SCHEDULING STATUS

S4

TRIOVIR 600 mg/200 mg/245 mg (film- coated tablets)

Efavirenz/emtricitabine/tenofovir disoproxil

Contains sugar: lactose 120mg

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'

LACTIC ACIDOSIS (EXCESSIVE BUILD-UP OF ACID IN BLOOD), SEVERE ENLARGED LIVER WITH FATTY LIVER DISEASE, INCLUDING DEATH, HAVE BEEN REPORTED WITH THE USE OF NUCLEOSIDE ANOLOGUES AS IN TRIOVIR ALONE OR IN COMBINATION WITH OTHER ANTI-RETROVIRALS (*SEE SECTION 2*). EARLY SYMPTOMS INCLUDE NAUSEA, VOMITING AND ABDOMINAL PAIN, GENERALLY FEELING UNWELL, LOSS OF APPETITE, WEIGHT LOSS, RAPID AND/OR DEEP BREATHING OR NEUROLOGICAL SYMPTOMS E.G. SLURRED SPEECH, IMPAIRED BALANCE OR COORDINATION, CONFUSION (INCLUDING MUSCLE WEAKNESS). LACTIC ACIDOSIS MAY RESULT IN DEATH. IT MAY BE ASSOCIATED WITH PANCREAS INFLAMMATION, LIVER FAILURE OR KIDNEY FAILURE. LACTIC ACIDOSIS GENERALLY OCCURRED AFTER A FEW OR SEVERAL MONTHS OF TREATMENT. YOUR DOCTOR WILL DISCONTINUE TREATMENT WITH TRIOVIR IF YOU DEVELOP LACTIC ACIDOSIS, PROGRESSIVE ENLARGED LIVER, OR RAPIDLY ELEVATING LIVER ENZYMES.

CAUTION SHOULD BE EXERCISED WHEN YOU ARE GIVEN TRIOVIR (PARTICULARLY OBESE WOMEN) WITH ENLARGED LIVER, HEPATITIS OR OTHER KNOWN RISK FACTORS FOR LIVER DISEASE AND FATTY LIVER DISEASE (INCLUDING CERTAIN MEDICINES AND ALCOHOL). IF YOU ARE CO-INFECTED

WITH HEPATITIS C AND TREATED WITH ALPHA-INTERFERON AND RIBAVIRIN YOU MAY CONSTITUTE A SPECIAL RISK.

PATIENTS AT INCREASED RISK SHOULD BE FOLLOWED CLOSELY. TRIOVIR SHOULD NOT BE USED FOR THE TREATMENT OF CHRONIC HEPATITIS B VIRUS (HBV) INFECTION. THE SAFETY AND EFFICACY OF TRIOVIR HAVE NOT BEEN ESTABLISHED IN PATIENTS CO-INFECTED WITH HBV AND HIV. SEVERE ACUTE EXACERBATIONS OF HEAPTITIS B HAVE BEEN REPORTED IN PATIENTS WHO HAVE DISCONTINUED EMTRICITABINE OR TENOFOVIR, WHICH ARE COMPONENTS OF TRIOVIR. YOUR DOCTOR WILL MONITOR YOUR LIVER FUNCTION CLOSELY WITH BOTH CLINICAL AND LABORATORY FOLLOW-UP FOR AT LEAST SEVERAL MONTHS IF YOU ARE CO-INFECTED WITH HIV AND HBV AND DISCONTINUE TRIOVIR IF APPROPRIATE, INITIATION OF ANTI-HEPATITIS B THERAPY MAY BE WARRANTED. (*SEE SECTION 2*)

Read all of this leaflet carefully before you start taking TRIOVIR

- 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.
- **TRIOVIR** 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 TRIOVIR is and what it is used for.
2. What you need to know before you take TRIOVIR.
3. How to take TRIOVIR.
4. Possible side effects

5. How to store TRIOVIR
6. Contents of the pack and other information

1. WHAT TRIOVIR IS AND WHAT IT IS USED FOR

- TRIOVIR contains efavirenz, emtricitabine and tenofovir belonging to a group of antiviral medicines, called as non-nucleoside reverse transcriptase inhibitors (NNRTIs), nucleoside reverse transcriptase inhibitors (NRTIs) and nucleotide reverse transcriptase inhibitors (NtRTIs) respectively and also known as antiretrovirals.
  They work by interfering with an enzyme (reverse transcriptase) that is essential for the virus to multiply.
- It is used to treat Human Immunodeficiency Virus (HIV-1) infection in adults aged 18 years and over. TRIOVIR can be given alone or in combination with other antiretrovirals.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE TRIOVIR

Do not take TRIOVIR:

- if you are allergic to efavirenz, emtricitabine, tenofovir, tenofovir disoproxil or any of the other ingredients of TRIOVIR (*listed in section 6*).
- if you have severe liver disease.
- If you had a liver disorder or liver failure attributed to treatment with TRIOVIR.
- if you have a heart condition, such as an abnormal electrical signal called prolongation of the QT interval that puts you at high risk for severe heart rhythm problems (*Torsade de Pointes*).
- if your doctor has told you that you have high or low levels of electrolytes such as potassium or magnesium in your blood.
- If you have moderate to severe kidney problem or are undergoing kidney dialysis treatment.

- If you are pregnant or planning to become pregnant.
- If you are breastfeeding your baby.
- If you are younger than 18 years of age.
- if you are currently taking any of the following medicines (*see also "Other Medicines and TRIOVIR"*):
  - astemizole or terfenadine (used to treat hay fever or other allergies)
  - bepridil (used to treat heart disease)
  - cisapride (used to increase emptying of stomach)
  - elbasvir/grazoprevir (used to treat hepatitis C)
  - ergot alkaloids (for example, ergotamine, dihydroergotamine, ergonovine, and methylergonovine) (used to treat migraines and cluster headaches)
  - midazolam or triazolam (used to help you sleep)
  - pimozide, imipramine, amitriptyline or clomipramine (used to treat certain mental conditions)
  - St. John's wort (*Hypericum perforatum*) (a herbal preparation used for depression and anxiety)
  - voriconazole (used to treat fungal infections)
  - flecainide, metoprolol (used to treat irregular heartbeat)
  - certain antibiotics (macrolides, fluoroquinolones, imidazole)
  - triazole antifungal agents
  - certain antimalarial agents
  - methadone (used to treat opiate addiction)

Do not take TRIOVIR if you are already taking lamivudine/zidovudine, lamivudine, abacavir sulphate/lamivudine, abacavir sulphate/lamivudine/zidovudine, tenofovir disoproxil fumarate, efavirenz, emtricitabine or adefovir dipivoxil because these medicines contain the same or similar active ingredients.

Discuss with your doctor if you are unsure whether the above applies to you.

Warnings and precautions

Tell your healthcare professional if you:

- Are pregnant or planning to become pregnant (see Pregnancy and breastfeeding and fertility).
- Are breastfeeding (see Pregnancy and breastfeeding and fertility).
- Have kidney problems or are undergoing kidney dialysis treatment.
- Have ever had mental illness or are using medicines for mental illness or alcohol.
- Have ever had seizures or are taking medicine for seizures.

Take Special Care with **TRIOVIR:**

- If you are older than 65 years of age.
- If you taking other medicines, as **TRIOVIR** may interact with these other medicines.
- If you use medicines that may affect your kidney function, since use of such medicines in combination with **TRIOVIR** will require careful monitoring of your kidney function. Speak to your doctor about this.
- If you have liver problems, including hepatitis B infection.
- Monitoring your cholesterol.
- If you experience nausea and weakness as these could be symptoms of lactic acidosis (lactic acidosis is when lactic acid builds ups in the bloodstream faster than it can be removed. Lactic acid is produced when oxygen levels in the body drop). This condition can be caused by the use of **TRIOVIR.**
- If you are not be able to bend or move your joints very well, and you experience pain in the joint- this may be signs of a condition known as osteonecrosis and you must speak to your healthcare professional about this (Osteonecrosis is a disease caused by reduced blood flow to bones in the joints. With too little blood, the bone starts to break down.
- If you experience muscle weakness, visual problems, hearing problems, learning disabilities, abnormal behaviour, heart disease, liver disease, kidney disease, stomach

problems or respiratory (breathing) problems as these can be disorders associated with the use of TRIOVIR called mitochondrial dysfunction.

- If you notice humps on the back or back of the neck. Some patients taking combination antiretroviral therapy may develop a dorso-cervical fat, enlargement (buffalo hump), facial wasting and breast enlargement.
- If you continue to develop infections and other complications of HIV infection, inform your healthcare professional as they need to monitor your CD4 counts regularly.
- If you are currently taking ARV medicines, including TRIOVIR this does not prevent you from transmitting the HIV to others during sex or blood contamination and therefore condoms and appropriate precautions must be taken.
- If you have hepatitis B or C and are also taking ARV medicines, there is an increased risk of getting liver complications and disease. It is important to inform your healthcare professional so that they may admit you and monitor you closely.
- “Flare-ups” of Hepatitis B Virus (HBV) infection, in which the disease suddenly returns in a worse way than before, can occur if you have HBV and you stop taking TRIOVIR. Your healthcare professional will monitor your condition for several months after stopping TRIOVIR if you have both HIV and HBV infection and may recommend treatment for your HBV.
- There is a possibility that your bones may weaken or soften while on this medication which may result in fractures and therefore it is important to inform your doctor if you suffer from any bone problems such as arthritis or osteoporosis. Supplements of Vitamin D and calcium may be beneficial.
- There is a possibility that you may develop rash when you first start the medicine and this should go away after a month. However, if you develop severe blistering or rash or fever then inform your doctor immediately.
- If your infection worsens or takes longer to heal or you get fever or a re-infection of a prior infection when first placed on ARV medication inform your doctor immediately. If

you have an infection, it is also important to inform your doctor of any infections you may have before they place you on ARV medicine as it is important to get this treated first so that it does not result in relapse of the infection.

- **Kidney problems.** If you have had kidney problems in the past or take other medicines that can cause kidney problems, your healthcare professional should do regular blood tests to check your kidneys.
- **Serious psychiatric problems.** A small number of patients may experience severe depression, strange thoughts, or angry behaviour while taking TRIOVIR. Some patients have thoughts of suicide and a few have actually committed suicide. These problems may occur more often in patients who have had mental illness. Contact your healthcare professional right away if you think you are having these psychiatric symptoms, so your healthcare provider can decide if you should continue to take TRIOVIR.

Children and adolescents

- Do not give TRIOVIR to children and adolescents under 18 years of age. The use and safety of TRIOVIR in children and adolescents have not been studied.

Other medicines and TRIOVIR

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

- The following medicines may cause serious and life-threatening side effects when taken with TRIOVIR. You should not take any of these medicines while taking TRIOVIR: astemizole (a medicines used to treat certain allergies), peridil (used to treat venous thrombosis), cisapride (a medicine that increases motility in the upper gastrointestinal tract), midazolam (a medicine used to cause sleepiness, muscle relaxation, and to reduce anxiety.), pimozide (an antipsychotic medicine), triazolam (a medicine used to treat difficulty falling asleep or staying asleep) ,ergot medications (a

medicine used to treat severe headaches and ketoconazole (a medicine used to treat fungal infections).

- TRIOVIR also should not be used with lamivudine/zidovudine, emtricitabine, lamivudine, abacavir sulphate/lamivudine, abacavir sulphate/lamivudine/zidovudine, efavirenz, emtricitabine/tenofovir disoproxil fumarate or tenofovir disoproxil fumarate. These are all medicines used to treat HIV infections.
- Voriconazole (a medicine used to treat severe fungal infections) should not be taken with TRIOVIR since it may lose its effect or may increase the chance of having side effects from TRIOVIR.
- It is also important to tell your healthcare provider if you are taking any of the following:
- Saquinavir (a medicine used to treat HIV infections), clarithromycin (an antibiotic medicine used to treat certain infections) or itraconazole (a medicine used to treat fungal infections); these medicines may need to be replaced with another medicine when taken with TRIOVIR as their effects may be decreased when taken together with TRIOVIR.
- Calcium channel blockers such as diltiazem or verapamil and others (medicines used to treat hypertension); indinavir (a medicine used to treat HIV), rifabutin (a medicine used to treat tuberculosis), rifampicin (a medicine used to treat tuberculosis), cholesterol-lowering medicines such as atorvastatin, pravastatin sodium and simvastatin or sertraline; these medicines may need to have their dose changed when taken with TRIOVIR, as their effects are reduced when taken together.
- Didanosine (a medicine used to treat HIV); tenofovir DF (a component of TRIOVIR) may increase the amount of didanosine in your blood, which could result in more side effects. You may need to be monitored more carefully if you are taking TRIOVIR and didanosine together. Also, the dose of didanosine may need to be changed.
- Atazanavir sulphate or lopinavir/ritonavir; these medicines (used to treat HIV) may increase the amount of tenofovir DF (a component of TRIOVIR) in your blood, which

could result in more side effects. You may need to be monitored more carefully if you are taking TRIOVIR and either atazanavir sulphate or lopinavir/ritonavir (medicines used to treat HIV) together. Also, the dose of atazanavir sulphate or lopinavir/ritonavir (medicines used to treat HIV) may need to be changed.

- Medicine for seizures (for example, phenytoin, carbamazepine or phenobarbital); your healthcare professional may want to switch you to another medicine or check medicine levels in your blood from time to time.
- Taking St. John's Wort (*Hypericum perforatum)*, or products containing St. John's Wort with TRIOVIR is not recommended. St. John's Wort is a herbal product sold as a dietary supplement. Talk with your healthcare professional if you are taking or are planning to take St. John's Wort. Taking St. John's Wort may decrease TRIOVIR levels and lead to increased viral load and possible resistance to TRIOVIR or cross-resistance to other anti-HIV medicines.
- Taking TRIOVIR with alcohol or other medicines causing similar side effects as TRIOVIR such as drowsiness, may increase those side effects.
- It is important to use a reliable barrier contraception if you are taking oral contraception and you are given TRIOVIR as your oral contraception levels may be altered in the blood not giving you enough protection from falling pregnant.

TRIOVIR with food and drink and alcohol

TRIOVIR should not be taken with alcohol. Refer to section 3 on how TRIOVIR should be taken.

Pregnancy and 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 health care provider for advice before taking TRIOVIR.

- If you are taking TRIOVIR you should not become pregnant. Serious birth defects have been seen in the babies of animals and women treated with efavirenz (a component of TRIOVIR) during pregnancy. Efavirenz is teratogenic.
- You should not rely only on hormone-based birth control, such as pills, injections or implants, because TRIOVIR may make these contraceptives ineffective. Women must use a reliable form of barrier contraception, such as a condom or diaphragm, even if they also use other methods of birth control.
- You should not be treated with TRIOVIR if you plan to be pregnant or if you are pregnant. A medical/ laboratory supervised pregnancy urine/blood test should be done to exclude pregnancy before you are treated with TRIOVIR. Continue with contraception for 12 weeks after treatment with TRIOVIR before you consider becoming pregnant.
- Do not breastfeed if you are taking TRIOVIR. Mothers with HIV should not breastfeed because they can pass the HIV through their milk to the baby. TRIOVIR may pass through breast milk and cause serious harm to the baby.
- Talk with your healthcare professional if you are breastfeeding. You should stop breastfeeding or may need to use a different medicine.

Driving and using machines

TRIOVIR may cause dizziness, impaired concentration and drowsiness which can affect your ability to drive and use machines. If you are affected, do not drive and do not use any tools or machines.

TRIOVIR contains lactose and sodium:

TRIOVIR contain lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

This medicine contains less than 1 mmol sodium per dose and essentially can be regarded as ‘sodium-free’.

3. HOW TO TAKE TRIOVIR

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

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

- The usual dose of TRIOVIR is: one tablet once a day taken orally at about the same time each day.
- You should take TRIOVIR on an empty stomach.
- Swallow the TRIOVIR tablet whole with water.
- Taking TRIOVIR at bedtime may make some side effects less bothersome.

Your doctor will tell you how long your treatment with TRIOVIR will last. Do not stop treatment early. If you have the impression that the effect of TRIOVIR is too strong or too weak, tell your doctor or pharmacist.

TRIOVIR is not recommended for patients less than 18 years of age.

If you take more TRIOVIR than you should

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

Take this leaflet and the rest of the remaining TRIOVIR with you so the doctor will know what you have taken. If you accidentally take too many TRIOVIR tablets you may be at increased risk of experiencing possible side effects with this medicine (*see section 4, Possible side effects*).

If you forget to take TRIOVIR

It is important not to miss a dose of TRIOVIR.

If you do miss a dose of TRIOVIR within 12 hours of when it is usually taken, take it as soon as you can, and then take your next dose at its regular time.

If it is almost time (less than 12 hours) for your next dose anyway, do not take the missed dose. Wait and take the next dose at the regular time. Do not take a double dose to make up for a forgotten tablet.

If you throw up the tablet (within 1 hour after taking TRIOVIR), you should take another tablet. Do not wait until your next dose is due. You do not need to take another tablet if you were sick more than 1 hour after taking TRIOVIR.

Don't stop taking TRIOVIR without talking to your doctor.

Stopping TRIOVIR can seriously affect your response to future treatment. If TRIOVIR is stopped, speak to your doctor before you restart taking TRIOVIR tablets. Your doctor may consider giving you the components of TRIOVIR separately if you are having problems or need your dose adjusted.

When your supply of TRIOVIR starts to run low, get more from your doctor or pharmacist. This is very important because the amount of virus may start to increase if the medicine is stopped for even a short time. The virus may then become harder to treat.

4. POSSIBLE SIDE EFFECTS

TRIOVIR can have side effects.

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

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

- Lactic acidosis (build-up of lactic acid in the blood). Lactic acidosis can be a medical emergency and may need to be treated in the hospital. Call your healthcare professional right away if you get the following signs of lactic acidosis:

  - weakness and tiredness
  - muscle pain
  - stomach pain with nausea and vomiting
  - fast, shallow breathing
  - dizzy and lightheaded
  - a fast and irregular heartbeat

- Allergic reaction (hypersensitivity) to TRIOVIR which include:
  - severe skin reactions (including red spots or blotches sometimes with blistering and swelling of the skin)
  - swelling of the face, lips, tongue or throat
- Serious psychiatric problems. Some patients may experience severe depression, strange thoughts, thoughts of suicide or angry behaviour, paranoia, unable to think clearly, mood being affected, seeing or hearing things that are not really there (hallucinations), personality change (psychosis), catatonia (a condition in which the patient is rendered motionless and speechless for a period), while taking TRIOVIR. Contact your doctor right away if you think you are having these psychiatric symptoms.

These are all very serious side effects. If you have them, you may have had a serious reaction to TRIOVIR. 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:

- Serious liver problems (hepatotoxicity) with liver enlargement (hepatomegaly) and fat in the liver (Steatosis). Call your healthcare professional right away if you get any of the following signs of liver problems:
  - yellow discolouration of your skin and the white part of your eyeballs
  - darkening of your urine
  - bowel movements turn lighter in colour
  - nauseous
  - stomach pain

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:

- dizziness, headache, diarrhoea, feeling sick (nausea), being sick (vomiting)

- feeling weak
- decreases in phosphate levels in the blood
- increased levels of creatine kinase in the blood that may result in muscle pain and weakness
- disturbances of coordination and balance
- feeling worried or depressed
- difficulty sleeping, abnormal dreams, difficulty concentrating, drowsiness
- pain, stomach pain
- problems with digestion resulting in discomfort after meals, feeling bloated, wind (flatulence)
- loss of appetite
- tiredness
- itching
- changes in skin colour including darkening of the skin in patches often starting on hands and soles of feet
- low white blood cell count (a reduced white blood cell count can make you more prone to infection)
- liver and pancreas problems
- increased fatty acids (triglycerides), bilirubin or sugar levels in the blood

Less frequent side effects:

- breakdown of muscle, muscle pain or weakness
- anaemia (low red blood cell count)
- a feeling of spinning or tilting (vertigo), whistling, ringing or other persistent noise in the ears
- blurred vision
- chills
- breast enlargement in males

- decreased sexual drive
- flushing
- dry mouth
- increased appetite
- decreases in potassium in the blood
- increases in creatinine in the blood
- proteins in urine
- increased cholesterol in the blood
- The breakdown of muscle, softening of the bones (with bone pain and sometimes resulting in fractures), muscle pain, muscle weakness and decreases in potassium or phosphate in the blood may occur due to damage to kidney tubule cells.
- itchy rash to the skin caused by a reaction to sunlight

Side effects with unknown frequencies include:

- accumulation of body fat
- skin discolouration
- itchy skin
- flushing
- nail disorders
- lack of energy and strength
- excessive urination
- muscle pain and weakness
- constipation, improper absorption of food.
- increase in Amylase (enzyme in body that breaks down starch)
- breathing difficulty
- palpitations
- loss of sensation
- loss of position sense resulting in improper movement.

- Impaired coordination
- excessive sleepiness
- fat accumulation
- brain disease
- coma
- anxiousness
- increased urination and renal disease

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. 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 TRIOVIR**.**

5. HOW TO STORE TRIOVIR

- TRIOVIR tablets should be stored at or below 30 °C.
- The bottle should be kept tightly closed and the silica gel sachet should not be removed from the bottle after opening.
- Protect from moisture and light.
- Keep well closed.
- Keep out of reach of children.
- Any unused medicine or waste material should be returned to the pharmacy for destruction.
- Do not dispose of unused medicine in drains or sewerage systems (e.g toilets).
- Do not store in bathrooms.
- Do not use after the expiry date stated on the label.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What TRIOVIR contains

The active substances are efavirenz, emtricitabine and tenofovir disoproxil. Each TRIOVIR film-coated tablet contains 600 mg of efavirenz, 200 mg of emtricitabine and 245 mg of tenofovir disoproxil (as fumarate).

The other ingredients in the tablet are:

The core contains croscarmellose sodium, hydroxypropyl cellulose, lactose, microcrystalline cellulose, magnesium stearate and sodium lauryl sulphate.

The film-coating contains polyvinyl alcohol, titanium dioxide, macrogol, talc, iron oxide red, iron oxide black or polyvinyl alcohol, macrogol/PEG, talc, titanium dioxide, iron oxide red, iron oxide black.

What TRIOVIR looks like and contents of the pack

Contents of pack:

TRIOVIR is packed in high density polypropylene (HDPE) bottle pack comprising of white opaque wide mouth HDPE bottle with a white opaque polypropylene (PP) screw closure with desiccant, packed in an outer carton in 28’s and 30’s.

TRIOVIR is packed in high density polypropylene (HDPE) bottle pack comprising of white opaque wide mouth HDPE bottle with a white opaque polypropylene (PP) screw closure with desiccant without outer carton in pack sizes of 28’s and 30’s.

TRIOVIR is packed in high density polypropylene (HDPE) bottle pack comprising of white opaque wide mouth HDPE bottle with a white opaque polypropylene (PP) screw closure along with wad containing aluminium induction sealing liner with desiccant sieve sachet, packed in an outer carton in 90’s.

TRIOVIR is packed in high density polypropylene (HDPE) bottle pack comprising of blue opaque wide mouth HDPE bottle with a blue opaque polypropylene screw closure with desiccant, packed in an outer carton in 28’s and 30’s.

TRIOVIR is packed in high density polypropylene (HDPE) bottle pack comprising of blue opaque wide mouth HDPE bottle with a blue opaque polypropylene screw closure with desiccant sachet or desiccant canister without outer carton, packed in 28's and 30's.

TRIOVIR is packed in high density polypropylene (HDPE) bottle pack comprising of white opaque wide mouth HDPE bottle with a white opaque polypropylene screw closure along with wad containing aluminium induction sealing liner with desiccant sieve sachet packed without carton, packed in 84's.

What TRIOVIR looks like:

TRIOVIR is a pink coloured, capsule shaped, film-coated tablets debossed with "M171" on one side and plain on the other side.

Holder of Certificate of Registration

Viatris Healthcare (Pty) Ltd

4 Brewery Street, Isando,

Johannesburg, 1600,

Gauteng, South Africa

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Access to the corresponding Professional information.

A copy of the professional Information is contained in the packaging of TRIOVIR**.**