PACKAGING RESEARCH & DEVELOPMENT

Restricted Circulation

(Front Page)

ARTWORK / PRINTPROOF APPROVAL FORM

335 mm

300 mm

RIOVEX 300
(film-coated tablets)
PM04339671

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

RIOVEX 300 (Film-coated tablet)
Tenofovir disoproxil fumarate 300 mg
Contains sugar (208,95 mg lactose monohydrate)

RIOVEX 300 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 RIOVEX 300 in patients who are infected with both human immunodeficiency virus (HIV) and hepatitis B virus (HBV) have not been established. RIOVEX 300 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 RIOVEX 300.

Read all of this leaflet carefully before you start taking RIOVEX 300
- Keep this leaflet. You may need to read it again.
- Ask your health care provider or pharmacist if you need more information or advice.
- **RIOVEX 300** 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 **RIOVEX 300** is and what it is used for
2. What you need to know before you take **RIOVEX 300**
3. How to take **RIOVEX 300**
4. Possible side effects
5. How to store **RIOVEX 300**
6. Contents of the pack and other information

1. What RIOVEX 300 is and what it is used for

RIOVEX 300 contains the active substance tenofovir disoproxil, a type of antiretroviral medicine called an HIV-1 (human immunodeficiency virus-1) nucleotide analogue reverse transcriptase inhibitor (NRTI).

RIOVEX 300 is always used in combination with other antiretroviral medicines to treat patients with HIV-1 infection

2. What you need to know before you take RIOVEX 300

Do not take RIOVEX 300:
- If you are hypersensitive (allergic) to tenofovir disoproxil fumarate, or any of the other ingredients of **RIOVEX 300** (listed in section 6).
- If you suffer from lactose intolerance, you should avoid this product as it contains lactose monohydrate.
- If you have kidney problems.
- If you are pregnant or breastfeeding.
- If you are already taking other medicines containing the active substance tenofovir.

Warnings and precautions
Tell your doctor or healthcare provider before you take **RIOVEX 300**.
Take special care with **RIOVEX 300**:
- **RIOVEX 300** 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, fatigue and weight loss might indicate the development of lactic acidosis. Lactic acidosis occurs more often in women. Patients who are overweight are more at risk.
- Tell your doctor if you have had kidney disease, or if tests have shown problems with your kidneys. **RIOVEX 300** may affect your kidneys.
- **RIOVEX 300** should not be taken with other medicines that can damage your kidneys. If this is unavoidable, your doctor will monitor your kidney function.
- Tell your doctor if you have liver disease (including hepatitis B). **RIOVEX 300** should not be used to treat chronic hepatitis B virus infection (HBV; an on-going liver infection).
- Inform your doctor if you are taking other medicines for HIV such as lamivudine in combination with abacavir or in combination with didanosine as combining **RIOVEX 300** with these medicines may lead to early treatment failure and resistance.
- Take your child, if exposed during pregnancy to **RIOVEX 300**, 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.
- If you are taking **RIOVEX 300** together with didanosine (another medicine used to treat HIV infection), inform your doctor if you develop symptoms of severe upper stomach pain with nausea (feeling sick) and vomiting which are signs of pancreatitis, a dangerous inflammation of the pancreas and may cause death or if you develop symptoms of numbness or weakness in the arms and legs.
- **RIOVEX 300** decreases bone mineral density which could result in fractures. Your doctor may prescribe calcium and vitamin D supplements while taking **RIOVEX 300**.
- 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.
- **RIOVEX 300** 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 **RIOVEX 300** is started. If you notice signs of inflammation or infection, or deterioration thereof, tell your doctor at once.
- **RIOVEX 300** 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 **RIOVEX 300** 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 **RIOVEX 300** 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.
- You will need to take **RIOVEX 300** every day. **RIOVEX 300** 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 **RIOVEX 300** 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.

Children and patients younger than 18 years
- The safety and effectiveness of **RIOVEX 300** in children and patients younger than 18 years has not been determined.

Other medicines and RIOVEX 300
Always tell your healthcare provider 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 or lamivudine (for HIV infection).
- Tell your doctor if you are taking atazanavir and/or 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 **RIOVEX 300**.
- If you are taking **RIOVEX 300** and atazanavir together, you should also be taking ritonavir.
- Tell your doctor if you are taking other medicines containing didanosine (for HIV infection). Taking **RIOVEX 300** 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 other medicines that may reduce your kidney function. Some examples include adefovir dipivoxil, cidofovir, acyclovir, valacyclovir, ganciclovir and valganciclovir.
- Non-steroidal anti-inflammatory medicines (NSAIDs). When these medicines are used at a high dose or many NSAIDS are used together, there is a risk of kidney failure when used with **RIOVEX 300**. Speak to your healthcare provider on alternative medicines that may be used. Examples of these medicines include diclofenac and ibuprofen.

RIOVEX 300 with food and drink and alcohol
RIOVEX 300 can be taken with or without food.

Pregnancy, breastfeeding and fertility
If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before taking **RIOVEX 300**.
- You must not take **RIOVEX 300** during pregnancy.
- Tenofovir, the active substance in **RIOVEX 300**, passes into human breast milk. You should not breastfeed your baby whilst you are on treatment with **RIOVEX 300**.

Driving and using machines
RIOVEX 300 may cause dizziness. You should not drive, use machinery or perform any tasks that require concentration, until you are certain that **RIOVEX 300** does not adversely affect your ability to do so.

RIOVEX 300 contains lactose
RIOVEX 300 contains lactose which may have an effect on the control of your blood sugar if you have diabetes mellitus.
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking **RIOVEX 300**.

3. How to take RIOVEX 300

- Do not share medicines prescribed for you with any other person.
- Always take **RIOVEX 300** in combination with other anti-HIV medicines.
- The usual dose of **RIOVEX 300** is one tablet, once a day, taken with or without food.
- Always take **RIOVEX 300** exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.
- Your doctor will tell you how long your treatment with **RIOVEX 300** will last. Do not stop treatment early.
- If you have the impression that the effect of **RIOVEX 300** is too strong or too weak, tell your doctor or pharmacist.
- Stay under a healthcare provider's care when taking **RIOVEX 300**. Do not change your treatment or stop treatment without first talking with your healthcare provider.

If you take more RIOVEX 300 than you should
Seek emergency medical attention if you think you have taken too much of **RIOVEX 300**.
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 RIOVEX 300
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 RIOVEX 300
You should not stop treatment unless your doctor instructs you to. When your **RIOVEX 300** 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 **RIOVEX 300** and become difficult to treat.

4. Possible side effects

RIOVEX 300 can have side effects.
Not all side effects reported for **RIOVEX 300** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking **RIOVEX 300**, please consult your doctor, pharmacist or other healthcare provider for advice.
If any of the following happens, stop taking **RIOVEX 300** and tell your doctor immediately or go to the casualty department at your nearest hospital:
- 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 **RIOVEX 300**. 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.

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.
- Feeling depressed, feeling anxious, sleep problems (inability to sleep).
- Nausea (feeling sick), being sick (vomiting), diarrhoea, flatulence.
- Skin rashes.
- Lack of energy.

Less frequent side effects:
- Problems with nerves, numbness, tingling, pins and needles.
- Sweating.
- Muscle pain, joint pain.

Frequency unknown:
- Weight loss, low levels of phosphate in the blood, low levels of potassium in the blood, high triglyceride levels in the blood, 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.
- Shortness of breath, chest pain.
- Pain in the abdomen (tummy); heartburn, increase amylase enzyme levels in the blood.
- Increased liver enzymes in the blood, fatty liver (symptoms include pain, fever, yellowing of the skin or eyes).
- Itching.
- Muscle tenderness or weakness, breakdown of muscle tissue, softening or weakening of the bones, causing an increased risk of broken bones, back pain.
- Kidney problems, excessive urination, increased levels of protein in the urine.
- Fever.

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 **RIOVEX 300**.

5. How to store RIOVEX 300

Store all medicines out of reach of children.
Store at or below 30 °C. (Room temperature)
Keep in original packaging until required for use.
Keep the bottle tightly closed.
Protect from light and moisture.
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 RIOVEX 300 contains
- The active substance is tenofovir disoproxil fumarate 300 mg.
- The other ingredients are croscarmellose sodium, lactose monohydrate, magnesium stearate, microcrystalline cellulose and pregelatinized starch, coating agent containing hydroxypropyl methyl cellulose, indigo carmine aluminum lake, lactose monohydrate, titanium dioxide and triacetin.

What RIOVEX 300 looks like and contents of the pack
Blue coloured, oval shaped, biconvex film-coated tablets debossed with "CL 77" on one side and plain on the other side.

HDPE container pack:
Tablets are packed in a 75 ml round white HDPE container with 38 - 400 mm neck finish, closed with either a white 38 mm child resistant closure with pulp and heat seal liner or a white 38 mm continuous thread closure with pulp and heat seal liner, packed in an outer carton. Each HDPE container contains a 3 g silica gel sachet.
Pack sizes include 28 or 30 tablets.
Not all packs and pack sizes are necessarily marketed.

Holder of Certificate of Registration
MACLEODS PHARMACEUTICALS SA (PTY) LTD
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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

PACKAGING RESEARCH & DEVELOPMENT

Restricted Circulation

(Back Page)

ARTWORK / PRINTPROOF APPROVAL FORM

335 mm

300 mm

PASIËNTINLIGTINGSTUK

SKEDULERING STATUS: S4

RIOVEX 300 (filmbedekte tablette)
Tenofovirdisoproksielfumaraat 300 mg
Bevat suiker (208,95mg laktosemonohidraat)

RIOVEX 300 kan tot ernstige probleme met u lewer lei of te veel suur in u bloed veroorsaak. As u nie behandeling ontvang nie, kan dit die dood veroorsaak. Die veiligheid en effektiwiteit van RIOVEX 300 in pasiënte wat met beide die menslike immuniteitsgebreksvirus (MIV) en die hepatitis B-virus (HBV) besmet is, is nie vasgestel nie. RIOVEX 300 moet nie gebruik word vir die behandeling van chroniese HBV-infeksie nie. U dokter moet u vir 'n paar maande lank dophou indien u besmet is met HBV en die gebruik van RIOVEX 300 stop.

Lees hierdie hele inligtingstuk noukeurig deur, voordat u begin om RIOVEX 300 te gebruik
- Hou hierdie inligtingstuk. U mag dit dalk weer moet lees.
- Indien u nog vrae het, vra asseblief vir u dokter of u apteker.
- **RIOVEX 300** is vir u persoonlik voorgeskryf en u moet nie u medisyne met ander mense deel nie. Dit kan hul skaad, selfs al is hulle simptome dieselfde as u s'n.

Wat is in hierdie inligtingstuk

1. Wat **RIOVEX 300** is en waarvoor dit gebruik word
2. Wat u behoort te weet voordat u **RIOVEX 300** neem
3. Hoe om **RIOVEX 300** te neem
4. Moontlike newe effekte
5. Hoe om **RIOVEX 300** te berg
6. Inhoud van die pak en ander inligting

1. Wat RIOVEX 300 is en waarvoor dit gebruik word

RIOVEX 300 bevat die aktiewe bestanddeel tenofovirdisoproksiel, 'n tipe van 'n antiretrovirale middel genaamd 'n MIV-1 (menslike immuniteitsgebreksvirus-1) nukleotiedanaloog-trutranskriptase-remmer (NRTI).
RIOVEX 300 word altyd gebruik in kombinasie met ander antiretrovirale middels om pasiënte met MIV-1-infeksie te behandel.

2. Wat u behoort te weet voordat u RIOVEX 300 neem

Moet nie RIOVEX 300 neem
- Indien u hipersensitief (allergies) vir tenofovirdisoproksielfumaraat of enige van die ander bestanddele van **RIOVEX 300** is nie.
- Indien u 'n laktose-intoleransie het, moet u hierdie produk vermy, aangesien dit laktosemonohidraat bevat.
- Indien u nierprobleme het
- Indien u swanger is of u baba borsvoed
- Indien u alreeds ander medisyne neem, wat die aktiewe bestanddeel tenofovir bevat.

Waarskuwings en voorsorgmaatreëls
Vertel u dokter of gesondheidsorgwerker voordat u **RIOVEX 300** neem.
Neem spesiale sorg met **RIOVEX 300**
- **RIOVEX 300** kan laktiese asidose (te veel suur in die bloed) veroorsaak, tesame met 'n vergrote lewer, wat dodelik kan wees. Diep, vinnige asemhaling, slaperigheid en simptome soos naarheid, braking en maagpyn, moegheid en gewigsverlies kan dui op die ontwikkelling van laktiese asidosis. Laktiese asidose kom meer gereeld voor in vrouens. Pasiënte wat oorgewig is, loop 'n groter risiko.
- Vertel u dokter of u 'n niersiekte gehad het, of indien toetse getoon het dat daar probleme met u niere is. **RIOVEX 300** kan u niere beïnvloed.
- **RIOVEX 300** moet nie saam met ander medisyne geneem word wat u niere kan beskadig nie. As dit onvermydelik is, sal u dokter u nierfunksie monitor.
- Vertel u dokter as u 'n lewersiekte het (insluitend hepatitis B). **RIOVEX 300** moet nie gebruik word om chroniese hepatitis B-virusinfeksie (HBV; 'n voortdurende lewerinfeksie) te behandel nie.
- Stel u dokter in kennis indien u ander medisyne vir MIV, soos lamivudien, in kombinasie met abasavir of in kombinasie met didanosien neem, aangesien die kombinasie van **RIOVEX 300** met hierdie medisyne kan lei tot vroeë mislukking en weerstand van die behandeling.
- Neem u kind, indien sy/hy tydens die swangerskap aan **RIOVEX 300** blootgestel is, onmiddellik na u dokter wanneer u kind bleek lyk, swak voorkom, die hele tyd slaperig lyk, vinniger asemhaal, die hart vinniger klop, die kind nie lyk of hy gewig optel nie, hy braak, koors het, 'n seerkeel het, mondsere het, styf voorkom, stuiptrekkings (stuipe) kry, of tree abnormaal op. U dokter sal die nodige mediese - en laboratoriumtoetse op u kind uitvoer.
- As u **RIOVEX 300** neem saam met didanosien ('n ander medisyne wat gebruik word om MIV -infeksie te behandel), moet u, u dokter inlig indien u simptome van erge maagpyn met naarheid ('n siek gevoel) en braking ervaar, hierdie is tekens van pankreatitis, 'n gevaarlike ontsteking van die pankreas en kan tot die dood lei, of as u simptome van gevoelloosheid of swakheid in u arms en bene ontwikkel.
- **RIOVEX 300** verlaag beenmineraaldigtheid wat tot frakture kan lei. U dokter mag kalsium- en vitamien D-aanvullings voorskryf terwyl u **RIOVEX 300** gebruik.
- Sommige pasiënte wat kombinasie-antiretrovirale behandeling gebruik, kan 'n beensiekte, wat osteonekrose genoem word, (die dood van beenweefsel, veroorsaak deur verlies van bloedtoevoer na die been) ontwikkel. Tekens van osteonekrose is styfheid in die gewrigte, pyn (veral van die heup, knie en skouer) en moeilike beweging. Praat met u dokter as u enige van hierdie simptome ervaar.
- **RIOVEX 300** kan u liggaamsvorm verander deur die verspreiding van liggaamsvet te verander. U kan vet van u bene, arms en gesig verloor en/of vet om die buik (maag) en inwendige organe opdoen; groter borste kry of vetterige knoppe agter op die rug of nek (buffelskof).
- Indien u gevorderde MIV-infeksie (VIGS) het, en enige ander infeksie het, kan u akute simptome van die infeksie of inflammasie opdoen en die simptome van 'n bestaande infeksie kan vererger sodra u behandeling met **RIOVEX 300** begin. Vertel onmiddellik u dokter wanneer u tekens van inflammasie of infeksie of agteruitgang daarvan opmerk.
- **RIOVEX 300** kan inflammasie van die pankreas veroorsaak. Kontak u dokter onmiddellik indien u simptome van erge maagpyn met naarheid ('n siek gevoel) en braking ervaar.
- Stel u dokter in kennis indien u 'n lewersiekte gehad het, insluitend hepatitis B of C, aangesien behandeling met **RIOVEX 300** in pasiënte met lewersiekte, ernstige newe-effekte wat die lewer affekteer, insluitend die dood, kan veroorsaak. U dokter sal u lewerfunksies monitor deur gereeld bloedtoetse uit te voer.
- Indien u 'n voortdurende hepatitis B-infeksie het, moet u nie **RIOVEX 300** stop sonder u dokter se advies nie, want u hepatitis kan terugkom. Die hepatitis kan selfs erger wees as u ook 'n ernstige lewersiekte het.
- U moet **RIOVEX 300** elke dag neem. **RIOVEX 300** help om u toestand te beheer en die vordering van siektes te vertraag, maar dit is nie 'n kuur teen MIV-infeksie nie. U kan aanhou om ander infeksies en ander siektes wat met MIV-siekte verband hou, te ontwikkel. U moet gereeld kontak met u dokter hou. Moet nie ophou om u medisyne te neem sonder om eers met u dokter te praat nie.
- Dit is nie bewys dat die behandeling met **RIOVEX 300** die risiko om MIV-infeksie aan ander oor te dra, deur onbeskermde seksuele kontak of deur bloedoordrag (byvoorbeeld bloedoortappings of om naalde te deel) verminder nie. U moet aanhou om toepaslike voorsorgmaatreëls toe te pas en te gebruik om dit te voorkom.

Kinders en pasiënte jonger as 18 jaar
- Die veiligheid en doeltreffendheid van **RIOVEX 300** in kinders en pasiënte jonger as 18 jaar, is nie vasgestel nie.

Neem van ander medisyne saam met RIOVEX 300
Vertel altyd vir u gesondheidsorgdeskundige indien u enige ander medisyne gebruik. (Dit sluit komplementêre en tradisionele medisyne in).
- Vertel u dokter indien u enige ander medisyne neem of onlangs geneem het.
- Vertel u dokter indien u abasavir, emtrisitabien, indinavir of lamivudine (vir MIV infeksie) neem.
- Vertel u dokter indien u atasanavir en/of lopinavir/ritonavir (vir MIV infeksie) neem; indien u enige van die middels neem,moet u dokter u behandeling moontlik meer noukeurig monitor of daar kan 'n moontlikheid wees dat u nie **RIOVEX 300** kan gebruik nie.
- Indien u **RIOVEX 300** en atasanavir saam gebruik, behoort u ook ritonavir te neem.
- Vertel u dokter indien u ander medisyne gebruik wat didasonien bevat (vir MIV infeksie). As u **RIOVEX 300** saam met ander antivirale medisyne neem wat didanosien bevat, kan dit die vlak van didanosien in u bloed verhoog. Inflammasie van die pankreas en neuropatie (senuweeafwykings) kan voorkom. U dokter sal dit noukeurig oorweeg om u met kombinasies van tenofovir en didanosien te behandel.
- Vertel u dokter indien u ander medisyne neem wat u nierfunksie kan verminder. Sommige voorbeelde sluit in adefovirdipivoksiel, sidofovir, asiklovir, valasiklovir, gansiklovir en valgansiklovir.
- Nie-steroïdale anti-inflammatoriese medisyne (NSAID's). As hierdie medisyne in 'n hoë dosis gebruik word, of as baie NSAID's saam gebruik word, bestaan die risiko van nierversaking wanneer dit saam met **RIOVEX 300** gebruik word. Praat met u gesondheidsorgdeskundige oor alternatiewe medisyne wat moontlik gebruik kan word, voorbeelde van hierdie medisyne sluit in diklofenak en ibuprofen.

Neem van RIOVEX 300 saam met voedsel, vloeistof en alkohol
RIOVEX 300 kan geneem word met of sonder kos.

Swangerskap, borsvoeding en voortplanting
Indien u swanger is of u baba borsvoed, dink dat u swanger is of van plan is om 'n baba te hê, raadpleeg asseblief u dokter, apteker of enige ander gesondheidsorgdeskundige vir advies voordat u **RIOVEX 300** neem.
- U moet nie **RIOVEX 300** neem terwyl u swanger is nie.
- Tenofovir, die aktiewe bestanddeel in **RIOVEX 300**, gaan in die borsmelk van die mens. U moet nie u baba borsvoed terwyl u met **RIOVEX 300** behandel word nie.

Bestuur en gebruik van masjinerie
RIOVEX 300 kan duiseligheid veroorsaak. U mag nie bestuur, masjinerie gebruik of take verrig wat konsentrasie benodig nie, totdat u seker is dat **RIOVEX 300** nie u vermoë om dit te doen, nadelig beïnvloed nie.

RIOVEX 300 bevat laktose
RIOVEX 300 bevat laktose wat 'n invloed kan hê op die beheer van u bloedsuiker, as u diabetes mellitus het. Indien u dokter aan u gesê het dat u 'n onverdraagsaamheid vir suikers het, kontak u dokter voordat u **RIOVEX 300** begin gebruik.

3. HOE OM RIOVEX 300 TE NEEM

- Moet nie medisyne wat vir u voorgeskryf is met enige ander persoon deel nie.
- Neem altyd **RIOVEX 300** in kombinasie met ander teen-MIV medisyne.
- Die aanbevole dosis van **RIOVEX 300** is een filmbedekte tablet, eenkeer per dag, geneem met of sonder voedsel.
- Neem altyd **RIOVEX 300** presies soos wat u dokter of apteker u aanbeveel het. Raadpleeg u dokter of apteker indien u twyfel.
- U dokter sal u vertel hoe lank u behandeling met **RIOVEX 300** sal duur. Moet nie die behandeling vroeg stop nie.
- As u onder die indruk is dat die effek van **RIOVEX 300** te sterk of te swak is, vertel u dokter of apteker.
- Bly onder die sorg van 'n gesondheidsorgverskaffer wanneer u **RIOVEX 300** gebruik. Moet nie u behandeling verander of stop voordat u nie eers met u gesondheidsorgverskaffer gepraat het nie.

Indien u meer RIOVEX 300 geneem het as wat u moes
Soek dadelik mediese hulp indien u vermoed dat u te veel **RIOVEX 300** geneem het.
In die geval van 'n oordosis, kontak u dokter of apteker onmiddellik. Indien nie een beskikbaar is nie, soek hulp of kontak die naaste hospitaal of vergiftigingsbeheersentrum.

Indien u vergeet om RIOVEX 300 te neem
Indien u vergeet om 'n dosis te neem, neem dit sodra u onthou, en gaan dan voort met die behandeling soos voorheen. Moet nie 'n dubbele dosis neem om vir die oorgeslane dosis op te maak nie.

Indien u stop om RIOVEX 300 te neem
Moet nie ophou om **RIOVEX 300** te neem nie, tensy u dokter u beveel om die behandeling te staak.
As u **RIOVEX 300** voorraad begin min raak, kry weer voorraad by u gesondheidsorgverskaffer of apteek. Dit is baie belangrik aangesien die hoeveelheid virus in u bloed sal toeneem as die medisyne vir 'n kort tydjie gestaak word. Die virus kan weerstandigheid teen **RIOVEX 300** ontwikkel en moeilik word om te behandel.

4. Moontlike newe-effekte

RIOVEX 300 kan newe-effekte hê.
Nie alle newe-effekte wat vir **RIOVEX 300** aangemeld is, is in hierdie inligtingstuk ingesluit nie. Indien u algemene gesondheidstoestand vererger of indien u enige ongewenste effekte ervaar terwyl u **RIOVEX 300** gebruik, raadpleeg asseblief u dokter, apteker of ander gesondheidsorgwerker vir advies.
Indien enige van die volgende gebeur, staak die gebruik van **RIOVEX 300** en vertel dadelik vir u dokter of gaan na die naaste hospitaal se ongevalle-afdeling.
- Netelroos: swelling van die gesig, lippe, mond, keel of tong, wat probleme met sluk en asemhaling kan veroorsaak.

Hierdie is ernstige newe-effekte en indien u dit het, kan u 'n ernstige allergiese reaksie op **RIOVEX 300** hê. U kan dringende mediese aandag of hospitalisasie benodig.

Vertel u dokter onmiddellik of gaan na die naaste hospitaal se ongevalle-afdeling indien u enige van die volgende waarneem:
- Laktiese asidose (ernstige toename van melksuur in die bloed, 'n ernstige newe-effek wat dodelik kan wees). Die volgende newe-effekte kan tekens wees van laktiese asidosis: diep vinnige asemhaling, slaperigheid, 'n siek gevoel (naarheid), braking en maagpyn.
- Lewerskade - naarheid; maagpyn; lae koors; verlies aan eetlus; donker uriene; klei-kleurige stoelgang; geelsug (vergeling van die vel of oë).
- Nierskade - min of geen urinering, swelling in die enkels en voete, kortasem, naarheid en braking, metaalagtige smaak in die mond.
- Koors, kouekoors, seer keel, hoes of ander tekens van infeksie.
- Inflammasie van die pankreas. erge pyn in die boonste deel van die maag met naarheid en braking.
- Veranderinge in liggaamsvorm as gevolg van veranderinge in vetverspreiding.
- Styfheid in die gewrigte, pyn (veral in die heup, knie of skouer), moeilike beweging; hierdie is tekens van osteonekrose.

Hierdie is ernstige newe-effekte en u kan dringende mediese aandag benodig.

Vertel ook vir u dokter indien u enige van die volgende opmerk:
Gereelde newe-effekte:
- Hoofpyn, duiseligheid.
- Voel depressief, angstige gevoel, probleme om te slaap (slaap-onvermoë)
- Naarheid (siek gevoel), braking, diaree, winderigheid.
- Uitslag van die vel.
- Verlies aan energie.

Minder gereelde newe-effekte:
- Probleme met senuwees, gevoelloosheid, tinteling, spelde en naalde gevoel.
- Sweet.
- Spierpyne, gewrigspyne.

Frekwensie onbekend:
- Gewigsverlies, lae vlakke van fosfaat in die bloed, lae kaliumvlakke in die bloed, hoë trigliseriedvlakke in die bloed, veranderinge in liggaamsvet, insluitend 'n verhoogde hoeveelheid vet in die boonste deel van die rug en nek, borste en rondom die romp, verlies van vet van die bene, arms en gesig kan ook voorkom.
- Kortasem, borskaspyn.
- Pyn in die buik (maag); sooibrand, amilase-ensiemvlakke in die bloed verhoog.
- Verhoogde lewerensieme in die bloed, vetterige lewer (simptome sluit in pyn, koors, vergeling van die vel of oë).
- Jeuk.
- Spierteerheid of - swakheid, afbreek van spierweefsel, versagting of verswakking van die bene, wat 'n verhoogde risiko van rugpyn en gebreekte bene kan veroorsaak.
- Nierprobleme, oormatige urinering, verhoogde proteïenvlakke in die uriene.
- Koors.

Indien u enige newe-effekte opmerk of ervaar wat nie in hierdie inligtingstuk aangemeld is nie, stel asseblief u dokter of apteker in kennis.

Rapportering van newe effekte
Indien u enige newe effekte waarneem of ervaar, praat asseblief met u dokter of apteker of verpleegster. Dit sluit enige moontlike newe-effekte wat nie in hierdie inligtingstuk gelys is nie, in.
U kan newe effekte aanlyn rapporteer aan die Suid-Afrikaanse Reguleringsowerheid vir Gesondheidsprodukte via die "**6.04 Adverse Drug Reaction Reporting Form**", onder SAHPRA se publikasies: https//www.sahpra.org.za/Publications/Index/8.
Indien u newe effekte rapporteer, kan u bydrae om meer inligting oor die veiligheid van **RIOVEX 300** te verskaf.

5. Hoe om RIOVEX 300 te bewaar

Bewaar alle medisyne buite bereik van kinders.
Bewaar by of benede 30 °C. (Kamertemperatuur)
Bewaar in die oorspronklike verpakking, totdat u dit benodig om te gebruik.
Hou die bottel dig toe.
Beskerm teen lig en vogtigheid.
Moet nie hierdie medisyne in 'n badkamer bêre nie.
Moet nie na die vervaldatum, aangedui op die etiket/kartonverpakking/bottel, gebruik nie.
Neem alle ongebruikte medisyne terug na jou apteker.
Moet nie ongebruikte medisyne in afvoerpype of rioolsisteme (bv. toilette) gooi nie.

6. Inhoud van die verpakking en ander inligting

Wat RIOVEX 300 bevat
- Die aktiewe bestanddeel is tenofovirdisoproksielfumaraat 300 mg.
- Die ander onaktiewe bestanddele is: Natriumkruiskarmellose, laktosemonohidraat, magnesiumstearaat, mikrokristallyne sellulose, pregelatiniseerde stysel. Die tablette is bedek met 'n deklaag wat bestaan uit hidroksiepropielmetielsellulose, indigokarmynaluminiumlak, laktosemonohidraat, titaandioksied en triasetien.

Hoe lyk RIOVEX 300 en die inhoud van die verpakking
Blou gekleurde, ovaalvormige, bikonvekse filmbedekte tablette, met "CL 77" op die een kant gedruk.

HDPE verpakking:
Die tablette word verpak in 'n 75 mL ronde wit HDPE houer met 38 – 400 mm nekafwerking, afgesluit met óf 'n wit 38 mm kinderbestande deksel met pulp- en hitteseëlvoering óf 'n wit 38 mm-deurlopende draad-deksel met pulp- en hitteseëlvoering, verpak in 'n buitenste karton. Elke HDPE-houer bevat 'n 3g silika gel-sakkie.
Pakgroottes bevat 28 of 30 tablette.
Nie alle pakke en pakgroottes word noodwendig bemark nie.

Houer van die Registrasiesertifikaat en vervaardiger
MACLEODS PHARMACEUTICALS SA (EDMS) BPK
Kantoorblok 1, Bassonia Estate Kantoor Park (Oos),
1 Cussonia Weg, Bassonia Rock, Uitbreiding 12,
Alberton, Suid Afrika

Hierdie inligtingstuk is laas hersien in
Datum van registrasie: 24 Julie 2020

Registrasienommer
46/20.2.8/0852

Toegang tot die ooreenstemmende Professionele Inligting
Die ooreenstemmende professionele inligting 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

1. Product : RIOVEX 300 (Tenofovir Disoproxil Fumarate Tablets 300 mg)	
2. Country: South Africa (Tender)	**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 300 (W) mm**
9. Design / Style: Booklets	**10. Item code No.: PM04339671**
11. Artwork has been made: Actual Size	**12. Pharma code No.: 40378 mini**
13. Barcode/NDC no: NA	**14. Supersedes Item code No: NA**
15. Revision no: 00	**16. File Name : Z:\South Africa\Tenofovir Tablet\Activo\02\RIOVEX 300 PIL - PM03393102.cdr**
Approved By:	**17. Location: Daman**

PRD	M.A. HOLDER	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: 2025.08.14 16:42:25 +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/021/04-02

Reason for revision :	Item code	Artwork Send for Printing Date	Artwork Implementation Date
1) New Artwork for South Africa	PM04339671		