Front Top
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ELTENO TABLETS
PM02411103

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS S4

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM
ELTENO TABLETS (film coated tablets)

Read all of this leaflet carefully before you start taking **ELTENO TABLETS.**
- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- **ELTENO TABLETS** 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 ELTENO TABLETS CONTAIN

Each film-coated tablet contains efavirenz 600 mg, lamivudine 300 mg and tenofovir disoproxil fumarate 300 mg. Contains sugar (lactose monohydrate).
Other ingredients include lactose monohydrate, microcrystalline cellulose, croscarmellose sodium, poloxamer, hydroxypropyl cellulose, sodium lauryl sulfate, magnesium stearate (vegetable grade) and pregelatinized starch. Tablet film coating consisting of hypromellose, titanium dioxide (C.I. No. 77891) and triacetin.

WHAT ELTENO TABLETS ARE USED FOR

ELTENO TABLETS is used to treat Human Immunodeficiency Virus (HIV) infection in adults. **ELTENO TABLETS** is used alone or in combination with other anti-HIV medicines to treat patients with HIV-1 infection. **ELTENO TABLETS** will be prescribed for you if you are already stabilised on the individual medicines efavirenz, lamivudine and tenofovir contained in **ELTENO TABLETS.**

BEFORE YOU TAKE ELTENO TABLETS

Do not take ELTENO TABLETS:
- If you are hypersensitive (allergic) to efavirenz, lamivudine and tenofovir disoproxil fumarate, or any of the other ingredients of **ELTENO TABLETS.**
- If you have kidney problems.
- If you are pregnant or breastfeeding.
- If you have severe liver disease.
- If you had a liver disorder or liver failure attributed to treatment with **ELTENO TABLETS.**
- If you are under 18 years of age.
- Tell your doctor if you are taking other medicines that contain efavirenz, emtricitabine, tenofovir disoproxil, or lamivudine or adefovir dipivoxil. **ELTENO TABLETS** should not be taken with any of these medicines.
- Tell your doctor if you are taking St. John's Wort (*Hypericum perforatum*) (a herbal remedy used for depression and anxiety). St. John's Wort and **ELTENO TABLETS** should not be taken simultaneously.
- If you are currently taking any of the following medicines:
  - cisapride (used to treat heartburn)
  - bepridil (used to treat heart disease)
  - 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)
  - voriconazole (for fungal infections)
  - zalcitabine (for HIV infection).

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

Take special care with ELTENO TABLETS:

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

- **ELTENO TABLETS** 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, 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 liver disease (including hepatitis B). **ELTENO TABLETS** should not be used to treat chronic hepatitis B virus infection (HBV; an on-going liver infection). Independent of a history of liver disease, your doctor will consider regular blood tests to check how your liver is working.
- Tell your doctor if you have had kidney disease, or if tests have shown problems with your kidneys. **ELTENO TABLETS** may affect your kidneys.
- **ELTENO TABLETS** is not usually taken with other medicines that can damage your kidneys. If this is unavoidable, your doctor will monitor your kidney function.
- Take your child, if exposed during pregnancy to **ELTENO TABLETS**, 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.
- Rashes may be caused by **ELTENO TABLETS.** If you see any signs of a severe rash with blistering or fever, stop taking **ELTENO TABLETS** and tell your doctor at once.
- Tell your doctor 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.
- Tell your doctor if you ever had seizures or are taking medicines for seizures.
- Tell your doctor if you experience 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. Taking **ELTENO TABLETS** with didanosine (medicine used to treat HIV infection) may increase the risk for pancreatitis.
- **ELTENO TABLETS** decreases bone mineral density which could result in fractures. Your doctor may prescribe calcium and vitamin D supplements while taking **ELTENO TABLETS.**
- 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.
- **ELTENO TABLETS** 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 **ELTENO TABLETS** is started. If you notice signs of inflammation or infection, or deterioration thereof, tell your doctor at once.
- You will need to take **ELTENO TABLETS** every day. **ELTENO TABLETS** helps to control your condition and stop your illness getting worse, 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.
- HIV infection is spread by sexual contact with someone who has the infection, or by transfer of infected blood (for example, by sharing injection needles). **ELTENO TABLETS** will not stop you passing HIV infection on to other people.
- To protect other people from becoming infected with HIV:
  - Use a condom when you have oral or penetrative sex
  - Do not risk blood transfer – for example, do not share needles.
- The safety and effectiveness of **ELTENO TABLETS** in children and patients younger than 18 years has not been determined.
- **ELTENO TABLETS** is not recommended for the elderly who are more than 65 years of age.
- **ELTENO TABLETS** may increase blood cholesterol, triglyceride and sugar levels and your doctor will perform blood tests at regular intervals to monitor cholesterol, triglyceride and sugar levels.

Taking ELTENO TABLETS with food and drink:
ELTENO TABLETS should be taken without food. Grapefruit juice should be avoided. Alcohol should be avoided.

Pregnancy and breastfeeding:
- Do not take **ELTENO TABLETS** if you are pregnant. Malformations have been seen in foetuses from animals treated with **ELTENO TABLETS** during pregnancy; therefore, pregnancy should be avoided in women receiving **ELTENO TABLETS.**
- Inform your doctor immediately if you are pregnant or intend to become pregnant.
- If you are a woman receiving **ELTENO TABLETS**, a reliable form of barrier contraception (for example, a condom), should always be used with other methods of contraception including oral (pill) or other hormonal contraceptives (for example, implants, injection).
- Do not breastfeed if you are taking **ELTENO TABLETS.**

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking **ELTENO TABLETS.**

Important information about some of the ingredients of ELTENO TABLETS
ELTENO TABLETS contains lactose. Patients with the rare hereditary conditions of lactose/fructose or galactose intolerance should not take **ELTENO TABLETS.**
ELTENO TABLETS contains lactose which may have an effect on the control of your blood sugar if you have diabetes mellitus.

Driving and using machinery
ELTENO TABLETS can cause dizziness, impaired concentration and/or drowsiness. If you feel dizzy or drowsy while taking **ELTENO TABLETS** do not drive and do not use any tools or machines.

Taking other medicines with ELTENO TABLETS:

Always tell your healthcare professional 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 efavirenz, abacavir, emtricitabine, tenofovir, indinavir or lamivudine (for HIV infection).
- If you are currently taking any of the following medicines:
  - cisapride (used to treat heartburn)
  - bepridil (used to treat heart disease)
  - 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)
  - voriconazole (for fungal infections)
  - zalcitabine (for HIV infection).

If you are taking any of these medicines, tell your doctor immediately.
- 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 **ELTENO TABLETS.**
- Tell your doctor if you are taking other medicines containing didanosine (for HIV infection). Taking **ELTENO TABLETS** 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.
- Medicines used to lower blood fats (also called statins): Atorvastatin, pravastatin, simvastatin. **ELTENO TABLETS** can reduce the amount of statins in your blood. Your doctor will check your cholesterol levels and will consider changing the dose of your statin, if needed.
- Medicines used to treat convulsions/seizures (anticonvulsants): Carbamazepine, phenytoin, phenobarbital. **ELTENO TABLETS** can reduce the amount of the anticonvulsant in your blood. Carbamazepine can reduce the amount of efavirenz, one of the components of **ELTENO TABLETS**, in your blood. Your doctor may need to consider giving you a different anticonvulsant.
- Medicines used to treat bacterial infections: Clarithromycin, rifabutin, rifampicin (for TB). Your doctor may need to consider changing your dose or giving you an alternative antibiotic. In addition, your doctor may consider giving you an additional dose of efavirenz to treat your HIV infection.
- Medicines used to treat fungal infections (antifungals): Itraconazole or ketoconazole. **ELTENO TABLETS** can reduce the amount of itraconazole or ketoconazole in your blood. Your doctor may need to consider giving you a different antifungal.
- Hormonal contraceptive, such as birth control pills, an injected contraceptive (for example, Depo-Provera), or a contraceptive implant: You must also use a reliable barrier method of contraception such as a condom as **ELTENO TABLETS** may make hormonal contraceptives less likely to work.
- Methadone, a medicine used to treat addiction, as your doctor may need to change your methadone dose.
- Sertraline, a medicine used to treat depression, as your doctor may need to change your dose of sertraline.
- Diltiazem or similar medicines (called calcium channel blockers): When you start taking **ELTENO TABLETS**, your doctor may need to adjust your dose of the calcium channel blocker.
- Warfarin (a medicine used to reduce clotting of the blood): Your doctor may need to adjust your dose of warfarin.
- St. John's wort (*Hypericum perforatum*) (a herbal remedy used for depression and anxiety) is not recommended to take with **ELTENO TABLETS.**
- Tell your doctor if you are taking other medicines that may reduce your kidney function. Some examples include
  - Aminoglycosides (for bacterial infection)
  - Adefovir dipivoxil (for viral infection)
  - Cidofovir (for viral infection)
  - Aciclovir (for viral infection)
  - Valaciclovir (for viral infection)
  - Ganciclovir (for viral infection)
  - Valganciclovir (for viral infection)
  - Amphotericin B (for fungal infection)
  - Foscarnet (for viral infection)
  - Pentamidine (for infections)
  - Interfoukin-2 (to treat cancer)

HOW TO TAKE ELTENO TABLETS

Do not share medicines prescribed for you with any other person.
Always take ELTENO TABLETS exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure. If you have the impression that the effect of ELTENO TABLETS is too strong or too weak, talk to your doctor or pharmacist.

- Stay under a healthcare provider's care when taking **ELTENO TABLETS.** Do not change your treatment or stop treatment without first talking with your healthcare provider.
- The usual dose of **ELTENO TABLETS** is one tablet, swallowed with water, once a day at bedtime, taken without food.

If you take more ELTENO TABLETS than you should:
- Seek emergency medical attention if you think you have taken too much of **ELTENO TABLETS.**

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

If you forget to take ELTENO TABLETS:
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.

POSSIBLE SIDE EFFECTS
ELTENO TABLETS can have side effects.
Not all side effects reported for **ELTENO TABLETS** are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking this medicine, please consult your doctor, pharmacist or other healthcare professional for advice.

If any of the following happens, stop taking **ELTENO TABLETS** and tell your doctor immediately or go to the casualty department at your nearest hospital:
- Hives; difficulty breathing; swelling of your face, lips, tongue, or throat.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to **ELTENO TABLETS.** 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).
- Back pain caused by kidney problems, including kidney failure. Your doctor may do blood tests to see if your kidneys are working properly.
- Fever, chills, sore throat, cough, or other signs of infection.
- Psychiatric symptoms including confusion, severe depression, suicidal thoughts, aggression, extreme fear, hallucinations, or unusual behaviour.
- Fever with a severe blistering, peeling and red skin rash or any severe skin reaction.
- Seizures (have a "fit" or convulsion).
- Inflammation of the pancreas (severe pain in the abdomen).

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
- difficulty falling asleep
- headache
- feeling depressed or anxious
- nausea, vomiting
- diarrhoea or constipation, flatulence
- stomach pain or cramps
- skin rash, increased swelling
- loss of hair
- muscle or joint pain
- fatigue or lack of energy
- generally feeling unwell
- cough
- runny or stuffy nose

Less frequent side effects:
- weight gain or weight loss
- numbness, tingling, pins and needles
- tremor (shake), disturbances of co-ordination and balance
- confusion, forgetfulness, difficulty concentrating, drowsiness, abnormal thinking, feeling agitated, inappropriate behaviour, lack of interest, abnormally happy mood, frequent mood changes, problems with speech, loss of control of bodily movements, loss of sensitivity to touch, unusual dreams
- abnormal vision, blurred vision
- ringing in the ears, a feeling of spinning or tilting (vertigo)
- palpitations (rapid irregular action of heart), increased rate of heart beat
- asthma, shortness of breath, cough, runny or stuffy nose, sinusitis, chest infections
- indigestion, upset stomach, increased appetite, lack of appetite, taste disturbances, heartburn
- itching, increased sweating, hives, eczema, acne, changes in skin and nail colour, skin exfoliation, infection of the hair follicles, allergic skin reaction to sunlight
- joint pain, breakdown of muscle, muscle pain or weakness, back pain, chest pain, softening of the bones (with bone pain and sometimes resulting in fractures)
- impotence (loss of male sexual ability); increased and decreased sexual drive (libido), enlarged breasts in males
- fainting, hot flushes, flu-like symptoms, shortness of breath
- blood in the urine, inflammation of the kidney, passing a lot of urine and feeling thirsty
- changes in shape or location of body fat (especially in your arms, legs, face, neck, breasts, and waist)
- increased sweating, fever

Blood tests may also show:
- decreases in phosphate levels in the blood
- increased levels of creatine kinase in the blood that may result in muscle pain and weakness
- anaemia (low red blood cell count)
- low white blood cell count (a reduced white blood cell count can make you more prone to infection)
- increased fatty acids (triglycerides), bilirubin or sugar levels in the blood
- liver and pancreas problems
- decreases in potassium in the blood
- increases in creatinine in the blood
- proteins in urine

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

STORING AND DISPOSING OF ELTENO TABLETS
Store at or below 25 °C (room temperature). Keep the HDPE containers closed.
KEEP ALL MEDICINES OUT OF REACH OF CHILDREN.

Return all unused medicine to your pharmacist.
Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

PRESENTATION OF ELTENO TABLETS
HDPE Container Pack:
Tablets are packed in 120 ml round white HDPE bottle with 38-400 neck finish closed with 38 mm white polypropylene closure, with pulp and heat seal liner (123 white printed liner). Each container contains 28 or 30 tablets and 2 silica gel sachets. The containers are packed in a pre-printed unit carton.

IDENTIFICATION OF ELTENO TABLETS
White to off-white, capsule shaped, biconvex film coated tablets plain on both sides.

REGISTRATION NUMBER/REFERENCE NUMBER
49/20.2.8/0224

NAME AND ADDRESS OF REGISTRATION HOLDER
Mediceds Pharmaceuticals SA (Pty) Ltd
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TO ACCESS THE PROFESSIONAL INFORMATION:
Please visit https://activo.co.za/downloads/pi/Elteno-PI.pdf or scan the QR code below.

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335 mm

320 mm

INLIGTINGSBLAD VIR PASIËNTE

SKEDULERINGSTATUS S4

EIENDOMSNAAM, STERKTE EN FARMASEUTIESE VORM
ELTENO TABLETS (filmbedekte tablette)

Lees die hele brosjure sorgvuldig voordat u begin om **ELTENO TABLETS** te neem.
- Hou hierdie bladsie. U mag dit moontlik weer wil lees.
- Indien u enige verdere vrae het, moet u asseblief u dokter of apteker raadpleeg.
- **ELTENO TABLETS** is vir u persoonlik voorgeskryf en u behoort nie u medisyne met ander mense te deel nie. Dit mag hulle skade aandoen, ookal het hulle dieselfde simptome as u.

WAT ELTENO TABLETS BEVAT
Elke filmbedekte tablet bevat efavirens 600 mg, lamivudien 300 mg en tenofovirdisoproksielfumaraat 300 mg. Bevat laktose.
Ander bestanddele sluit laktosemonohidraat, mikrokristalsiine sellulose, kroskarmellose natrium, poloksamer, hidroksipropiel sellulose, natriumlourielsulfaat, magnesiumstearaat (plantaardig) en gepregelatiniseerde stysel. Die filmbedekking van die tablet bestaan uit hipromellose, titaandioksied (C.I. Nr. 77891) en triasetien.

WAARVOOR ELTENO TABLETS GEBRUIK WORD
ELTENO TABLETS word gebruik om menslike immuuntekortvirus (MIV) besmetting in volwassenes te behandel. **ELTENO TABLETS** word alleen of in kombinasie met ander anti-MIV medisyne gebruik om pasiënte met MIV-1 besmetting te behandel. **ELTENO TABLETS** sal aan u voorgeskryf word as u reeds op die individuele medisyne efavirens, lamivudien en tenofovir wat in **ELTENO TABLETS** voorkom, gestabiliseer is.

VOORDAT U ELTENO TABLETS NEEM
Moenie ELTENO TABLETS neem nie:
- As u hipersensitief (allergies) teen efavirens, lamivudien of tenofovirdisoproksielfumaraat, of enige van die ander bestanddele van **ELTENO TABLETS** is.
- As u aan nierprobleme ly.
- As u swanger is of borsvoed.
- As u aan erge lewersiekte ly.
- As u jonger as 18 jaar oud is.
- As u 'n lewerversteuring of lewerversaking gehad het wat toegeskryf word aan behandeling met **ELTENO TABLETS.**
- Stel u dokter in kennis as u enige ander medisyne wat efavirens, emtrisitabien, tenofovirdisoproksiel, lamivudien of adefovirdipivoksiel bevat, neem. **ELTENO TABLETS** behoort nie saam met enige van hierdie medisyne geneem te word nie.
- Stel u dokter in kennis as u St. John se kruid (*Hypericum perforatum*) ('n kruiemiddel wat vir depressie en angs gebruik word) neem. St. John se kruid en **ELTENO TABLETS** behoort nie terselfdertyd geneem te word nie.
- As u iets enige van die volgende medisyne gebruik:
  - kisapried (gebruik om soolbrand te behandel)
  - bepridiel (gebruik om hartsiekte te behandel)
  - ergotalkaloïede (bv. ergotamien, dihidroërgotamien, ergonovien en metielergonovien) (gebruik om migraine en troshoofpyne te behandel)
  - midasolaam of triasolaam (gebruik om u te help slaap)
  - pimosied (gebruik om sekere geestaskondisies te behandel)
  - vorikonasool (vir swaminfeksies)
  - salsitabien (vir MIV-infeksies).

As u enige van hierdie medisyne gebruik, moet u onmiddellik u dokter daarvan in kennis stel. Die neem van hierdie medisyne saam met **ELTENO TABLETS** te neem kan ernstige of lewensbedreigende newe-effekte veroorsaak of keer dat hierdie medisyne behoorlik werk.

Neem spesiale sorg met ELTENO TABLETS:

ELTENO TABLETS kan tot ernstige probleme met u lewer lei of te veel suur in u bloed veroorsaak. Indien nie behandel word nie, kan dit tot die dood lei. Die veiligheid en effektiwiteit van ELTENO TABLETS in pasiënte wat met beide menslike immuuntekortvirus (MIV) en hepatitis B virus (HBV) besmet is, is nie vasgestel nie. U behoort vir etlike maande noukeurig deur u dokter gemonitor te word as u met HBV besmet is en met die gebruik van ELTENO TABLETS ophou.

- **ELTENO TABLETS** kan melksuurasidose veroorsaak wat saam met 'n vergrootte lewer, fataal kan wees. Diep, vinnige asemhaling en simptome soos naarheid, braking en maagpyn kan op die ontwikkeling van melksuurasidose dui. Melksuurasidose kom meer dikwels in vroue voor. Pasiënte wat oorgewig is het 'n groter risiko.
- Stel u dokter in kennis as u aan 'n lewersiekte ly (insluitende hepatitis B). **ELTENO TABLETS** behoort nie gebruik te word om chroniese hepatitis B infeksie te behandel nie (HBV: 'n aanhoudende lewerinfeksie). Ongeag 'n geskiedenis van lewersiekte sal u dokter gereelde bloedtoetse oorweeg om na te gaan hoe u lewer funksioneer.
- Stel u dokter in kennis as u aan 'n niersiekte gely het, of as toetse aangedui het dat u probleme met u niere het. **ELTENO TABLETS** kan u niere aantas.
- **ELTENO TABLETS** word gewoonlik nie saam met ander medisyne wat u niere kan aantas, geneem nie. As dit egter onafwendbaar is, sal u dokter u nierfunksie monitor.
- Neem u kind, indien gedurende swangerskap aan **ELTENO TABLETS** blootgestel is, onmiddellik na u dokter as die kind bleek, swak, ten alle tye slaperig is, vinnig asemhaal, die hart vinniger klop, en dit nie lyk asof die kind wil massa optel nie, breek, 'n koors seer keel, mondulkusse het, styfheid en stuipaanvalle of abnormale gedrag toon. U dokter sal bykomende mediese en laboratoriumtoetse op u kind uitvoer.
- **ELTENO TABLETS** kan uitslag veroorsaak. As u enige tekens van 'n erge uitslag met blaasvorming of koors waarneem, moet u onmiddellik met die gebruik van **ELTENO TABLETS** ophou en u dokter onmiddellikin kennis stel.
- Stel u dokter in kennis as u 'n geskiedenis van 'n geestessiekte het, insluitende depressie of aan misbruik van alkohol of substanse ly. Stel u dokter onmiddellik in kennis as u depressief voel, aan selfmoordideas dink of vreemde gedagtes het.
- Stel u dokter in kennis as u ooit stuipaanvalle gehad het of as u medikasie vir stuipaanvalle neem.
- Stel u dokter in kennis as u erge boonste maagpyn met naarheid en braking ondervind wat tekens van pankreatitis is, 'n gevaarlike inflammasie van die pankreas wat die dood kan veroorsaak. Die neem van **ELTENO TABLETS** saam met didanosien (medisyne wat gebruik word om MIV te behandel) kan die risiko vir pankreatitis verhoog.
- **ELTENO TABLETS** verminder beenmineraaldigtheid wat tot fraktuure kan lei. U dokter mag kalsium en vitamien D supplemente voorskryf terwyl u **ELTENO TABLETS** neem.
- Sommige pasiënte wat kombinasie antiretrovirusterapie gebruik kan 'n beensiekte wat osteonekrose genoem word (afsterwing van beenweefsel wat deur 'n verlies aan bloedtoevoer aan die been veroorsaak word), ontwikkel. Tekens van osteonekrose is gewrigsstyfheid, pyn (veral in die heup, knie en skouer) en moeite met beweging. As u enige van hierdie simptome waarneem, moet u u dokter in kennis stel.
- **ELTENO TABLETS** kan u liggaamsvorm verander deur die manier waarop vet in u liggaam verspreid word, te verander. U kan vet van u bene, arms en gesig verloor en/of vet in die buik en om interne organe opgaar; groter borste of knoppe op die agterkant van die nek (buffelskof) ontwikkel.
- As u aan gevorderde MIV-infeksie en ook aan 'n ander infeksie ly, kan u akute simptome van 'n bestaande infeksie ontwikkel wanneer u met **ELTENO TABLETS** terapie begin. As u tekens van inflammasie of infeksie of agteruitgang daarvan waarneem, moet u onmiddellik u dokter daarvan in kennis stel.
- U sal **ELTENO TABLETS** elke dag moet neem. **ELTENO TABLETS** help om u kondisie te kontroleer en keer dat u siekte erger word. Dit is egter nie 'n genesing vir MIV-siekte nie. U kan aanhou om ander infeksies en siektes wat met MIV-siekte geassosieer word, op te doen. U behoort op 'n gereelde basis in kontak met u dokter te bly. Moenie met die gebruik van die medisyne ophou alvorens u nie met u dokter gepraat het nie.
- MIV-infeksie versprei deur seksuele kontak met iemand wat aan die infeksie ly, of deur oordraging van besmette bloed (byvoorbeeld om inspuitmaalde te deel). **ELTENO TABLETS** sal nie keer dat u MIV-infeksie na ander mense oordra nie.
- Om te voorkom dat ander mense met MIV besmet word:
  - Gebruik 'n kondoom wanneer u orale seks of penetrerende seks beoefen.
  - Vermy die risiko van bloedoordragings - bv. moenie naalde deel nie.
  - Die veiligheid en effektiwiteit van **ELTENO TABLETS** in kinder en pasiënte jonger as 18 jaar oud is nie vasgestel nie.
  - **ELTENO TABLETS** word nie vir bejaardes van ouer as 65 jaar aanbeveel nie.
  - **ELTENO TABLETS** kan die bloedcholesterol, trigliseried en glukosevlakke verhoog en u dokter sal met gereelde tussenposes bloedtoetse uitvoer om u cholesterol, trigliseried en glukosevlakke te monitor.

Die neem van ELTENO TABLETS saam met voedsel en vloeistof:
ELTENO TABLETS behoort sonder voedsel geneem te word. Pomelosap en alkohol behoort vermy te word.

Swangerskap en borsvoeding:
- Moenie **ELTENO TABLETS** neem as u swanger is nie. Wanvormings is in fetusse van diere wat met **ELTENO TABLETS** gedurende dragtigheid behandel is, waargeneem; daarom behoort swangerskap vermy te word in vroue wat **ELTENO TABLETS** gebruik.
- Stel u dokter onmiddellik in kennis as u swanger is of beplan om swanger te raak.
- As u 'n vrou is en **ELTENO TABLETS** ontvang, behoort 'n betroubare vorm van skeidingskontrasepsie (bv. 'n kondoom) saam met ander metodes van kontrasepsie, insluitende oraal (die pil) of ander hormonale voorbehoedmiddels (bv. implante, inspuiting) gebruik te word.
- Moenie borsvoed as **ELTENO TABLETS** gebruik nie.

As u swanger is of u baba borsvoed, moet u asseblief u dokter, apteker of ander professionele gesondheidswerker vir advies nader voordat u **ELTENO TABLETS** neem.

Belangrike inligting oor sommige van die bestanddele van ELTENO TABLETS
ELTENO TABLETS bevat laktose. Pasiënte met die seldsame erflike toestande van laktose / fruktose of galaktose-intoleransie moet nie **ELTENO TABLETTE** neem nie.
ELTENO TABLETS bevat laktose wat 'n uitwerking op die beheer van jou bloedsuiker kan hê as jy diabetes mellitus het.

Bestuur en die gebruik van masjinerie
ELTENO TABLETS kan duiseligheid, ingekorte konsentrasie en/of lomerigheid veroorsaak. As u duiselig of lomerig voel terwyl u **ELTENO TABLETS** neem, behoort u nie te bestuur of met enige gereedskap of masjinerie te werk nie.

Die neem van ander medisyne saam met ELTENO TABLETS:

Stel altyd u professionele gesondheidswerker in kennis as u enige ander medisyne gebruik. Dit sluit komplimentêre of tradisionele medisyne in.

- Stel u dokter in kennis as u enige medikasie neem of onlangs geneem het.
- Stel u dokter in kennis as u efavirens, abakavir, emtrisitabien, tenofovir, indinavir of lamivudien (vir MIV-infeksie) neem.
- As u tans enige van die volgende medisyne neem:
  - kisapried (gebruik om soolbrand te behandel)
  - bepridiel (gebruik om hartsiekte te behandel)
  - ergotalkaloïede (bv. ergotamien, dihidroërgotamien, ergonovien en metielergonovien) (gebruik om migraine en troshoofpyne te behandel)
  - midasolaam of triasolaam (gebruik om u te help slaap)
  - pimosied (gebruik om sekere geestaskondisies te behandel)
  - vorikonasool (vir swaminfeksies)
  - salsitabien (vir MIV-infeksie)

As u enige van hierdie medisyne neem, moet u onmiddellik u dokter in kennis stel.
- Stel u dokter in kennis as u atasanavir en/of lopinavir/ritonavir (vir MIV-infeksie) neem: as u enige van hierdie medisyne neem, mag u dokter u terapie meer noukeurig monitor of u sal moontlik nie **ELTENO TABLETS** kan neem nie.
- Stel u dokter in kennis as u enige ander medisyne wat didanosien (vir MIV-infeksie) neem. Die neem van **ELTENO TABLETS** saam met ander medisyne wat didanosien bevat, kan die vlakke van didanosien in u bloed verhoog. Inflammasie van die pankreas en neuropatie (afwykings van die senuwees) kan voorkom. U dokter sal dit deeglik oorweeg om u met kombinasies van tenofovir en didanosien te behandel.
- Medisyne wat bloedvette verlaag (ook statiene genoem): Atorvastatien, pravastatien, simvastatien. **ELTENO TABLETS** kan die hoeveelheid van hierdie statiene in u bloed verminder. U dokter sal u cholesterolvlakke nagaan en oorweeg om die dosis van u statien, indien nodig te verander.
- Medisyne wat gebruik word om stuipaanvalle (teenstuipmiddels) te behandel: Karbamasepien, fenitoïen, fenobarbital. **ELTENO TABLETS** kan die hoeveelheid van hierdie teenstuipmiddels in u bloed verminder. Karbamasepien kan die hoeveelheid efavirens, een van die komponente van **ELTENO TABLETS**, in u bloed verminder. U dokter kan dit oorweeg om 'n ander teenstuipmiddel aan u te gee.
- Medisyne wat gebruik word om bakteriese infeksies te behandel: Klaritromisien, rifabutien, rifampisien (vir TB). U dokter kan dit moontlik oorweeg om u dosis te verander of 'n alternatiewe antibiotika te gee. Boonop kan u dokter dit oorweeg om u 'n bykomende dosis efavirens te gee om u MIV-infeksie te behandel.
- Medisyne wat gebruik word om swaminfeksies te behandel (antifungale): Itrakonasool of ketokonasool. **ELTENO TABLETTE** kan die hoeveelheid van itrakonasool of ketokonasool in u bloed verminder. U dokter kan dit oorweeg om 'n ander antifungale medisyn aan u te gee.
- Hormonale kontrasepsie soos geboortebeperkingspille, inspuitbare kontrasepsie (bv. Depo-Provera), of 'n kontrasepsie-implant: U moet ook 'n betroubare metode van skeidingskontrasepsie soos 'n kondoom te gebruik aangesien **ELTENO TABLETS** die werking van hormonale kontrasepsie kan verminder.
- Metadoon, 'n middel wat gebruik word om verslawing te behandel,aangesien dit moontlik is dat u dokter u metadoondosis moet verander.
- Sertralien, 'n middel wat gebruik word om depressie te behandel, aangesien dit moontlik is dat u dokter u sertraliendosis moet verander.
- Diltiasem of soortgelyke medisyne (kalsiumkanaalblokkeerders): Wanneer u begin om **ELTENO TABLETS** te neem, kan u dokter moontlik die dosis van u kalsiumkanaalblokkeerder aanpas.
- Warfarien ('n middel wat gebruik word om bloedklontering te verminder): U dokter kan moontlik die warfariendosis aanpas.
- Daar word aanbeveel dat St. John se kruid (*Hypericum perforatum*) ('n kruiemiddel wat vir depressie en angs gebruik word) nie saam met **ELTENO TABLETS** gebruik word nie.
- Stel u dokter in kennis as u enige ander medisyne wat u nierfunksie mag verminder, neem. Somnige voorbeelde is:
  - Aminoglikoslede (vir bakteriese infeksies)
  - Adefovir (vir virusinfeksies)
  - Sidofovir (vir virusinfeksies)
  - Asiklovir (vir virusinfeksies)
  - Valasiklovir (vir virusinfeksies)
  - Gansiklovir (vir virusinfeksies)
  - Valgansiklovir (vir virusinfeksies)
  - Amfoterisien B (vir swaminfeksies)
  - Foskarnet (vir virusinfeksies)
  - Pentamidien (vir infeksies)
  - Interleukin-2 (om kanker te behandel)

HOE OM ELTENO TABLETS TE NEEM

Moenie jou medisyne met ander deel nie.
Neem ELTENO TABLETS altyd presies soos deur u dokter voorgeskryf. Bevestig met u dokter of apteker as u onseker is. As u van mening is dat die effek van ELTENO TABLETS te sterk of te swak is, moet u u dokter of apteker raadpleeg.

- Bly onder u gesondheidsorgverskaffer se sorg wanneer u **ELTENO TABLETS** neem. Moenie u behandeling verander of daarmee ophou sonder om eers met u gesondheidswerker te praat nie.
- Die normale dosis **ELTENO TABLETS** is een tablet met water, een keer per dag met slapenstyd.

As u te veel ELTENO TABLETS geneem het:
Kry nood mediese hulp as u dink dat u te veel **ELTENO TABLETS** geneem het.

In die geval van oordosering, raadpleeg u dokter of apteker. As hulle nie beskikbaar is nie, kontak u naaste hospitaal of giftebeheersentrum.

As u vergeet het om ELTENO TABLETS te neem:
Neem die oorgeslaande dosis sodra u daarvan onthou en gaan dan soos voorheen voort. Moenie 'n dubbel dosis neem om vir 'n oorgeslaande dosis op te maak nie.

MOONTLIKE NEWE-EFFEKTE
ELTENO TABLETS kan newe-effekte hê
Nie al die newe-effekte wat vir **ELTENO TABLETS** aangemeld is, word in hierdie brosjure ingesluit nie. As u algemene gesondheid agteruitgaan of as u enige ongewone effekte ondervind terwyl u **ELTENO TABLETS** neem, moet u asseblief u dokter, apteker of ander professionele gesondheidswerker om advies raadpleeg.

Indien enige van die volgende gebeur, stop met die neem van **ELTENO TABLETS** en raadpleeg u dokter onmiddellik of gaan na die ongevalle-afdeling by u naaste hospitaal:
- Urtikarie; moeite met asemhaling, swelling van u gesig, lippe, tong of keel.

Dit is almal baie ernstige newe-effekte. As jy dit het, het jy dalk 'n ernstige allergiese reaksie gehad met **ELTENO TABLETS**. Jy mag dringende mediese aandag of hospitalisasie benodig.

Raadpleeg onmiddellik u dokter of gaan na die ongevalle-afdeling by u naaste hospitaal as u enige van die volgende newe-effekte waarneem::
- Melksuurasidose (ernstige toename van melksuur in die bloed, 'n ernstige newe-effek wat fataal kan wees - Die volgende newe-effekte kan tekens van melksuurasidose wees: diep, vinnige asemhaling, lomerigheid, naarheid, braking en maagpyn.
- Lewerbeskadiging - naarheid; maagpyn; erfense koors; verlies aan eetlus; donker urien; kleigekleurde stoelgang, geelsug (geel verkleuring van die vel of oë).
- Rugpyn veroorsaak deur nierprobleme, insluitende nierversaking. U dokter kan bloedtoetse uitvoer om te sien of u niere behoorlik funksioneer.
- Koors, koue koors, seer keel, hoes of ander tekens van infeksie.
- Psigiatriese simptome insluitende verwardheid, erge depressie, selfmoordideas, aggressie, uitermatige vrees, hallusinering of ongewone gedrag.
- Koors met erge blaasvorming, afskilfering en rooi veluitslag of enige velreaksie.
- Stuipaanvalle.
- Inflammasie van die pankreas (erge pyn in die buik).

Dit is almal ernstige newe-effekte. Jy benodig dringende mediese aandag.

Raadpleeg jou dokter as jy enige van die volgende opmerk:
Dikwels voorkomende newe-effekte:
- duiseligheid
- moeite om aan die slaap te raak
- hoofpyn
- gevoel van depressie of angs
- naarheid, braking
- diarree of hardlywigheid, windengheid
- maagpyn of krampe
- veluitslag, toename in swelling
- haarverlies
- spier- of gewrigspyn
- moegheid of tekort aan energie
- algemene gevoel van ongesteldheid
- hoes

Minder dikwels voorkomende newe-effekte:
- massatoename of -verlies
- gevoelloosheid, prikkeling, spolde en naalde
- bewerasie, afwykings van koördinasie en balans
- verwardheid, vergeetagtigheid, moeite met konsentrasie, lomerigheid, abnormale danke, gevoel van angs, onvanpaste gedrag, tekort aan belangstelling, abnormale plesierigheid, gereelde bui veranderings, probleme met spraak, verlies aan beheer van liggaamlike bewegings, verlies van sensitiwiteit vir aanraking, ongewone drome
- abnormale gesig, onduidelike gesig
- suising van die ore, draaigevoel (vertigo)
- hartkloppings (vinnige, ongereelde hartklop), toename in harttempo
- asma, asma, kortademheid, hoes, loperige of verstopte neus, sinusitis, borsinfeksie
- indigestie, omgekrapte maag, toename in eetlus, verlies aan eetlus, smaakafwykings, sooibrand
- jeuk, toename in sweet, korwe, ekseem, aknee, veranderinge in vel- en naakkleur, velafskilming, infeksie van die haarfollikels, allergiese velreaksie teen sonlig
- gewrigspyn, afbreek van spiere, spierpyn of swakheid, rugpyn, borspyn, versagting van die been (met boonpyn en soms tot fraktuure)
- impotensie (verlies aan manlike seksuele funksionering); toename en afname in seksdrang (libido), vergrootte borste in mans
- flou, hittegloede, griepagtige simptome, kortademheid
- bloed in die urien, inflammasie van die niere, groot hoeveelhede urien en dors
- verandering in die vorming of lokaliteit van liggaamsvet (veral in u arms, bene, gesig, nek, borste en heupe)
- verhoogde sweet, koors.

Bloedtoetse kan ook die volgende aandui:
- afname van fosfaatvlakke in die bloed
- toename in die vlakke van kreatienkinase in die bloed wat kan lei tot spierpyn en -swakheid
- anemie (lae rooibloedseltelling)
- lae witbloedseltelling ('n lae witbloedseltelling kan veroorsaak dat u meer tot infeksies geneig is)
- toename in vetsure (trigliserede), bilirubien of suikervlakke in die bloed
- probleme met die lewer en pankreas
- 'n afname in kalium in die bloed
- toename in kreatinien in die bloed
- proteïene in die urien

As u enige newe-effekte waarneem wat nie in hierdie brosjure genoem word nie, moet u asseblief u dokter of apteker daarvan in kennis stel.

OPBERGING EN WEGDOEN VAN ELTENO TABLETS
Berg by of benede 25 °C (kamertemperatuur). Beskerm teen lig. Hou die HDPE houer toe.
HOU ALLE MEDISYNE BUITE BEREIK VAN KINDERS

Neem alle ongebruikte medisyne na u apteker terug.
Moenie enige ongebruikte medisyne in die drein of riolering (bv. toilette) weggooi nie.

AANBIEDING VAN ELTENO TABLETS
HDPE houer:
Tablette word in 'n 120 ml ronde, wit HDPE houer met 'n 38-400 nek en 38 mm wit polipropileen deksel met pulp en hitte seëllaag (123 wit gedrukte voering) verpak. Elke houer bevat 28 of 30 tablette en 2 silikagelsakkies. Die houers word in 'n voorafgedrukte kartonhouer verpak.

IDENTIFIKASIE VAN ELTENO TABLETS
Wit tot byna-wit, kapsulevormige, bikonvekse, ongedrukte, filmbedekte tablette.

REGISTRASIENOMMER / VERWYSINGSNOMMER
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PACKAGING RESEARCH & DEVELOPMENT

(Front Page)

ARTWORK / PRINTPROOF APPROVAL FORM

Note : Removal of English and African PI, updating storage condition, inclusion of website URL and QR code and dimension change in PIL.

1. Product : ELTENO TABLETS	
2. Country: South Africa	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 320 (W) mm
9. Design / Style: Booklet	10. Item code No.: PM02411103
11. Artwork has been made: Actual Size	12. Pharma code No.: 32985 mini
13. Barcode/NDC no: NA	14. Supersedes Item code No: PM02411102
15. Revision no: 02	16. File Name E:\X-Efs, Laml & Teno\Activo\03\ELTENO TABLETS PIL PM02411103.cdr
Approved By:	17. Location: Baddi

PRD	M.A. HOLDER	RAD	QC	PRODN	QA
28/05/23	Vanita Rajoo!	26/05/23	01/06/23	01/06/23	01/06/23

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.

QA 01/06/23

FRM/CQA/021/04-01

Reason for revision :	Item code	Artwork Release Date	Artwork Implementation Date
1) New Artwork for South Africa	PM02411101	9/2/17	15/06/2017
2) Text matter change	PM02411102	21/12/18	18/03/2019
3) Removal of English and African PI, updating storage condition, inclusion of website URL and QR code and dimension change in PIL.	PM02411103		

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