation or infection
- Any signs of inflammation or infection. In some patients with advanced HIV infection (AIDS) and who have had opportunistic infections in the past (infections that occur in people with a weak immune system), signs and symptoms of inflammation from previous infections may occur soon after antiretroviral treatment, such as with **EMTRITAF 200/25**, is started. It is thought that these symptoms are due to an improvement in the body's immune response, enabling the body to fight infections that may have been present with no obvious symptoms.

Joint pain, stiffness or bone problems
Bone problems. Some patients taking combination antiretroviral medicines such as **EMTRITAF 200/25** may develop a bone disease called osteonecrosis (death of bone tissue caused by loss of blood supply to the bone). Taking this type of medicine for a long time, taking corticosteroids, drinking alcohol, having a very weak immune system, and being overweight, may be some of the many risk factors for developing this disease. Signs of osteonecrosis are:
- Joint stiffness
- Joint aches and pains (especially of the hip, knee and shoulder)
- Difficulty with movement

If you notice any of these symptoms, tell your doctor immediately. For more information see section 4, Possible side effects.
Although kidney problems have not been observed with **EMTRITAF 200/25**, there is a possibility that you may experience kidney problems when taking **EMTRITAF 200/25** over a long period of time.

Use in children and adolescents
Do not give this medicine to children under 12 years of age, or weighing less than 35 kg. The use of **EMTRITAF 200/25** in children under 12 years of age has not been studied.

Other medicines and EMTRITAF 200/25
Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines.)
Medicines used in treating hepatitis B infection:
You should not take **EMTRITAF 200/25** with medicines containing:
- Tenofovir alafenamide
- Tenofovir disoproxil
- Lamivudine
- Adefovir dipivoxil

Tell your doctor if you are taking any of these medicines.
Other types of medicine:
Talk to your doctor if you are taking:
- Antibiotics, used to treat bacterial infections including tuberculosis, containing: rifabutin, rifampicin, and rifapentine

antiviral medicines used to treat HIV: emtricitabine and tipranavir
anticonvulsants, used to treat epilepsy, such as: carbamazepine, oxcarbazepine, phenobarbitone and phenytoin
herbal remedies used to treat depression and anxiety containing:
- St. John's wort (*Hypericum perforatum*)

Tell your doctor if you are taking these or any other medicines. Do not stop your treatment without contacting your doctor.

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 **EMTRITAF 200/25**.

Use effective contraception while taking **EMTRITAF 200/25**.
Ask your doctor or pharmacist for advice before taking any medicine when pregnant.
If you have taken **EMTRITAF 200/25** during your pregnancy, your doctor may request regular blood tests and other diagnostic tests to monitor the development of your child. In children whose mothers took NRTIs during pregnancy, the benefit from the protection against HIV outweighed the risk of side effects.
Do not breast-feed your baby during treatment with **EMTRITAF 200/25**.
One of the active substances in **EMTRITAF 200/25** (emtricitabine) passes into breast milk and possible harm to your baby cannot be excluded.
It is also recommended that you do not breast-feed your baby to avoid passing the HIV virus to the baby through your breast milk.

Driving and using machines
EMTRITAF 200/25 may affect your ability to drive and use machines. Do not drive and use machines until you know how treatment with **EMTRITAF 200/25** affects you.

3. How to take EMTRITAF 200/25

Do not share medicines prescribed for you with any other person.

Always take **EMTRITAF 200/25** exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are not sure.

The recommended dose is:
Adults: one tablet each day, with or without food
Adolescents 12 years of age and older, who weigh at least 35 kg: one tablet each day with or without food
Do not chew, crush or split the tablet.
Always take the dose recommended by your doctor. This is to make sure that your medicine is fully effective, and to reduce the risk of developing resistance to the treatment. Do not change the dose unless your doctor tells you to.
If you are on dialysis, take your daily dose of **EMTRITAF 200/25** following completion of dialysis.

If you have the impression that the effect of **EMTRITAF 200/25** is too strong or too weak, talk to your doctor or pharmacist.

If you take more EMTRITAF 200/25 than you should
In the event of over dosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you forget to take EMTRITAF 200/25
It is important to take your **EMTRITAF 200/25** regularly at the same time each day.
It is important not to miss a dose of **EMTRITAF 200/25**.
If you do miss a dose:
If you notice within 18 hours of the time you usually take **EMTRITAF 200/25**, you must take the tablet as soon as possible. Then take the next dose as usual.
If you notice 18 hours or more after the time you usually take **EMTRITAF 200/25**, then do not take the missed dose. Wait and take the next dose at your usual time.
If you vomit less than 1 hour after taking **EMTRITAF 200/25**, take another tablet.

Do not stop taking EMTRITAF 200/25

4. Possible side effects

EMTRITAF 200/25 can have side effects.
Not all side effects reported for **EMTRITAF 200/25** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking **EMTRITAF 200/25**, please consult your doctor, pharmacist or other healthcare professional for advice.

If any of the following happens, stop taking **EMTRITAF 200/25** and tell your doctor immediately or go to the casualty department at your nearest hospital:
- Any signs of inflammation or infection. In some patients with advanced HIV infection (AIDS) and who have had opportunistic infections in the past (infections that occur in people with a weak immune system), signs and symptoms of inflammation from previous infections may occur soon after antiretroviral treatment such as with **EMTRITAF 200/25** is started. It is thought that these symptoms are due to an improvement in the body's immune response, enabling the body to fight infections that may have been present with no obvious symptoms.
- Autoimmune disorders (the immune system attacks healthy body tissue), may also occur after you start taking medicines for HIV infection such as **EMTRITAF 200/25**. Autoimmune disorders may occur many months after the start of treatment. Look out for any symptoms of infection or other symptoms such as:
- muscle weakness
- weakness beginning in the hands and feet and moving up towards the trunk of the body
- palpitations, tremor or hyperactivity

If you notice the side effects described above, tell your doctor immediately.

- Swelling of the face, lips or throat with difficult breathing (angioedema)

These are all very serious side effects. If you have them, you may have had a serious reaction to **EMTRITAF 200/25**. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:
Frequent
- Feeling sick (nausea)
- Abnormal dreams
- Headache
- Dizziness
- Diarrhoea
- Vomiting
- Stomach pain
- Wind (flatulence)
- Rash
- Tiredness (fatigue)

Less frequent:
- Itching (pruritus),
- Hives (urticaria)
- Low red blood cell count (anaemia)
- Problems with digestion resulting in discomfort after meals (dyspepsia)
- Joint pain (arthralgia)

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.
Should your general health worsen or if you experience any untoward effects while taking **EMTRITAF 200/25**, please consult your healthcare provider for advice.

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 Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website or to Macleods Pharmaceuticals SA (Pty) Ltd. at safety@macleodspharma.com. By reporting side effects, you can help provide more information on the safety of **EMTRITAF 200/25.**

5. How to store EMTRITAF 200/25

Store at or below 25 °C.
KEEP OUT OF THE REACH OF CHILDREN.
Store in the original package / container.
Keep the HDPE container tightly closed.
Do not store in a bathroom.
Do not use after the expiry date stated on the blister / 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 EMTRITAF 200/25 contains
The active ingredients are emtricitabine and tenofovir alafenamide.
The other ingredients are:
Tablet Core:
Microcrystalline Cellulose
Croscarmellose Sodium
Magnesium Stearate
Tablet Coat:
Opadry White, Isopropyl Alcohol and Methylene Chloride
Opadry White: HPMC /Hypromellose, Titanium dioxide, Macrogol/PEG, Talc

What EMTRITAF 200/25 looks like and contents of the pack
EMTRITAF 200/25 : White to off-white, oval shaped, film coated tablets, debossed with 'J 57' on one side and plain on other side.

Contents of the pack:
Round, white, HDPE container with neck finish, containing tablets and silica gel sachets, closed with polypropylene white closure with pulp and heat seal liner and packed in a pre-printed unit carton.
Pack sizes include 28's and 30's tablets.
Not all pack sizes may be marketed.

7. HOLDER OF CERTIFICATE OF REGISTRATION

MACLEODS PHARMACEUTICALS SA (PTY) LTD
GROUND FLOOR, BLOCK 1,
BASSONIA ESTATE OFFICE PARK (EAST),
1 CUSSONIA DRIVE,
BASSONIA ROCK EXT 12
ALBERTON
GAUTENG

This leaflet was last revised in
08 July 2025

Registration number
58/20.2.8/0027.026

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

335 mm

Back Side

335 mm

PASIËNTINLIGTINGSTUK

SKEDULERINGSTATUS: S4

EMTRITAF 200/25 mg
emtrisitabien/tenofovir alafenamied
Suikervry

WAARSKUWING:
TE VEEL MELKSUUR IN JOU BLOED (LAKTIESE ASIDOSE) IS 'n ERNSTIGE MAAR SKAARS MEDIESE NOODGEVAL WAT TOT DIE DOOD KAN LEI. VERTEL ONMIDDELLIK JOU GESONDHEIDSORGVERSKAFFER INDIEN JY HIERDIE SIMPTOME KRY: SWAKHEID, OF IS MEER MOEG AS GEWOONLIK, ONGEWONE SPIERPYN, KORT VAN ASEM WEES OF VINNIGE ASEMHALING, MAAGPYN MET NAARHEID EN BRAKING, KOUE OF BLOU HANDE EN VOETE, VOEL DUISELIG OF LIGHOOFDIG, OF 'N VINNIGE OF ABNORMALE HARTKLOP.
INDIEN JY HEPATITIS B INFEKSIE HET, SAL JOU DOKTER DIE BESTE BEHANDELINGS REGIMEN VIR JOU OORWEEG. INDIEN JY HEPATITIS B INFEKSIE HET, KAN LEWERPROBLEME ERGER WORD NADAT JY OPHOU OM EMTRITAF TE NEEM. DIT IS BELANGRIK OM NIE OP TE HOU OM EMTRITAF TE NEEM SONDER OM MET JOU DOKTER TE PRAAT NIE. JY MOET ONDER DIE SORG VAN JOU DOKTER BLY TERWYL JY EMTRITAF NEEM.

Lees hierdie hele inligtingstuk noukeurig deur, voordat jy EMTRITAF begin neem
- Hou hierdie inligtingstuk. Dit mag nodig wees dat jy dit weer moet lees.
- Indien jy verdere vrae het, vra asseblief jou dokter, apteker, verpleegkundige of ander gesondheidsorgverskaffer.
- **EMTRITAF** is vir jou persoonlik voorgeskryf en jy moet nie jou medisyne met ander mense deel nie. Dit mag skadelik vir hulle wees, selfs al is hulle simptome dieselfde as joune.

Wat is in hierdie inligtingstuk

1. Wat **EMTRITAF** is en waarvoor dit gebruik word.
2. Wat jy behoort te weet voordat jy **EMTRITAF** neem
3. Hoe om **EMTRITAF** te neem
4. Moontlike newe-effekte
5. Hoe om **EMTRITAF** te bewaar
6. Inhoud van die pak en ander inligting

1. Wat EMTRITAF is en waarvoor dit gebruik word.

EMTRITAF bevat twee aktiewe bestanddele:
- emtrisitabien, 'n anti-retrovirale medisyne van 'n soort wat bekend staan as 'n nukleosied-omgekeerde transkriptase-inhibeerder (NRTI)
- tenofovir alafenamied, 'n anti-retrovirale medisyne van 'n soort wat bekend staan as 'n nukleotied-omgekeerde transkriptase-inhibeerder (NtRTI)

EMTRITAF blokkeer die werking van die omgekeerde transkriptase-ensiem, wat noodsaaklik is vir die virus om te vermeerder. **EMTRITAF** verminder dus die hoeveelheid MIV in jou liggaam.
EMTRITAF in kombinasie met ander medisyne is vir die behandeling van menslike immuniteitsgebreksvirus 1 (MIV-1) infeksie in volwassenes en adolessente van 12 jarige ouderdom en ouer, wat minstens 35 kg weeg.

2. Wat jy behoort te weet voordat jy EMTRITAF neem

Moet nie EMTRITAF neem nie:
Indien jy allergies is vir emtrisitabien, tenofovir alafenamied of enige van die ander bestanddele van hierdie medisyne (gelys in afdeling 6 van hierdie inligtingstuk).

Waarskuwings en voorsorgmaatreëls
Te veel bloedmelksuur (lakties in jou asidose) is 'n ernstige maar seldsame mediese noodgeval wat tot die dood kan lei. Vertel onmiddellik jou gesondheidsorgverskaffer indien jy hierdie simptome kry: swakheid, of is meer moeg as gewoonlik, ongewone spierpyn, kort van asem of vinnige asemhaling, maagpyn met naarheid en braking, koue of blou hande en voete, voel duiselig of lighoofdig, of 'n vinnige of abnormale hartklop.

Indien jy hepatitis B infeksie het, sal jou dokter die beste behandelings regimen vir jou oorweeg. Indien jy hepatitis B infeksie het, kan lewerprobleme erger word nadat jy ophou om **EMTRITAF** te neem. Dit is belangrik om nie op te hou om **EMTRITAF** te neem sonder om met jou dokter te praat nie.
Jy moet onder die sorg van jou dokter bly terwyl jy **EMTRITAF** neem.
Jy kan steeds MIV oordra wanneer jy **EMTRITAF** neem. Bespreek met jou dokter die voorsorgmaatreëls wat nodig is om te verhoed dat ander mense besmet word.
EMTRITAF is nie 'n kuur vir MIV-infeksie nie. Terwyl jy **EMTRITAF** neem, kan jy steeds infeksies of ander siektes ontwikkel wat met MIV-infeksie geassosieer word.
Tydens MIV-behandeling soos met **EMTRITAF** kan daar 'n toename in gewig en in vlakke van bloedlipiede en glukose wees. Dit hou deels verband met herstelde gesondheid en lewenstyl, en in die geval van bloedlipiede soms met die MIV-medisyne self. Jou dokter sal vir hierdie veranderinge toets.
Outo-immuun afwykings (die immuunstelsel val gesonde liggaamsweefsel aan), kan ook voorkom nadat jy medisyne vir MIV-infeksie begin neem het, soos **EMTRITAF**. Outo-immuun afwykings kan etlike maande na die aanvang van die behandeling voorkom. Wees op die uitkyk vir enige simptome van infeksie of ander simptome soos:
- Spierswakheid
- Swakheid wat in die hande en voete begin en opbeweeg na die romp van die liggaam
- Hartkloppings, bewing of hiperaktiwiteit

Vertel jou dokter voordat jy EMTRITAF neem:
- Indien jy lewerprobleme het of lewersiekte gehad het, insluitend hepatitis.
- Pasiënte met lewersiekte insluitend chroniese hepatitis B of C, wat met anti-retrovirale middels behandel word, het 'n hoër risiko van ernstige en potensieel dodelike lewerkomplikasies. Indien jy hepatitis B infeksie het, sal jou dokter noukeurig die beste behandelings regime vir jou oorweeg.
- Indien jy hepatitis B lewerprobleme het, kan dit erger word nadat jy opgehou het om **EMTRITAF** te neem. Moet nie ophou om **EMTRITAF** te neem sonder om met jou dokter te praat nie: sien afdeling 3, Moet nie ophou om **EMTRITAF** te neem nie.
- Jou dokter mag nie **EMTRITAF** aan jou voorskryf indien die virus 'n K65R-mutasie het nie.

Sodra jy **EMTRITAF** begin neem, kyk uit vir:
- Tekens van inflammasie of infeksie
- Enige tekens van inflammasie of infeksie. In sommige pasiënte met gevorderde MIV-infeksie (VIGS) en wie in die verlede opportunistiese infeksies gehad het (infeksies wat voorkom in mense met 'n swak immuunstelsel), kan tekens en simptome van inflammasie van vorige infeksies voorkom, kort nadat anti-retrovirale behandeling, soos met **EMTRITAF**, begin is. Daar word vermoed dat hierdie simptome te wyte is aan 'n verbetering in die liggaam se immuunrespons, wat die liggaam in staat stel om infeksies te beveg wat moontlik teenwoordig was sonder duidelike simptome.

Gewrigspyn, styfheid of beenprobleme
- Beenprobleme. Sommige pasiënte wat kombinasie anti-retrovirale medisyne soos **EMTRITAF** neem, kan 'n beensiekte genaamd osteonekrose ontwikkel (dood van beenweefsel wat veroorsaak word deur verlies van bloedtoevoer na die been). Neem van hierdie soort medisyne vir 'n lang tyd, neem van kortikosteroïede, om alkohol te drink, 'n baie swak immuunstelsel te hê en oorgewig te wees, kan 'n paar van die vele risiko faktore wees vir die ontwikkeling van hierdie siekte. Tekens van osteonekrose is:
  - Gewrigstyfheid
  - Gewrigspyn en -pyne (veral van die heup, knie en skouer)
  - Moeilik met beweging

Indien jy enige van hierdie simptome opmerk, vertel onmiddelllik jou dokter. Vir meer inligting, sien afdeling 4, Moontlike newe-effekte.
Alhoewel nierprobleme nie met **EMTRITAF** waargeneem is nie, is daar 'n moontlikheid dat jy nierprobleme kan ervaar wanneer jy **EMTRITAF** oor 'n lang tydperk neem.

Gebruik in kinders en adolessente
Moet nie hierdie medisyne aan kinders onder 12 jarige ouderdom, of wat minder as 35 kg weeg, gee nie. Die gebruik van **EMTRITAF** in kinders onder 12 jarige ouderdom is nie bestudeer nie.

Ander medisyne en EMTRITAF
Vertel altyd jou professionele gesondheidsorgwerker indien jy enige ander medisyne neem. (Dit sluit komplementêre of tradisionele medisyne in).
Medisyne wat gebruik word in die behandeling van hepatitis B infeksie:
Jy moet nie **EMTRITAF** neem saam met medisyne bevattende:
- Tenofovir alafenamied
- Tenofovir disoproksiel
- Lamivudien
- Adefovir dipivoksiel

Vertel jou dokter indien jy enige van hierdie medisyne neem.
Ander soorte medisyne:
Praat met jou dokter indien jy neem:
- Antibiotika, wat gebruik word om bakteriële infeksies te behandel insluitend tuberkulose, bevattende: rifabutien, rifampisien, en rifapentien
- antivirale medisyne wat gebruik word om MIV te behandel: emtrisitabien en tipranavir
- antikonvulsiewe middels, wat gebruik word om epilepsie te behandel, soos: karbamasepien, okskarbasepien, fenobarbitoon en fenitoïen
- kruiemiddels wat gebruik word om depressie en angs te behandel bevattende:
- St. Johanneskruid (*Hypericum perforatum*)

Vertel jou dokter indien jy hierdie of enige ander medisyne gebruik. Moet nie jou behandeling stop sonder om jou dokter te kontak nie.

Swangerskap, borsvoeding en fertiliteit
Indien jy swanger is of jou baba borsvoed, raadpleeg asseblief jou dokter, apteker of ander professionele gesondheidsorgwerker vir advies voordat jy **EMTRITAF** neem.

Gebruik effektiewe voorbehoeding terwyl jy **EMTRITAF** neem.
Vra jou dokter of apteker vir advies voordat jy enige medisyne neem tydens swangerskap.
Indien jy **EMTRITAF** tydens jou swangerskap geneem het, kan jou dokter gereelde bloedtoetse en ander diagnostiese toetse aanvra om die ontwikkeling van jou kind te monitor. In kinders wie se moeders NRTI's tydens swangerskap geneem het, was die voordeel van die beskerming teen MIV groter as die risiko van newe-effekte.
Moet nie jou baba borsvoed tydens behandeling met **EMTRITAF** nie.
Een van die aktiewe stowwe in **EMTRITAF** (emtrisitabien) gaan in borsmelk oor en moontlike skade aan jou baba kan nie uitgesluit word nie.
Dit word ook aanbeveel dat jy nie jou baba borsvoed nie om te verhoed dat die MIV-virus deur jou borsmelk na die baba oorgedra word.

Bestuur en gebruik van masjinerie
EMTRITAF kan jou vermoë om te bestuur en masjiene te gebruik beïnvloed. Moet nie bestuur en masjiene gebruik totdat jy weet hoe behandeling met **EMTRITAF** jou affekteer nie.

3. Hoe om EMTRITAF te neem

Moet nie medisyne wat vir jou voorgeskryf is met enige ander persoon deel nie.

Neem altyd **EMTRITAF** presies soos wat jou dokter jou opdrag gegee het. Jy moet met jou dokter of apteker bevestig indien jy nie seker is nie.

Die aanbevole dosis is:
Volwassenes: een tablet elke dag, met of sonder kos
Adolessente van 12 jarige ouderdom en ouer, wat minstens 35 kg weeg: een tablet elke dag met of sonder kos
Moet nie die tablet kou, fynmaak of breek nie.
Neem altyd die dosis wat deur jou dokter aanbeveel is. Dit is om seker te maak dat jou medisyne ten volle effektief is, en om die risiko te verminder om weerstand teen die behandeling te ontwikkel. Moet nie die dosis verander nie, tensy jou dokter jou beveel om dit te doen.
Indien jy op dialise is, neem jou daaglikse dosis van **EMTRITAF** na voltooiing van dialise.
Indien jy die indruk het dat die effek van **EMTRITAF** te sterk of te swak is, praat met jou dokter of apteker.

Indien jy meer EMTRITAF inneem as wat jy moet
In die geval van oordosering, kontak jou dokter of apteker. Indien nie een beskikbaar is nie, kontak die naaste hospitaal of gifbeheersentrum.

Indien jy vergeet om EMTRITAF te neem
Dit is belangrik om jou **EMTRITAF** gereeld op dieselfde tyd elke dag te neem.
Dit is belangrik om nie 'n dosis van **EMTRITAF** te mis nie.
Indien jy wel 'n dosis mis:
Indien jy binne 18 ure van die tyd wat jy gewoonlik **EMTRITAF** neem agterkom, moet jy die tablet so gou as moontlik neem. Neem dan die volgende dosis soos gewoonlik.
Indien jy 18 ure of meer agterkom na die tyd wat jy gewoonlik **EMTRITAF** neem, moet dan nie die vergete dosis neem nie. Wag en neem die volgende dosis op jou gewone tyd.
Indien jy braak minder as 1 uur nadat jy **EMTRITAF** geneem het, neem nog 'n tablet.

Moet nie ophou EMTRITAF neem nie

4. Moontlike newe-effekte

EMTRITAF kan newe-effekte hê.
Nie alle newe-effekte wat vir **EMTRITAF** aangemeld is, is in hierdie inligtingstuk ingesluit nie. Sou jou algemene gesondheid verswak of indien jy enige ongunstige effekte ervaar terwyl jy **EMTRITAF** neem, raadpleeg asseblief jou dokter, apteker of ander professionele gesondheidsorgwerker vir advies.

Indien enige van die volgende gebeur, hou op om **EMTRITAF** te neem en vertel onmiddellik vir jou dokter of gaan na die ongevalle-afdeling by jou naaste hospitaal:
- Enige tekens van inflammasie of infeksie. In sommige pasiënte met gevorderde MIV-infeksie (VIGS) en wie in die verlede opportunistiese infeksies gehad het (infeksies wat voorkom in mense met 'n swak immuunstelsel), kan tekens en simptome van inflammasie van vorige infeksies voorkom, kort nadat anti-retrovirale behandeling, soos met **EMTRITAF**, begin is. Daar word vermoed dat hierdie simptome te wyte is aan 'n verbetering in die liggaam se immuunrespons, wat die liggaam in staat stel om infeksies te beveg wat moontlik teenwoordig was sonder duidelike simptome.
- Outo-immuun afwykings (die immuunstelsel val gesonde liggaamsweefsel aan), kan ook voorkom nadat jy medisyne vir MIV-infeksie begin neem het, soos **EMTRITAF**. Outo-immuun afwykings kan etlike maande na die aanvang van die behandeling voorkom. Wees op die uitkyk vir enige simptome van infeksie of ander simptome soos:
- spierswakheid
- swakheid wat in die hande en voete begin en opbeweeg na die romp van die liggaam
- hartkloppings, bewing of hiperaktiwiteit

Indien jy die newe-effekte wat hierbo beskryf word opmerk, vertel onmiddellik jou dokter.

- Swelling van die gesig, lippe of keel, met probleme om asem te haal (angioëdeem)

Hierdie is alles baie ernstige newe-effekte. Indien jy dit het, het jy moontlik 'n ernstige reaksie op **EMTRITAF** gehad. Jy sal dringende mediese hulp of hospitalisering benodig.

Vertel jou dokter indien jy enige van die volgende opmerk:
Dikwels
- Voel siek (naarheid)
- Abnormale drome
- Hoofpyn
- Duiseligheid
- Diarree
- Braking
- Maagpyn
- Winderigheid (flatulensie)
- Uitslag
- Moegheid (vermoeidheid)

Minder dikwels:
- Gejeuk (pruritus)
- Galbulte (urtikarie)
- Lae rooibloedseltelling (anemie)
- Probleme met vertering wat lei tot ongemak na etes (dispepsie)
- Gewrigspyn (artralgie)

Indien jy enige newe-effekte opmerk wat nie in hierdie inligtingstuk genoem word nie, stel asseblief jou dokter of apteker in kennis.
Sou jou algemene gesondheid verswak of indien jy enige ongunstige effekte ervaar terwyl jy **EMTRITAF** neem, raadpleeg asseblief jou gesondheidsorgverskaffer vir advies.

Rapportering van newe-effekte
Indien jy newe-effekte kry, praat met jou dokter of apteker of verpleegkundige. Dit sluit enige moontlike newe-effekte in wat nie in hierdie inligtingstuk gelys word nie. Jy kan ook newe-effekte aan SAHPRA rapporteer deur middel van die Med Safety APP (Medsafety X SAHPRA) en eReporting platform (who-umc.org) wat op SAHPRA se webwerf gevind word of aan Macleods Pharmaceuticals SA (Edms) Bpk. by safety@macleodspharma.com. Deur newe-effekte aan te meld kan jy help om meer inligting beskikbaar te stel aangaande die veiligheid van **EMTRITAF**.

5. Hoe om EMTRITAF te bewaar

Bewaar by of benede 25°C.
HOU BUITE DIE BEREIK VAN KINDERS.
Bewaar in die oorspronklike verpakking / houer.
Hou die HDPE houer dig toe.
Moet nie in 'n badkamer bêre nie.
Moet nie gebruik na die vervaldatum wat op die stulptrook / etiket / karton / bottel aangedui is nie.
Neem alle ongebruikte medisyne terug na jou apteker.
Moet nie ongebruikte medisyne in dreine of rioolstelsels (bv. toilette) weggooi nie.

6. Inhoud van die pak en ander inligting

Wat EMTRITAF bevat
Die aktiewe bestanddele is emtrisitabien en tenofovir alafenamied.
Die ander bestanddele is:
Tabletkern:
Mikrokristallyne sellulose
Natrium kroskarmellose
Magnesiumstearaat
Tabletfilm:
Opadry Wit, Isopropielalkohol en Metileenchloried
Opadry Wit: HPMC/Hipromellose, Titaandioksied, Makrogol/PEG, Talk

Hoe EMTRITAF lyk en die inhoud van die pak
EMTRITAF 200/25 mg: Wit tot naaswit, ovaalvormige, filmbedekte tablette, gegraveer met 'J 57' aan die een kant en glad aan die ander kant.

Inhoud van die pak:
Ronde, wit HDPE-houer met nek-afwerking, wat tablette en silikagel-sakkies bevat, gesluit met 'n wit polipropileen-sluiting met pulp- en hitteverseëlde voering en verpak in 'n voorafgedrukte eenheidsdoos.
Verpakkingsgroottes sluit 28's en 30's tablette in
Nie alle verpakkingsgroottes word noodwendig bemark nie.

7. HOUER VAN DIE SERTIFIKAAT VAN REGISTRASIE

MACLEODS PHARMACEUTICALS SA (EDMS) BPK
GRONDVLOER, BLOK 1,
BASSONIA ESTATE KANTOORPARK (OOS),
1 CUSSONIA-RYLAAN,
BASSONIA ROCK UITBR. 12,
ALBERTON
GAUTENG

Hierdie inligtingstuk is laas hersien in
08 Julie 2025

Registrasienommer
58/20.2.8/0027.026

Toegang tot die ooreenstemmende Professionele Inligting
Die ooreenstemmende professionele inligting kan verkry word by https://www.macleodssaproducts.co.za of e-pos macleodsrsa@macleodspharma.com of kontak 011 682 1169

335 mm

PACKAGING RESEARCH & DEVELOPMENT

Restricted Circulation

(Front Page)

ARTWORK / PRINTPROOF APPROVAL FORM

1. Product: EMTRITAF 200/25 mg (Emtricitabine 200 & Tenofovir AF 25 mg Tablets g)	
2. Country: South Africa (Private Market)	**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 335 (W) mm**
9. Design / Style: Booklet	**10. Item code No.: PM04340699**
11. Artwork has been made: Actual Size	**12. Pharma code No.: 40685 mini**
13. Barcode/NDC no: NA	**14. Supersedes Item code No:**
15. Revision No: 0	**16. A/W File name:Z:\South Africa\Emtricitabine 200 & Tenofovir AF\SA Private Market\EMTRITAF 200-25 PIL - PM.cdr**
Approved By:	**17. Location: Baddi**

PRD	M.A. HOLDER	RAD	QC	PRODN	QA
	12/12/2025				

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 Send for Printing Date	Artwork Implementation Date
1) New Artwork for South Africa	PM04340699		