SCHEDULING STATUS

S4

TEEVIR (film-coated tablets)

Tenofovir disoproxil fumarate 300 mg, efavirenz 600 mg, emtricitabine 200 mg

Contains sugar (lactose monohydrate 120 mg per tablet).

Read all of this leaflet carefully before you start taking TEEVIR

- 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.
- TEEVIR 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 TEEVIR is and what it is used for
2. What you need to know before you take TEEVIR
3. How to take TEEVIR
4. Possible side effects
5. How to store TEEVIR
6. Contents of the pack and other information

1. What TEEVIR is and what it is used for

TEEVIR is used to treat Human Immunodeficiency Virus (HIV-1) infection. HIV-1 is the virus that causes Acquired Immune Deficiency Syndrome (AIDS). TEEVIR can be given alone or in

combination with other antiretrovirals.

2. What you need to know before you take TEEVIR

Do not take TEEVIR :

- If you are hypersensitive (allergic) to efavirenz, emtricitabine and/or tenofovir disoproxil fumarate or any of the other ingredients of TEEVIR (listed in section 6).
- You had a liver disorder or liver failure attributed to treatment with TEEVIR.
- If you have moderate to severe kidney failure.
- If you are pregnant or breastfeeding.
- 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 any member of your family (parents, grandparents, brothers or sisters) has died suddenly due to a heart problem or was born with heart problems.
- If your doctor has told you that you have high or low levels of electrolytes such as low potassium or low magnesium in your blood.
- If you are also taking the following medicines: antiarrhythmics of classes IA and III, neuroleptics, antidepressants, terfenadine, astemizole, bepridil, cisapride, ergot derivatives, midazolam, pimozide, triazolam, voriconazole, St. John's wort, flecainide, certain antibiotics (macrolides, fluoroquinolones, imidazole), triazole antifungals, certain antimalarial medicines and methadone.

Do not take TEEVIR with the following related medicines:

- Medicines containing the same active ingredients as TEEVIR such as emtricitabine, tenofovir

disoproxil fumarate, emtricitabine/tenofovir disoproxil fumarate and efavirenz.

- Medicines containing lamivudine, which is similar to emtricitabine including lamivudine/zidovudine, lamivudine, abacavir sulphate/ lamivudine or abacavir sulphate/lamivudine/zidovudine (see Other medicines and TEEVIR).

Warnings and precautions

Take special care with TEEVIR:

- If you have been diagnosed with chronic hepatitis B or have a history of hepatitis B infections as you may experience a severe exacerbation of hepatitis upon discontinuation of treatment.
- If you have a history of liver disease or risk factors for liver disease because you may be at risk for lactic acidosis (low pH in the blood and bodily tissues accompanied by a build-up of lactic acid) and severe hepatomegaly with steatosis (enlargement of liver with fatty deposits in it). This risk is higher if you are female, obese and have had long term exposure to antiretrovirals.
- If you have kidney failure.
- If you have a history of psychiatric disorders, the use of psychiatric medication, injection medicine use or if you start experiencing psychiatric disturbance such as severe depression, suicidal thoughts, suicide attempts, aggressive behaviour, paranoid reactions and manic reactions.
- Because you may experience nervous system symptoms such as dizziness, difficulty sleeping, impaired concentration, drowsiness or a strong desire to sleep, abnormal dreams, hallucinations, being intensely happy and excited for no apparent reason, confusion, agitation, loss of memory, stupor, abnormal thinking and feeling detached from one’s self.

These symptoms would normally subside within 2 to 4 weeks of starting treatment. Beware of simultaneous intake of alcohol and other central nervous system depressants or operating hazardous machinery (see Driving and using machines).

- Tell your doctor if you develop or see signs of opportunistic infections or other complications even when you are on TEEVIR treatment as such could be detrimental to your health.
- As the use of TEEVIR does not eliminate the risk of HIV transmission to others through sexual contact or blood contamination, therefore you must always take appropriate precautions when involved in activities such as sexual intercourse or handling blood.
- You may experience skin rash in the first month of treatment with TEEVIR, tell your doctor about your skin rash if it is persistent. You must stop taking TEEVIR if your rash becomes severe with symptoms such as fever, blistering or skin peeling.
- Tell your doctor if you are suffering from osteomalacia (bone disorder indicated by bone pain especially in the hips, bone fractures with no known cause or injury and also by muscle weakness) as TEEVIR can aggravate your condition.
- Take TEEVIR with caution if you have a history of seizures and let your doctor know about them.
- TEEVIR is known to lead to fat redistribution in your body and this is usually indicated by gaining weight around the midriff, formation of buffalo hump-like structure on the trunk (also called enlargement of dorsocervical fat), facial wasting, losing weight on the arms and legs and breast enlargement.
- If you are under the age of 18 years because TEEVIR is not recommended for use in patients under the age of 18 years.



- If you are an elderly patient over the age of 65 years as this population tends to experience decreased kidney, liver and heart functioning and are usually taking other medications.
- If you are also taking products containing St. John's wort (Hypericum perforatum) because St. John's wort can reduce the effect of TEEVIR against HIV infection (see Other medicines and TEEVIR).
- You should not use TEEVIR if you are at increased risk of Torsade de Pointes (fast heartbeat) or if you are using medicine with a known risk for Torsade de Pointes.
- Tenofovir disoproxil may also cause loss of bone mass.
- Overall, the effects of tenofovir disoproxil on long term bone health and future fracture risk in adult and paediatric patients are uncertain.

Children and adolescents

Do not give TEEVIR to children who are younger than 18 years of age as safety and efficacy has not been established in paediatric and adolescent patients.

Other medicines and TEEVIR

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

Do not take TEEVIR with the following medicines

- Voriconazole: risk severity of side effects associated with the use of TEEVIR is increased.
- Astemizole, bepridil, cisapride, and pimozide: Life-threatening adverse events such as abnormal or irregular heart rates can occur.
- Ergot derivatives (dihydroergotamine, ergonovine, ergotamine, methylergonovine): effect of

TEEVIR is decreased and may lead to viral resistance of anti-HIV medicines like TEEVIR.

- Anti-retrovirals (efavirenz, emtricitabine, tenofovir disoproxil fumarate, lamivudine): efavirenz, emtricitabine and tenofovir disoproxil fumarate are already ingredients in TEEVIR, while lamivudine is closely related to emtricitabine.
- Benzodiazepines (midazolam, triazolam): prolonged or increased sedation or respiratory depression, e.g. difficulties in breathing.

TEEVIR with food and drink

TEEVIR must be swallowed whole with water on an empty stomach.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding your baby, 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 TEEVIR. TEEVIR should not be used during pregnancy. Studies in animals have associated efavirenz with birth defects. Women of childbearing age who are using TEEVIR should avoid falling pregnant and should ensure this by using a barrier method of contraception in combination with other methods of contraception. It is recommended to use adequate contraceptive measures for 12 weeks after you have stopped using TEEVIR. Do not breastfeed if you are taking TEEVIR. Studies in animals (rats) have shown that TEEVIR may appear in milk.

Driving and using machines

It is not always possible to predict to what extent TEEVIR may interfere with the daily activities of a patient. Do not drive or operate tools and machinery especially while you are on TEEVIR

therapy. You may experience dizziness, drowsiness or a strong desire to sleep, impaired concentration, hallucinations, being intensely happy and excited for no apparent reason, confusion, loss of memory, stupor and abnormal thinking. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which TEEVIR affects them.

TEEVIR contains lactose

TEEVIR contains lactose. Patients with the rare hereditary conditions of lactose or galactose intolerance should not take TEEVIR.

TEEVIR contains sodium

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

3. HOW TO TAKE TEEVIR

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

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

The usual dose is one tablet taken once daily without food.

Take TEEVIR at bedtime which will make some side effects less bothersome

Your doctor will tell you how long your treatment with **TEEVIR will** last.

Do not run out of TEEVIR tablets. The virus in your blood may increase and the virus may become harder to treat.

If you have the impression that the effect of TEEVIR is too strong or too weak, tell your doctor or pharmacist.

If you take more TEEVIR than you should

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

If you forget to take TEEVIR

Do not take a double dose to make up for forgotten individual doses. Do not miss a dose of TEEVIR.

If you miss a dose of TEEVIR take it as soon as you remember.

If you stop taking TEEVIR

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

4. POSSIBLE SIDE EFFECTS

TEEVIR can have side effects. Not all side effects reported for TEEVIR are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking TEEVIR, please consult your health care provider for advice.

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

- Allergic reaction, e.g. skin rash, itching.
- Erythema multiforme (skin disorder occurring due to allergic reaction and its symptoms may include fever, itching, joint aches and multiple skin lesions)
- Stevens-Johnson syndrome (life-threatening skin disorder whereby the outmost part of skin

peels off).

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

- Suicidal thoughts or attempts.
- Increased susceptibility to infection, for example, coughing, flu-like symptoms, pneumonia
- Diarrhoea
- Shortness of breath
- Irregular heartbeat
- Seizures or fits
- Bone pain
- Loss of bone mass

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

Tell your doctor if you notice any of the following:

- Anorexia (severely resisting food due to irrational fear of gaining weight).
- Aggressive behaviour
- Impaired concentration
- Anxiety
- Nervousness
- Sleeplessness
- Euphoria (intense feeling of happiness and excitement for no apparent reason)



- Confusion
- Depersonalisation
- Hallucination
- Agitation
- Being paranoid
- Partial loss of sensation and drowsiness
- Forgetfulness
- Abnormal thoughts or dreams
- Headache
- Fatigue
- Increased sweating
- Mild to severe depression, or mania
- Feeling of tingling or prickling, or numbness
- Vomiting
- Flatulence
- Breast growth in men and females
- Indigestion
- Constipation
- Bloatedness
- Abdominal pain
- Abnormal vision.
- Back pain.



- Joint pain and muscle pain.
- Dizziness.
- Feeling weak or sickly.
- Sensation of ringing in the ears.
- Frequent urination.
- Lack of voluntary coordination of movements, speech and movements such as walking may be affected.
- Tremors.
- Changes in body fat resulting in formation of buffalo hump-like structure on the trunk, weight gain in and around the stomach area, loss of weight on the limbs and face.
- Skin discolouration.
- Photoallergic skin reactions.

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, pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (whoumc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of TEEVIR.

Suspected adverse reactions can also be reported directly to the HCR via email: pv@innovata.co.za or tel: +27 86 999 0912

5. How to store TEEVIR

Store all medicines out of reach of children.

Store at or below 30 °C. Store in the original container. Do not remove from the carton until required for use. Keep the bottle tightly closed.

6. Contents of the pack and other information

What TEEVIR contains

The active substances are tenofovir disoproxil fumarate 300 mg, efavirenz 600 mg and emtricitabine 200 mg, per tablet.

The other ingredients are:

Croscarmellose sodium, hydroxypropyl cellulose, lactose monohydrate, magnesium stearate, microcrystalline cellulose, sodium lauryl sulfate.

Film coat: black iron oxide, iron oxide red, polyethylene glycol, polyvinyl alcohol, talc, titanium dioxide.

What TEEVIR looks like and contents of the pack

Pink coloured, capsule-shaped, film-coated tablets, debossed with “M171” on one side and plain on the other side.debossed with M on one side of the tablet and TD1 on the other side.

TEEVIR is packed in high density polypropylene (HDPE) bottle pack comprising of white or blue, opaque, wide mouth HDPE bottle with a white or blue opaque polypropylene (PP) screw closure with desiccant sachet or desiccant canister, packed in an outer carton in 28’s/ 30’s and 84’s/90’s.

Holder of Certificate of Registration

INNOVATA PHARMACEUTICALS (PTY) LTD

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This leaflet was last revised in

12 August 2026

Registration number

51/20.2.8/0579

Date of registration: 02 April 2020

Access to the corresponding Professional information.

Is contained in the packaging or follow the link for the corresponding Professional Information for

TEEVIR:

pi-pil-repository.innovata.co.za,

alternatively, please scan the QR code below: