PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

RIZENE 600 mg/200 mg/300 mg, film-coated tablets
Efavirenz, Emtricitabine, Tenofovir disoproxil fumarate
Sugar free

Read all of this leaflet carefully before you start taking RIZENE

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

1. What RIZENE is and what it is used for

RIZENE contains three active substances that are used to treat human immunodeficiency virus (HIV) infection: efavirenz is a non-nucleoside reverse transcriptase inhibitor (NNRTI), emtricitabine is a nucleoside reverse transcriptase inhibitor (NRTI) and tenofovir is a nucleotide reverse transcriptase inhibitor (NRTI).

Each of these active substances, also known as antiretroviral medicines, work by interfering with an enzyme (reverse transcriptase) that is essential for the virus to multiply.
RIZENE can be used alone as a complete regimen or in combination with other anti-retroviral medicines for the treatment of HIV-1 infection in adults**.**

2. What you need to know before you take RIZENE

Do not take RIZENE:

- If you are hypersensitive (allergic) to efavirenz, emtricitabine and/or tenofovir disoproxil fumarate or any of the other ingredients of RIZENE (listed in section 6).
- You had a liver disorder or liver failure attributed to treatment with RIZENE.
- 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 RIZENE with the following related medicines:
- Medicines containing the same active ingredients as RIZENE 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 RIZENE).

Warnings and precautions
Take special care with RIZENE:
- 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 RIZENE treatment as such could be detrimental to your health.

- As the use of RIZENE 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 RIZENE, tell your doctor about your skin rash if it is persistent. You must stop taking RIZENE 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 RIZENE can aggravate your condition.
- Take RIZENE with caution if you have a history of seizures and let your doctor know about them.
- RIZENE 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 RIZENE 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 RIZENE against HIV infection (see Other medicines and RIZENE).
- You should not use RIZENE 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.

Other medicines and RIZENE

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

Do not take RIZENE with the following medicines:

- *Voriconazole:* risk severity of side effects associated with the use of RIZENE 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 RIZENE is decreased and may lead to viral resistance of anti-HIV medicines like RIZENE.
- *Anti-retrovirals (efavirenz, emtricitabine, tenofovir disoproxil fumarate, lamivudine)*: efavirenz, emtricitabine and tenofovir disoproxil fumarate are already ingredients in RIZENE, while lamivudine is closely related to emtricitabine.

- *Benzodiazepines (midazolam, triazolam)*: prolonged or increased sedation or respiratory depression, e.g. difficulties in breathing.

RIZENE with food and drink
There are no studies for RIZENE in the presence of food but tenofovir disoproxil fumarate and efavirenz concentrations may be increased by taking them with a light meal or a high fat meal and may possibly expose you to more side effects. Please see section 3. How to take RIZENE.

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 RIZENE.

RIZENE should not be used during pregnancy. Studies in animals have associated efavirenz with birth defects.

Women of childbearing age who are using RIZENE 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 RIZENE.
Do not breastfeed if you are taking RIZENE. Studies in animals (rats) have shown that RIZENE may appear in milk.

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

Contains sodium
This medicine contains less than 1 mmol sodium (23 mg) per film-coated tablet, that is to say essentially ‘sodium-free’.

3. HOW TO TAKE RIZENE
Do not share medicines prescribed for you with any other person.
Always take RIZENE exactly as your doctor or pharmacist has instructed you. You should check with your doctor or pharmacist if you are unsure.

Take one tablet daily on an empty stomach.

Taking RIZENE at bedtime may improve the tolerability of nervous system symptoms.

Take your dose with water.

Do not stop taking RIZENE unless your doctor has told you so.

Taking your dose at the same time each day will have the best effect in controlling your viral load and will help you remember when to take the tablets.
Always get more tablets before your current supply is finished in order to avoid ever skipping a dose.

Children
RIZENE is not recommended for use in patients under the age of 18 years.

Kidney failure
RIZENE should not be used by patients who need dose adjustment because it is a fixed dose tablet. If your creatinine clearance is less than 50 ml/min you may not use RIZENE.

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

If you take more RIZENE 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 RIZENE
Take a missed dose as soon as you remember it. However, if it is almost time for your next dose rather leave it and continue with your normal schedule. Do not take a double dose to make up for forgotten individual doses. If you miss more than one dose, rather leave those doses and resume with the normal schedule when the time comes to take your normal dose.

Please consult your doctor or pharmacist if you are not sure about your dosing.

4. POSSIBLE SIDE EFFECTS

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

If any of the following happens, stop taking RIZENE 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 RIZENE. 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 (who-umc.org) found on SAHPRA website.

By reporting side effects, you can help provide more information on the safety of RIZENE.

5. How to store RIZENE

- Store all medicines out of the reach of children.
- Store at or below 25 °C.
- Store RIZENE in the original container.
- Keep the container tightly closed in order to protect the medicine from light and moisture.
- Do not store in a bathroom.
- Do not use after the expiry date stated on the label/carton /bottle.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What RIZENE contains

The active substances are: 600 mg of efavirenz; 200 mg of emtricitabine and 300 mg of tenofovir disoproxil fumarate.

The other ingredients are:
Tablet core: croscarmellose sodium, hydroxypropyl cellulose, magnesium stearate, microcrystalline cellulose, sodium lauryl sulphate
Film-coating: Opadry II Pink: macrogol/polyethylene glycol (E1521), iron dioxide black (E172), iron oxide red (E172), polyvinyl alcohol-part hydrolysed (E1203), talc (E553b), titanium dioxide (E171).

What RIZENE looks like and contents of the pack

RIZENE is a pink coloured, capsule shaped, film-coated tablet debossed with “H” on one side and “128” on the other side.

RIZENE is packed as 28’s, 30’s, 60’s, 84’s, 90’s, 120’s, 180’s and 500’s in white opaque, heavy weight high density polyethylene (HDPE) bottles with child-resistant closures and a silica gel desiccant sachet.
Not all pack sizes may be marketed.

Holder of certificate of registration

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PASIËNT INLIGTINGSBILJET

SKEDULERINGSTATUS: S4

RIZENE 600 mg/200 mg/300 mg, filmbedekte tablette
Efavirens, Emtrisitabien, Tenofovirdisoproksielfumaraat
Suikervry

Lees al hierdie biljet noukeurig deur voordat u RIZENE begin gebruik
- Bewaar hierdie biljet. U sal dit dalk weer moet lees.
- Indien u verdere vrae het, raadpleeg asseblief u dokter, apteker, verpleër of ander gesondheidsorg kundige.
- RIZENE is aan u persoonlik voorgeskryf en u moet nie u medisyne met ander mense deel nie. Dit kan hulle benadeel, selfs al ervaar hul dieselfde simptome as u.

Wat is in hierdie biljet
1. Wat RIZENE is en waarvoor dit gebruik word
2. Wat u moet weet voordat u RIZENE neem
3. Hoe om RIZENE te neem
4. Moontlike newe-effekte
5. Hoe om RIZENE te bêre
6. Inhoud van die verpakking en ander inligting

1. Wat is RIZENE en waarvoor dit gebruik word
RIZENE bevat drie aktiewe bestanddele wat gebruik word om menslike immuniteitsgebrekvirus (MIV) infeksie te behandel: efavirens is ‘n nie-nukleosied omgekeerde transkriptase inhibeerder (NNRTI), emtrisitabien is ‘n nukleosied omgekeerde transkriptase inhibeerder (NRTI) en tenofovir is ‘n nukleotied omgekeerde transkriptase inhibeerder (NRTI).

Elkeen van hierdie aktiewe stowwe, ook bekend as antiretrovirale medisyne, werk deur in te meng met ‘n ensiem (omgekeerde transkriptase) wat noodsaaklik is vir die virus om te vermeerder.
RIZENE kan alleen as ‘n volledige behandelingsreeks, of in kombinasie met ander antiretrovirale medisyne gebruik word vir die behandeling van MIV-1 infeksie by volwassenes.

2. Wat u moet weet voordat u RIZENE neem
Moenie RIZENE neem nie:
- Indien u hipersensitief (allergies) is vir efavirens, emtrisitabien en/of tenofovirdisoproksielfumaraat of enige van die ander bestanddele van RIZENE (gelys in afdeling 6).
- Indien u ‘n lewerafwyking of lewerversaking gehad het wat toegeskryf word aan behandeling met RIZENE.
- Indien u matige tot ernstige nierversaking het.
- Indien u swanger is of borsvoed.
- Indien u ‘n harttoestand het, soos ‘n abnormale elektriese sein wat verlenging van die QT-

interval genoem word, wat ‘n hoë risiko vir ernstige hartritmeprobleme (*Torsade de Pointes*) is.
- Indien enige lid van u familie (ouers, grootouers, broers of susters) skielik gesterf het weens ‘n hartprobleem, of met hartprobleme gebore is.
- Indien u dokter u ingelig het dat u hoë of lae vlakke van elektroliete soos lae kalium of lae magnesium in u bloed het.
- Indien u ook die volgende medisyne gebruik: middels teen aritmie van klasse IA en III, neuroleptika, antidepressante, terfenadien, astemisool, bepridiel, sisapried, ergotderivate, midasolaam, pimosied, triasolaam, vorikonasool, “St. John’s Wort”, flekaïnied, sekere antibiotika (makroliede, fluoorkinolone, imidasool), triasool-antifungus middels, sekere antimalaria medisyne en metadoon.

Moenie RIZENE saam met die volgende verwante medisyne neem nie:
- Medisyne wat dieselfde aktiewe bestanddele indien RIZENE bevat, soos emtrisitabien, tenofovirdisoproksielfumaraat, emtrisitabien/tenofovirdisoproksielfumaraat en efavirens.
- Medisyne wat lamivudien bevat, wat soortgelyk is aan emtrisitabien, insluitend lamivudien/sidovudien, lamivudien, abakavirsulfaat/lamivudien of abakavirsulfaat/lamivudien/sidovudien (sien Ander medisyne en RIZENE).

Waarskuwings en voorsorgmaatreëls
Wees veral versigtig met RIZENE:
- Indien u met chroniese hepatitis B gediagnoseer is, of ‘n geskiedenis van hepatitis B-infeksies het, aangesien u ‘n ernstige verergering van hepatitis kan ervaar wanneer die behandeling gestaak word.
- Indien u ‘n geskiedenis van lewersiekte of risikofaktore vir lewersiekte het, omdat u ‘n risiko vir laktiese asidose (lae pH in die bloed en liggaamsweefsel, gepaardgaande met ‘n opbou van melksuur) en ernstige hepatomegalie met steatose (vergroting van die lewer met vet-neerslae daarin) het. Hierdie risiko is hoër as u vroulik, vetsugtig is en langdurige blootstelling aan antiretrovirale middels gehad het.
- Indien u nierversaking het.
- Indien u ‘n geskiedenis van psigiatriese versteurings het, die gebruik van psigiatriese medikasie, inspuitbare medisyne gebruik of as u psigiatriese versteurings, soos erge depressie, selfdoodgedagtes, selfdoodpogings, aggressiewe gedrag, paranoïese reaksies en maniese reaksies begin ervaar.
- Omdat u senuweestelselsimptome soos duiseligheid, probleme om te slaap, verswakte konsentrasie, lomerigheid of ‘n sterk begeerte om te slaap, abnormale drome, hallusinasies, intense gelukkigheid kan ervaar en opgewonde kan wees sonder enige duidelike rede, verwarring, opgewondenheid, geheueverlies, stupor, abnormale denke en verwyder voel van ‘n uself. Hierdie simptome sal normaalweg binne 2 tot 4 weke na die aanvang van behandeling verdwyn. Pasop vir die gelyktydige inname van alkohol en ander sentrale senuweestelsel-depressante of die hantering van gevaarlike masjinerie (sien Bestuur van ‘n voertuig en gebruik van masjinerie).
- Lig u dokter in indien u simptome van opportunistiese infeksies of ander komplikasies

ontwikkel of sien, selfs wanneer u op RIZENE-behandeling is, aangesien dit nadelig vir u gesondheid kan wees.

- Aangesien die gebruik van RIZENE nie die risiko van MIV-oordrag na ander deur seksuele kontak of bloedbesmetting uitskakel nie, moet u altyd toepaslike voorsorgmaatreëls tref indien u betrokke is by aktiwiteite soos seksuele omgang of bloedhantering.
- U mag veluitslag ervaar in die eerste maand van behandeling met RIZENE, lig u dokter in van u veluitslag indien dit aanhou. U moet RIZENE staak indien u uitslag ernstig word met simptome soos koors, blaasvorming of afskilfering.
- Lig u dokter in indien u aan osteomalasie ly (beenafwyking wat aangedui word deur beenpyn veral in die heupe, beenfrakture sonder bekende oorsaak of besering en ook spierswakheid), aangesien RIZENE u toestand kan vererger.
- Neem RIZENE met omsigtigheid indien u ‘n geskiedenis van stuipaanvalle het en laat u dokter daarvan weet.
- Dit is bekend dat RIZENE tot vetherverspreiding in u liggaam lei en dit word gewoonlik aangedui deur gewigstoename rondom die middelrif, vorming van buffelskofagtige struktuur op die romp (ook genoem vergroting van dorso-servikale vet), gesigkwyning, gewigsverlies op die arms en bene en borsvergroting.
- Indien u onder die ouderdom van 18 jaar is, omdat RIZENE nie aanbeveel word vir gebruik by pasiënte onder die ouderdom van 18 jaar nie.
- Indien u ‘n bejaarde pasiënt ouer as 65 jaar is, aangesien hierdie populasie geneig is om verminderde nier-, lewer- en hartfunksie te ervaar en gewoonlik ander medikasie neem.
- Indien u ook produkte gebruik wat “St. John’s Wort” (*Hypericum perforatum*) bevat omdat “St. John’s Wort” die effek van RIZENE teen MIV-infeksie kan verminder (sien Ander medisyne en RIZENE).
- U moet nie RIZENE gebruik indien u ‘n groter risiko vir *Torsade de Pointes* (vinnige hartklop) het, of indien u medisyne gebruik met ‘n bekende risiko vir *Torsade de Pointes* nie.
- Tenofovirdisoproksiel kan ook ‘n verlies in beenmassa veroorsaak.
- Als in ag genome, is die effekte van tenofovirdisoproksiel op lang-termyn beengesondheid en toekomstige fraktuur-risiko in volwassenes en pediatriese pasiënte onseker.

Ander medisyne en RIZENE

Lig altyd u gesondheidsorg kundige in indien u enige ander medisyne gebruik.
(Dit sluit komplementêre of tradisionele medisyne in.)

Moenie RIZENE saam met die volgende medisyne neem nie:

- *Vorikonasool:* erns van die risiko tot newe-effekte wat verband hou met die gebruik van RIZENE is verhoog.
- *Astemisool, bepridiel, sisapried en pimosied:* lewensbedreigende nadelige effekte soos abnormale of onreëlmatige hartklop kan voorkom.
- *Ergotderivate (dihidro-ergotamien, ergonovien, ergotamien, metielergonovien*): effek van RIZENE word verminder en kan lei tot virale weerstand van anti-MIV-medisyne soos RIZENE.

- *Antiretrovirale middels (efavirens, emtrisitabien, tenofovirdisoproksielfumaraat, lamivudien):* efavirens, emtrisitabien en tenofovirdisoproksielfumaraat is reeds bestanddele in RIZENE, terwyl lamivudien nou verwant is aan emtrisitabien.
- *Bensodiasepiene (midasolaam, triasolaam):* langdurige of verhoogde sedasie of respiratoriese depressie, bv. probleme met asemhaling.

RIZENE saam met kos en drank
Daar is geen studies vir RIZENE in die teenwoordigheid van voedsel nie, maar konsentrasies van tenofovirdisoproksielfumaraat en efavirens kan verhoog word deur dit saam met ‘n ligte maaltyd of ‘n hoëvet-maaltyd te neem en kan u moontlik aan meer newe-effekte blootstel. Sien asseblief afdeling 3, Hoe om RIZENE te neem.

Swangerskap, borsvoeding en vrugbaarheid

Indien u swanger is of u baba borsvoed, dink u is dalk swanger of beplan om ‘n baba te hê, raadpleeg asseblief u dokter, apteker of ander gesondheidsorg kundige vir advies voordat u RIZENE neem.

RIZENE moet nie tydens swangerskap gebruik word nie. Studies in diere het efavirens met geboortedefekte geassosieer.

Vroue van vrugbare ouderdom wat RIZENE gebruik, moet vermy om swanger te raak en moet dit verseker deur ‘n versperringsmetode van voorbehoeding in kombinasie met ander voorbehoedmetodes te gebruik.
Dit word aanbeveel om voldoende voorbehoedmaatreëls te gebruik vir 12 weke nadat u opgehou het om RIZENE te gebruik.
Moenie borsvoed as u RIZENE neem nie. Studies in diere (rotte) het getoon dat RIZENE in melk kan voorkom.

Bestuur en gebruik van masjinerie
Dit is nie altyd moontlik om te voorspel in watter mate RIZENE die daaglikse aktiwiteite van 'n pasiënt kan beïnvloed nie.
Moenie gereedskap en masjinerie bestuur of gebruik nie, veral nie terwyl u RIZENE-terapie gebruik nie. U kan duiseligheid, lomerigheid of 'n sterk begeerte om te slaap, verswakte konsentrasie, hallusinasies, intens gelukkig en opgewonde wees sonder enige duidelike rede, verwarring, geheueverlies, stupor en abnormale denke ervaar.
Pasiënte moet verseker dat hulle nie aan bogenoemde aktiwiteite deelneem voordat hulle bewus is van die mate waarin RIZENE hulle beïnvloed nie.

Bevat natrium
Hierdie medisyne bevat minder as 1 mmol natrium (23 mg) per filmbedekte tablet, dit wil sê in wese 'natriumvry'.

3. HOE OM RIZENE TE NEEM

Moenie medisyne wat aan u voorgeskryf is, met enige ander persoon deel nie.

Neem altyd RIZENE presies soos u dokter of apteker u opdrag gegee het. U moet met u dokter of apteker nagaan indien u onseker is.

Neem een tablet daagliks op 'n leë maag.
Die neem van RIZENE voor slaaptyd kan die verdraagsaamheid van senuweestelsel simptome verbeter.

Neem u dosis met water.

Moenie ophou om RIZENE te neem tensy u dokter dit vir u gesê het nie.

Deur u dosis elke dag op dieselfde tyd te neem, sal die beste effek in beheer van u virale lading hê en sal u help onthou wanneer u die tablette moet neem.
Kry altyd meer tablette voordat u huidige voorraad klaar is om te verhoed dat u ooit ’n dosis oorslaan.

Kinders
RIZENE word nie aanbeveel vir gebruik by pasiënte onder die ouderdom van 18 jaar nie.

Nierversaking
RIZENE moet nie gebruik word deur pasiënte wat dosisaanpassing benodig nie, want dit is 'n vaste dosis tablet. Indien u kreatinienopruiming minder as 50 ml/min is, mag u nie RIZENE gebruik nie.

Indien u die indruk het dat die effek van RIZENE te sterk of te swak is, lig u dokter of apteker in.

Indien u meer RIZENE neem as wat u moes
In die geval van oordosering, raadpleeg u dokter of apteker. Indien nie een beskikbaar is nie, kontak die naaste hospitaal of gifbeheersentrum.

Indien u vergeet om RIZENE te neem
Neem ‘n oorgeslaande dosis sodra u dit onthou. Indien dit egter amper tyd is vir u volgende dosis, los die oorgeslaande dosis en gaan voort met u normale skedule. Moenie ‘n dubbele dosis neem om vergete individuele dosisse in te haal nie. Indien u meer as een dosis mis, los eerder daardie dosisse en gaan voort met die normale skedule wanneer die tyd aanbreek om u normale dosis te neem.

Raadpleeg asseblief u dokter of apteker indien u nie seker is oor u dosering nie.

4. MOONTLIKE NEWE-EFFEKTE

RIZENE kan newe-effekte hê.
Nie alle newe-effekte wat vir RIZENE aangemeld is, is in hierdie voubiljet ingesluit nie. Indien u algemene gesondheid verswak of indien u enige nadelige effekte ervaar terwyl u RIZENE neem, raadpleeg asseblief u gesondheidsorg kundige vir advies.

Indien enige van die volgende gebeur, staak die gebruik van RIZENE en lig u dokter dadelik in of gaan na die ongevalle-afdeling by u naaste hospitaal:

- Allergiese reaksie, bv. veluitslag, jeuk.
- Veelvormige eriteem (velafwyking wat voorkom as gevolg van allergiese reaksie en die simptome daarvan kan koors, jeuk, gewrigspyn en veelvuldige velletsels insluit).
- Stevens-Johnson se sindroom (lewensgevaarlike velversteuring waardeur die buitenste deel van die vel afskilfer).

Hierdie is alles baie ernstige newe-effekte. Indien u dit ervaar, het u dalk ‘n ernstige allergiese reaksie op RIZENE gehad. U benodig dalk dringende mediese aandag of hospitalisasie.

Lig u dokter dadelik in of gaan na die ongevalle-afdeling by u naaste hospitaal indien u enige van die volgende opmerk:

- Selfdoodgedagtes of -pogings.
- Verhoogde vatbaarheid vir infeksie, byvoorbeeld hoes, griepagtige simptome, longontsteking.
- Diarree.
- Kortasem.
- Onreëlmatige hartklop.
- Toevalle of stuipaanvalle.
- Beenpyn.
- Verlies van beenmassa.

Hierdie is alles ernstige newe-effekte. U benodig dalk dringende mediese hulp.

Lig u dokter in indien u enige van die volgende opmerk:

- Anoreksie (ernstige weerstand teen voedsel as gevolg van irrasionele vrees om gewig op te tel).
- Aggressiewe gedrag.
- Verswakte konsentrasie.
- Angs.
- Senuweeagtigheid.
- Slapeloosheid.
- Euforie (intense gevoel van geluk en opgewondenheid vir geen duidelike rede).
- Verwarring.
- Depersonalisering.
- Hallusinasie.
- Agitasie.
- Paranoia

- Gedeeltelike verlies van sensasie en lomerigheid.
- Vergeetagtigheid.
- Abnormale gedagtes of drome.
- Hoofpyn.
- Moegheid.
- Verhoogde sweet.
- Ligte tot ernstige depressie, of manie.
- Gevoel van tinteling of prikkeling, of gevoelloosheid.
- Braking.
- Winderigheid.
- Borsgroei by mans en vroue.
- Slegte spysvertering.
- Hardlywigheid.
- Opgeblaasdheid.
- Maagpyn.
- Abnormale visie.
- Rugpyn.
- Gewrigspyn en spierpyn.
- Duiseligheid.
- Om swak of sieklik te voel.
- Gevoel van lui in die ore.
- Gereelde urinering.
- Gebrek aan vrywillige koördinasie van bewegings, spraak en bewegings soos om te stap kan aangetas word.
- Bewerasies.
- Veranderinge in liggaamsvet wat lei tot die vorming van buffelskofagtige struktuur op die romp, gewigstoename in en om die maagarea, gewigsverlies op die ledemate en gesig.
- Velverkleuring.
- Foto-allergiese velreaksies.

Indien u enige newe-effekte opmerk wat nie in hierdie biljet genoem word nie, stel asseblief u dokter of apteker in kennis.

Aanmelding van newe-effekte

Indien u newe-effekte ervaar, lig u dokter, apteker of verpleër in. U kan ook newe-effekte by SAHPRA aanmeld via die Med Safety Toep (Medsafety X SAHPRA) en eAanmeldingsplatform (who-umc.org) wat gevind kan word op SAHPRA se webwerf.
Deur newe-effekte aan te meld, kan u help om meer inligting oor die veiligheid van RIZENE te verskaf.

5. Hoe om RIZENE te bêre

- Bêre alle medisyne buite die bereik van kinders.
- Bêre teen of benede 25 °C.
- Bêre RIZENE in die oorspronklike houer.
- Hou die houer dig toe om die medisyne teen lig en vog te beskerm.

- Moenie in 'n badkamer bêre nie.
- Moenie gebruik ná die vervaldatum wat op die etiket/karton/bottel vermeld word nie.
- Neem alle ongebruikte medisyne terug na u apteker.
- Moenie ongebruikte medisyne in afvoerpype of rioolstelsels (bv. toilette) weggooi nie.

6. Inhoud van die verpakking en ander inligting

Wat RIZENE bevat

Die aktiewe bestanddele is: 600 mg efavirens; 200 mg emtrisitabien en 300 mg tenofovirdisoproksielfumaraat.

Die ander bestanddele is:
Tabletkern: natriumkruiskarmellose, hidroksiepropielsellulose, magnesiumstearaat, mikrokristallyne sellulose, natriumlaurielsulfaat
Filmbedekking: “Opadry” II Pienk: makrogol/poliëtileenglikol (E1521), ysterdioksied swart (E172), ysteroksied rooi (E172), poliviniel alkohol - gedeeltelik gehidroliseer (E1203), talk (E553b), titaandioksied (E171).

Hoe RIZENE lyk en die inhoud van die verpakking

RIZENE is ‘n pienk-kleurige, kapsuul-vormige, filmbedekte tablet met “H” aan die een kant gegraveer, en “128” aan die ander kant.

RIZENE is verpak as 28's, 30's, 60's, 84's, 90's, 120's, 180's en 500's in wit ondeursigtige, swaargewig hoëdigtheid poliëtileen (HDPE) bottels met kinderbestande proppe en 'n silikajel droogmiddelsakkie.
Nie alle verpakkingsgroottes word dalk bemark nie.

Houer van sertifikaat van registrasie

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Hierdie biljet is mees onlangs hersien op

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Registrasienommer

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