

APPROVED PATIENT INFORMATION LEAFLET FOR TEERENZ

SCHEDULING STATUS

S4

TEERENZ 600 mg/200 mg/300 mg film-coated tablets

Efavirenz/emtricitabine/tenofovir disoproxil fumarate

Contains sugar: Lactose monohydrate 129 mg

SOME PEOPLE WHO HAVE TAKEN MEDICINE LIKE TEERENZ (WHICH CONTAINS NUCLEOSIDE ANALOGS) HAVE DEVELOPED A SERIOUS CONDITION CALLED 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 PROVIDER RIGHT AWAY IF YOU GET THE FOLLOWING SIGNS OR SYMPTOMS OF LACTIC ACIDOSIS:

- **YOU FEEL VERY WEAK OR TIRED.**
- **YOU HAVE UNUSUAL (NOT NORMAL) MUSCLE PAIN.**
- **YOU HAVE TROUBLE BREATHING.**
- **YOU HAVE STOMACH PAIN WITH NAUSEA AND VOMITING.**
- **YOU FEEL COLD, ESPECIALLY IN YOUR ARMS AND LEGS.**
- **YOU FEEL DIZZY OR LIGHTHEADED.**
- **YOU HAVE A FAST OR IRREGULAR HEARTBEAT.**

SOME PEOPLE WHO HAVE TAKEN MEDICINES LIKE TEERENZ HAVE DEVELOPED SERIOUS LIVER PROBLEMS CALLED HEPATOTOXICITY, WITH LIVER ENLARGEMENT (HEPATOMEGALY) AND FAT IN THE LIVER (STEATOSIS). CALL YOUR HEALTHCARE PROVIDER RIGHT AWAY IF YOU GET THE FOLLOWING SIGNS OR SYMPTOMS OF LIVER PROBLEMS:

- **YOUR SKIN OR THE WHITE PART OF YOUR EYES TURNS YELLOW (JAUNDICE).**
- **YOUR URINE TURNS DARK.**

- **YOUR BOWEL MOVEMENTS (STOOLS) TURN LIGHT IN COLOR.**
- **YOU DON'T FEEL LIKE EATING FOOD FOR SEVERAL DAYS OR LONGER.**
- **YOU FEEL SICK TO YOUR STOMACH (NAUSEA).**
- **YOU HAVE LOWER STOMACH AREA (ABDOMINAL) PAIN.**

IF YOU ALSO HAVE HEPATITIS B VIRUS (HBV) INFECTION AND YOU STOP TAKING TEERENZ, YOU MAY GET A FLARE-UP OF YOUR HEPATITIS. A FLARE-UP IS WHEN THE DISEASE SUDDENLY RETURNS IN A WORSE WAY THAN BEFORE. PATIENTS WITH HBV WHO STOP TAKING TEERENZ NEED CLOSE MEDICAL FOLLOW-UP FOR SEVERAL MONTHS, INCLUDING MEDICAL EXAMS AND BLOOD TESTS TO CHECK FOR HEPATITIS THAT COULD BE GETTING WORSE.

TEERENZ IS NOT APPROVED FOR THE TREATMENT OF HBV, SO YOU MUST DISCUSS YOUR HBV THERAPY WITH YOUR HEALTHCARE PROVIDER

Read all of this leaflet carefully before you start taking TEERENZ

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

1. What TEERENZ is and what it is used for

TEERENZ contains three active ingredients that are used to treat HIV-infection:

- Efavirenz is a non-nucleotide reverse transcriptase inhibitor (NNRTI)
- Emtricitabine is a nucleoside reverse transcriptase inhibitor (NRTI)
- Tenofovir is nucleotide reverse transcriptase inhibitor (NtRTI)

Each of these active substances, also known as anti-retroviral medicines, work by interfering with an enzyme (reverse transcriptase) that is essential for the virus to multiply.

TEERENZ is a treatment for HIV infection in adults aged 18 years and older. TEERENZ may be given alone or with other anti-retroviral medicines.

2. What you need to know before you take TEERENZ

Do not take TEERENZ:

- if you are hypersensitive (allergic) to efavirenz, emtricitabine, tenofovir or any of the other ingredients of TEERENZ (listed in section 6);
- if you have a severe kidney disease;
- if you had a liver disorder or liver failure attributed to treatment with TEERENZ.
- if you have a heart condition; or
- if you are currently taking any of the following medicines:
 - terfenadine, astemizole (used to treat hay fever or other allergies);
 - bepridil (used to treat heart disease);
 - cisapride (used to treat heartburn);
 - 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 (used to treat certain mental conditions);
 - St. John's wort (*Hypericum perforatum*) (an herbal preparation used for depression and anxiety);

- voriconazole (used to treat fungal infections);

If you are taking any of the above medicines, tell your doctor immediately. Taking these medicines with TEERENZ could cause serious or life-threatening side effects or stop these medicines from working properly.

Warnings and precautions

Take special care with TEERENZ

- if you have or have had kidney disease, or if tests have shown problems with your kidneys.
TEERENZ is not recommended if you have moderate to severe kidney disease. TEERENZ may affect your kidneys. Before starting treatment, your doctor may order blood tests to assess kidney function. Your doctor may also order blood tests during treatment to monitor your kidneys.
TEERENZ is not usually taken with other medicines that can damage your kidneys (see Other medicines and TEERENZ). If this is unavoidable, your doctor will monitor your kidney function once a week;
- if you have a history of mental illness, including depression, or of substance or alcohol abuse.
Tell your doctor immediately if you feel depressed, have suicidal thoughts or have strange thoughts (see section 4, Possible side effects);
- if you have a history of convulsions (fits or seizures) or if you are being treated with anticonvulsant therapy such as carbamazepine, phenobarbital and phenytoin. If you are taking any of these medicines, your doctor may need to check the level of anticonvulsant medicine in your blood to ensure that it is not affected while taking TEERENZ. Your doctor may give you a different anticonvulsant;
- if you have a history of liver disease, including chronic active hepatitis. Patients with liver disease including chronic hepatitis B or C, who are treated with combination antiretrovirals, have a higher risk of severe and potentially life-threatening liver problems. Your doctor may conduct blood tests in order to check how well your liver is working or may switch you to

another medicine. If you have severe liver disease, do not take TEERENZ;

- if you have hepatitis B infection, your doctor will carefully consider the best treatment regimen for you. Tenofovir disoproxil and emtricitabine, two of the active substances in TEERENZ, show some activity against hepatitis B virus although emtricitabine is not approved for the treatment of hepatitis B infection. Symptoms of your hepatitis may become worse after discontinuation of TEERENZ. Your doctor may then conduct blood tests at regular intervals in order to check how well your liver is working (see section 3, If you stop taking TEERENZ);
- if you have a liver problem or independent of a history of liver disease, your doctor will consider regular blood tests to check how your liver is working;
- if you are over 65. Insufficient numbers of patients over 65 years of age have been studied. If you are over 65 years of age and are prescribed TEERENZ, your doctor will monitor you carefully;
- if you are younger than 18 years old.

Tell your doctor, pharmacist or healthcare professional before taking TEERENZ:

- If you have a history of kidney problems, more frequent monitoring may be needed, as your kidney function and serum phosphate should be checked before and during treatment.
- If a skin rash occur. These may appear within the first 2 weeks of starting and may resolve within a month of continued treatment. TEERENZ treatment should be stopped if a severe skin rash, with blistering, scaling, mucosal involvement, or fever, develops.
- TEERENZ may cause lowering of your bone density, therefore you should be checked for bone abnormalities; especially if you have a history of bone fractures or are at risk of low bone mass.
- If you notice any of the following: redistribution/accumulation of body fat including increased body fat, "buffalo hump" - lump of fat on the back of the neck, bodily swelling, facial swelling, breast enlargement, and "cushingoid appearance" (a disease with moon face appearance) may occur.

- If you notice any signs of inflammation or infection. In some patients with advanced HIV infection (AIDS) and a history of opportunistic infection, signs and symptoms of inflammation from previous infections may occur soon after anti-HIV treatment is started. It is believed that these symptoms are due to improvement in the body's immune response, enabling the body to fight infections that may have been present with no obvious symptoms.
- In addition to the opportunistic infections, autoimmune disorders (a condition that occurs when the immune system attacks healthy body tissue) may also occur after you start taking medicines for the treatment of your HIV infection. Autoimmune disorders may occur many months after the start of treatment. If you notice 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, please inform your doctor immediately.
- Continue to use appropriate precautions as TEERENZ does not prevent transmission of HIV to others through sexual contact or blood contamination.
- Some medicines may interact with TEERENZ (see Other medicines and TEERENZ).

Other medicines and TEERENZ

Always tell your health care provider if you are taking any other medicine.

(This includes all complementary or traditional medicines.)

Do not take TEERENZ if you are currently taking one of the following medicines:

- terfenadine and astemizole (antihistamines to treat allergies),
- bepridil (calcium channel blocker used to treat heart disease),
- cisapride (gastrointestinal prokinetic/motility agent to treat heartburn),
- midazolam or triazolam (benzodiazepine sedative/hypnotics to help you sleep),
- efavirenz, emtricitabine, tenofovir, lamivudine (anti-retrovirals to treat HIV-infection),
- pimozide (antipsychotic/neuroleptic used to treat certain mental conditions),
- ergot derivatives (for example ergotamine, dihydroergotamine, ergonovine, and

methylergonovine, used to treat migraines and cluster headaches), because efavirenz could cause a lower metabolism of these medicines and create the potential for serious and/or life-threatening adverse events (e.g. cardiac dysrhythmias (heart problems), prolonged sedation or respiratory (lung) depression),

- voriconazole, because efavirenz significantly decreases voriconazole blood concentrations,
- if you are taking St John's wort (herbal medicine used for depression and anxiety), or other herbal medicines, such as *Ginkgo biloba* extracts, as this may lower the efavirenz concentrations in your blood.

TEERENZ could interact with other medicines and the dosages of the medicines might have to be changed by your doctor as the amounts of TEERENZ or other medicines in your blood may be affected e.g.

- aciclovir, adefovir dipivoxil, cidofovir, ganciclovir, famciclovir, valaciclovir and valganciclovir may increase blood concentrations of the emtricitabine and tenofovir in TEERENZ.
- other medicines used for HIV infections such as amprenavir, abacavir, fosamprenavir calcium, atazanavir, indinavir, ribavirin, lopinavir/ritonavir, ritonavir, saquinavir as they change each other's concentration in the blood.
- medicines containing didanosine (used for HIV infections) as the didanosine concentration may get too high and may reduce your CD4 cell counts. Inflammation of the pancreas may occur and excess lactic acid in your blood may be harmful.
- warfarin (used to lower clotting of blood) as blood concentrations are changed.
- medicines used to treat fits such as carbamazepine, phenytoin, phenobarbital (phenobarbitone), as TEERENZ can lower the concentration of these medicines in your blood and carbamazepine can also work the other way around.
- sertraline, used for depression.
- medicines used to treat fungal infections such as itraconazole and ketoconazole, as TEERENZ can lower the concentration in the blood.

- medicines to treat bacterial infections such as clarithromycin, rifabutin, aminoglycosides, amphotericin B and vancomycin.
- medicines called calcium channel blockers such as diltiazem or similar medicines.
- medicines used to lower blood fats, e.g. cholesterol, such as atorvastatin, pravastatin, simvastatin.
- methadone, used to treat opiate addiction.
- hormonal contraceptives, e.g. birth control pills, injections and implants as TEERENZ may make hormonal contraceptives less effective. You must also use a second (barrier) method of contraception.
- some urinary test results may be influenced e.g. the cannabinoid test may be false-positive.
- immunosuppressant medicines such as ciclosporin, tacrolimus, sirolimus.

Before you begin using any new medicine (prescription or non-prescription) or if you develop any new medical problem while you are using this medicine, check with your doctor, nurse, or pharmacist.

TEERENZ with food and drink and alcohol

TEERENZ tablets should be taken on an empty stomach.

Taking alcohol whilst on TEERENZ treatment, may increase or worsen some side effects of TEERENZ, such as drowsiness, dizziness and concentration problems.

Taking food (for example, grapefruit juice) with TEERENZ may lower the efavirenz concentrations in your blood

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 health care provider for advice before taking TEERENZ.

Pregnancy: Pregnancy should be avoided as TEERENZ may harm your unborn baby if you are pregnant or become pregnant whilst taking TEERENZ. Always use an additional second (barrier) contraceptive method (like hormonal tablets). Women who may have children or become pregnant should be tested for pregnancy before treatment with TEERENZ starts.

- Women who are taking TEERENZ should not become pregnant. Your doctor may require you to take a pregnancy test to ensure that you are not pregnant before starting treatment with TEERENZ. Serious birth defects have been seen in the babies of women who have been treated with TEERENZ.
- Women must use a barrier form of contraceptive such as a condom or diaphragm, even if they use other methods of birth control. You should continue to use contraceptive measures, as above, for 12 weeks after you stop taking TEERENZ.
- Tell your healthcare provider right away if you are pregnant.

Breastfeeding: Do not breastfeed your baby during treatment with TEERENZ. Both HIV and the ingredients of TEERENZ may pass through breast milk and cause serious harm to your baby.

Driving and using machines

TEERENZ may cause dizziness, impaired concentration and drowsiness. If you experience these symptoms while taking TEERENZ, do not drive and do not use any tools or operate machinery.

TEERENZ contains lactose

If you know you are lactose-intolerant, or if you have been told that you have an intolerance to any other sugars, talk to your doctor before taking TEERENZ.

3. How to take TEERENZ

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

Always take TEERENZ exactly as your doctor has told you. Check with your doctor or pharmacist

if you are not sure.

The usual dose for adults is one tablet taken each day by mouth. TEERENZ should be taken on an empty stomach preferably at bedtime.

Dosing at bedtime may help to make some side effects (for example, dizziness, drowsiness) less troublesome. Swallow the tablet whole with water.

Your doctor will tell you how long your treatment with TEERENZ will last. If you have the impression that the effect of TEERENZ is too strong or too weak, tell your doctor or pharmacist.

If you take more TEERENZ than you should

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

Take this leaflet and any remaining tablets with you, so that the doctor knows what you have taken.

You may experience an increase in side effects and their frequency. You might get symptoms caused by TEERENZ such as nervous system side effects, including e.g. agitation, memory loss, confusion, dizziness, abnormal sense of well-being, headache, sleeplessness or sleepiness, impaired concentration, abnormal thinking or dreaming, convulsions, feeling of not being part of your body or surroundings, and seeing, hearing or feeling things that are not there.

If you forget to take TEERENZ

Do not miss a dose of TEERENZ.

If you forget to take a tablet, take the missed dose right away, unless it is almost time for your next dose. Do not take a double dose to make up for forgotten individual doses.

If you stop taking TEERENZ

Don't stop taking TEERENZ without talking to your doctor. Stopping TEERENZ can seriously affect your response to future treatment. If TEERENZ is stopped, speak to your doctor before you restart taking TEERENZ tablets. Your doctor may consider giving you the components of

TEERENZ separately if you are having problems or need your dose adjusted.

4. Possible side effects

TEERENZ can have side effects.

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

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

- if you develop rapid breathing, drowsiness and /or feeling sick (nausea), being sick (vomiting) and stomach pain. This is a rare but serious side effect called lactic acidosis that can be fatal.
- swelling of the hands, feet, ankles, face, lips and mouth 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 reaction to TEERENZ. 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:

- allergic reaction (hypersensitivity) that may cause severe skin reactions (Stevens-Johnson syndrome, erythema multiforme),
- angry behaviour, suicidal thoughts, strange thoughts, paranoia, unable to think clearly, mood being affected, seeing or hearing things that are not really there (hallucinations), suicide attempts, personality change (psychosis),
- pain in the abdomen (stomach), caused by inflammation of the pancreas,
- forgetfulness, confusion, fitting (seizures), incoherent speech, tremor (shaking),

- yellow skin or eyes, itching, or pain in the abdomen (stomach) caused by inflammation of the liver,
- liver failure, in some cases leading to death or liver transplant,
- inflammation of the kidney, passing a lot of urine and feeling thirsty, damage to kidney tubules,
- back pain caused by kidney problems, including kidney failure. Your doctor may do blood tests to see if your kidneys are working properly,
- softening of the bones (with bone pain and sometimes resulting in fractures) which may occur due to damage to the kidney tubule cells,
- Combination antiretroviral therapy (such as TEERENZ) may change your body shape, by changing the way body fat is distributed. You may lose fat from your legs, arms and face; gain fat around the abdomen (tummy) and internal organs; get larger breasts or fatty lumps on the back of the neck. The cause and the long-term effects of these changes are not yet known.

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:

- feeling down, feeling anxious, abnormal dreams, struggle to sleep,
- being unbalanced, having trouble with coordination, having trouble to focus, dizziness, headache,
- diarrhoea, feeling sick (nausea), being sick (vomiting), stomach pain, indigestion, feeling windy and bloated after a meal,
- rashes (including red spots or blotches sometimes with blistering and swelling of the skin) which may be allergic reactions, change in skin colour, dry skin patches,
- feeling weak, pain, abnormal physical weakness or lack of energy.

Less frequent side effects

- blurred vision,
- a feeling of spinning or tilting (vertigo), whistling, ringing or other persistent noise in the ears,
- reddening of the skin,
- itchy rash to the skin caused by a reaction to sunlight,
- breast enlargement in males,
- breakdown of muscle, muscle pain.

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 TEERENZ.

5. How to store TEERENZ

Store all medicines out of reach of children.

Store at or below 25 °C.

Store in the original package. Keep the bottle tightly closed and the silica gel should not be removed from the bottle after opening.

Do not store your medicine in the bathroom.

Do not use TEERENZ. after the expiry date stated on the label or container.

Return any expired or unused medicine to your pharmacist for safe disposal.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What TEERENZ contains

The active substances are efavirenz, emtricitabine and tenofovir disoproxil. Each TEERENZ 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 tablets are:

Tablet core: Croscarmellose sodium, hydroxypropyl cellulose, lactose monohydrate, magnesium stearate, microcrystalline cellulose, sodium lauryl sulphate.

Film-coating: Polyethylene glycol, polyvinyl alcohol, talc, FD & C Blue #2/Indigo carmine aluminium lake and titanium dioxide

What TEERENZ looks like and contents of the pack

TEERENZ film-coated tablets are blue coloured, capsule-shaped, biconvex film-coated tablets engraved TEE on one side and plain on the other side. TEERENZ is packed in child resistant HDPE container of 28, 30 or 84 tablets

Holder of Certificate of Registration

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