Front Top

340 mm

330 mm

KYRIZ
1,5/3/4,5/6 MG
PM03918802

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S5

KYRIZ 1,5 MG CAPSULES
Contains rivastigmine tartrate equivalent to 1,50 mg rivastigmine base. Sugar free.

KYRIZ 3 MG CAPSULES
Contains rivastigmine tartrate equivalent to 3,0 mg rivastigmine base. Sugar free.

KYRIZ 4,5 MG CAPSULES
Contains rivastigmine tartrate equivalent to 4,50 mg rivastigmine base. Sugar free.

KYRIZ 6 MG CAPSULES
Contains rivastigmine tartrate equivalent to 6,0 mg rivastigmine base. Sugar free.

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

1. What you need to know before you take KYRIZ

Rivastigmine belongs to a class of substances called cholinesterase inhibitors. **KYRIZ** is used for the treatment of memory disorders in patients with Alzheimer's disease. It is also used for the treatment of dementia in patients with Parkinson's disease.

2. What you need to know before you take KYRIZ

Do not take **KYRIZ** if:
- are allergic to rivastigmine, other carbamates or any of the ingredients of **KYRIZ**
- are pregnant or breastfeeding.
- have severe liver or kidney disease.
- have bronchial asthma.

If you are not sure whether you should take **KYRIZ**, contact your doctor.

Warnings and precautions
Talk to your doctor or pharmacist before taking **KYRIZ**
Tell your doctor:
- about any past or present medical problems.
- if you have, or have ever had, irregular heartbeat.
- if you have, or have ever had, an active stomach ulcer.
- if you have, or have ever had, difficulties in passing urine.
- if you have, or have ever had, seizures.
- if you have, or have ever had, asthma or severe respiratory disease.
- if you have, or have ever had impaired kidney function.
- if you have, or have ever had, impaired liver function.
- if you suffer from trembling.
- if you have a low body weight.
- if you have gastrointestinal reactions such as feeling sick (nausea), being sick (vomiting) and diarrhoea. You may become dehydrated (losing too much fluid) if vomiting or diarrhoea are prolonged.

If any of these apply to you, your doctor may need to monitor you more closely while you are on this medicine.
If you have not taken **KYRIZ** for several days, do not take the next dose until you have talked to your doctor.

While taking KYRIZ:
- Medicines of this type may cause nausea and vomiting particularly when starting treatment and/or increasing the dose. These side effects occur more commonly in women.
- Weight loss has been seen in patients taking **KYRIZ**. You and your doctor should check your weight regularly.

Other medicines and KYRIZ
Always tell your healthcare provider if you are taking any other medicine. (This includes complementary or traditional medicines.)
It is especially important to inform your doctor if you are taking other medicines on a regular basis, including complementary or traditional medicines, the use of **KYRIZ** with these medicines may cause undesirable interactions.
- **KYRIZ** should not be taken at the same time as other medicines with similar effects to **KYRIZ**.
- **KYRIZ** might interfere with anticholinergic medicines (medicines used to relieve stomach cramps or spasms, to treat Parkinson's disease or to prevent travel sickness).
- If you have to undergo surgery whilst taking **KYRIZ**, tell your doctor before you are given any anaesthetics, because **KYRIZ** may exaggerate the effects of some muscle relaxants during anaesthesia.
- Tell your doctor you are taking a beta-blocker for treatment of irregular heartbeats, angina (chest pain) and high blood pressure (e.g. atenolol). The combined use of a beta-blocker with **KYRIZ** could lead to a very slow heart rate which could result in fainting.
- Tell your doctor if you taking other medicines for slowing the heart rate (e.g. amiodarone, sotalol, dofetilide, verapamil, diltiazem, digitalis and pilocarpine).
- Tell your doctor if you are taking the following medicines that could lead to abnormal heart rhythms:
  - chlorpromazine, levomepromazine, sulpiride, sultopride, amisulpride, tiapride, veralipride, pimozide, haloperidol, droperidol (for mental illness)
  - cisapride (for gastric reflux)
  - citalopram (for depression)
  - diphemanil (antispasmodic)
  - halofantrin (for malaria)
  - mizolastin (antihistamine)
  - methadone (for heroin addiction)
  - erythromycin IV, pentamidine and moxifloxacin (for infections)

KYRIZ with food and drink:
KYRIZ should be taken with food.

Pregnancy, breastfeeding and fertility
It is not known whether **KYRIZ** is harmful to an unborn baby when taken by a pregnant woman.
If you are:
- pregnant or plan to become pregnant,
- breastfeeding or plan to breastfeed your baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking **KYRIZ**.

Driving and using machines
Dizziness and drowsiness has been reported in patients receiving **KYRIZ**. It is not always possible to predict to what extent **KYRIZ** may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which **KYRIZ** affects them.

3. How to take KYRIZ

Do not share medicines prescribed for you with any other person.
Always take **KYRIZ** exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are not sure.
Take **KYRIZ** by mouth.
The usual dose is:
1,5 mg twice daily.
Your doctor will tell you how many **KYRIZ** to take and how long you should continue to take them. **KYRIZ** is taken twice daily.
Treatment usually starts with a low dose.
- Your doctor will slowly increase your dose depending on how you respond to treatment.
- The highest dose that should be taken is 6,0 mg twice a day.

Your doctor will regularly check if **KYRIZ** is working for you. Your doctor will also monitor your weight whilst you are taking this medicine.

If you have not taken **KYRIZ** for several days, do not take the next dose until you have talked to your doctor.
Consult your doctor if your symptoms return but do not stop taking **KYRIZ** unless your doctor tells you to.

If you take more KYRIZ than you should
If you accidentally take more **KYRIZ** than you should, inform your doctor. You may require medical attention. Some people who have accidentally taken too much **KYRIZ** have experienced feeling sick (nausea), being sick (vomiting), diarrhoea, high blood pressure and hallucinations. Slow heartbeat and fainting may also occur. 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 KYRIZ:
If you forget to take **KYRIZ**, take a dose as soon as you remember, then continue to take your capsules at the usual times. Do not take a double dose to make up for forgotten capsules.

If you stop taking KYRIZ:
Do not stop taking your capsules just because you feel better. It is important that you carry on taking **KYRIZ** for as long as your doctor tells you.

4. Possible side effects

KYRIZ can have side effects.
Not all side effects reported for KYRIZ 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 KYRIZ and tell your doctor immediately or go to the casualty department at your nearest hospital.
These are serious side effects and you may need urgent medical attention:
Allergic reaction. Symptoms of a severe allergic reaction such as:
- Swelling of face, tongue or throat
- Difficulties in swallowing
- Hives and difficulties in breathing
- Severe skin reactions that can include blistering of the skin.

Tell your doctor promptly about these or any other unusual symptoms. If the symptoms persist or worsen, seek medical attention.
Frequent side effects may include:
- Loss of appetite
- Restlessness, confusion, anxiety, nightmares
- Feeling dizzy, headache, sleepiness, shakes
- Nausea, vomiting, diarrhea, stomach pain, acid reflux or heartburn
- Sweating excessively
- Tiredness, weakness
- Weight loss

Less frequent side effects
- Urinary tract infection
- Difficulty in sleeping, feeling depressed, hallucinating (seeing things that are not there)
- Fainting, fits, the signs of Parkinson's disease get worse or getting similar signs – such as stiff muscles, difficulty in carrying out movements
- Chest pain, irregular heartbeat, fast heartbeat
- High blood pressure
- Ulcers bleeding in your stomach or intestine, bleeding in the gut – shows as blood in stools, swelling of the pancreas- the signs include serious upper stomach pain, often with feeling sick (nausea) or being sick (vomiting)
- Abnormal liver function test
- Rash
- Falling

Frequency unknown
- Dehydration
- Aggression, restlessness
- Irregular heart rhythms
- Severe vomiting with the food pipe tearing
- Liver disorders (yellow skin, yellowing of the whites of eyes, abnormal darkening of the urine or unexplained nausea, vomiting, tiredness and loss of appetite)

If you have dementia with Parkinson's disease you may experience the additional side effects below:
Frequent side effects:
- Decreased appetite, dehydration
- Difficulty sleeping, anxiety, restlessness, hallucinations, depression
- Trembling, dizziness, feeling sleepy, headache, the signs of Parkinson's disease get worse or getting similar signs – such as stiff muscles, difficulty in carrying out movements, slow movements and uncontrolled involuntary movements
- Slow heartbeat
- High blood pressure
- Nausea, vomiting, diarrhea, stomach pain, acid reflux, increased saliva
- Increased sweating
- Falling, tiredness and weakness, change in normal walking

Less frequent side effects:
- Movement disorder with muscles contracting uncontrollably
- Irregular heartbeat
- Low blood pressure

Frequency unknown
- Aggression
- Irregular heartbeat
- Swollen liver
- Rash and itchy skin

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. This includes any possible side effects not listed in this leaflet. 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/7. By reporting side effects, you can help provide more information on the safety of **KYRIZ**.

5. How to store KYRIZ

Store at or below 25 °C (room temperature). Protect from light.
Keep the blisters in the carton until required for use.
Keep HDPE containers tightly closed.
Store in the original package in order to protect from light and moisture.
Do not store in a bathroom.
Do not use after the expiry date stated on the blister / 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 pack and other information

What KYRIZ contains
Each capsule contains rivastigmine tartrate equivalent to 1,50 mg, 3,0 mg, 4,50 mg and 6,0 mg rivastigmine base. Sugar free.

Other ingredients include:
Excipients: Microcrystalline cellulose, hypromellose, colloidal silicon dioxide, magnesium stearate, gelatin, sodium lauryl sulphate, titanium dioxide (C.I. no. 77891).
In addition, **KYRIZ 1,5 MG** CAPSULES contain iron oxide yellow (C.I. no. 77492) and **KYRIZ 3 MG, KYRIZ 4,5 MG** and **KYRIZ 6 MG** CAPSULES contain iron oxide yellow (C.I. no. 77492) and iron oxide red (C.I. No. 77491).

What KYRIZ look like and contents of the pack
KYRIZ 1,5 mg CAPSULES: Yellow/Yellow size '2' hard gelatin capsules containing white to off-white powder with "CL7" on cap and "1.5 mg" on body imprinted in red ink.
KYRIZ 3 MG CAPSULES: Orange/Orange size '2' hard gelatin capsules containing white to off-white powder with "CL8" on cap and "3 mg" on body imprinted in red ink.
KYRIZ 4,5 mg CAPSULES: Red/Red size '2' hard gelatin capsules containing white to off-white powder with "CL9" on cap and "4.5 mg" on body imprinted in white ink.
KYRIZ 6 MG CAPSULES: Red/Orange size '2' hard gelatin capsules containing white to off-white powder with "CL10" on cap and "6 mg" on body imprinted in white ink.

Blister pack:
Cold form laminate (composed of 25 micron OPA/45 micron aluminium foil/60 micron PVC) and plain 30 micron aluminium foil with 6-8 GSM heat seal lacquer.
Pack size:
10's - Each carton contains 1 blister of 10 capsules each.
60's - Each carton contains 6 blisters of 10 capsules each.

HDPE Container Pack:
60 ml, round white HDPE bottle with 33-400 neck finish closed with a white 33 mm child resistant with pulp and heat seal closure.
Pack size: 60's - One HDPE container contains 60 capsules
Not all pack sizes will be marketed.

Holder of Certificate of Registration and Manufacturer
MACLEODS PHARMACEUTICALS SA (PTY) LTD
Office Block 1, Bassonia Estate Office Park (East).
1 Cussonia Drive, Bassonia Rock, Ext. 12,
Alberton, South Africa.

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Registration number
KYRIZ 1,5 MG CAPSULES : 47/5.3/0210
KYRIZ 3 MG CAPSULES : 47/5.3/0211
KYRIZ 4,5 MG CAPSULES : 47/5.3/0212
KYRIZ 6 MG CAPSULES : 47/5.3/0213

Access to the corresponding Professional Information
The corresponding professional information can be accessed at https://macleodspharmaproducts.co.za/ or contact 011 562 1169

Back Top
340 mm

330 mm

PASIËNTINLIGTINGSTUK

SKEDULERINGSTATUS: S5

KYRIZ 1,5 MG CAPSULES
Bevat rivastigmienartraat gelykstaande aan 1,50 mg rivastigmienbasis.
Suikervry.
KYRIZ 3 MG CAPSULES
Bevat rivastigmienartraat gelykstaande aan 3,0 mg rivastigmienbasis.
Suikervry.
KYRIZ 4,5 MG CAPSULES
Bevat rivastigmienartraat gelykstaande aan 4,50 mg rivastigmienbasis.
Suikervry.
KYRIZ 6 MG CAPSULES
Bevat rivastigmienartraat gelykstaande aan 6,0 mg rivastigmienbasis.
Suikervry.

Lees hierdie hele inligtingstuk sorgvuldig deur voordat jy KYRIZ begin neem
- Hou hierdie inligtingstuk. Dit mag nodig wees dat jy dit weer moet lees.
- Vra asseblief jou dokter, apteker, verpleegkundige of ander gesondheidsorgverskaffer indien jy verdere vrae het
- **KYRIZ** is vir jou persoonlik voorgeskryf, en jy moet nie jou medisyne met ander mense deel nie. Dit kan skadelik vir hulle wees, selfs al is hulle simptome dieselfde as joune.

Wat is in hierdie inligtingstuk

1. Wat **KYRIZ** is en waarvoor dit gebruik word
2. Wat jy behoort te weet voordat jy **KYRIZ** neem
3. Hoe om **KYRIZ** te neem
4. Moontlike newe-effekte
5. Hoe om **KYRIZ** te bewaar
6. Inhoud van die pak en ander inligting

1. Wat KYRIZ is en waarvoor dit gebruik word

Rivastigmien behoort aan 'n klas stowwe wat cholienesterase inhibeerders genoem word. **KYRIZ** word gebruik vir die behandeling van geheue versteurings in pasiënte met Alzheimer se siekte. Dit word ook gebruik vir die behandeling van demensie in pasiënte met Parkinson se siekte.

2. Wat jy behoort te weet voordat jy KYRIZ neem

Moet nie KYRIZ neem nie indien jy:
- allergies is vir rivastigmien, ander karbamate of enige van die bestanddele van **KYRIZ**
- swanger is of borsvoed.
- ernstige lewer- of niersiekte het.
- bronsiale asma het.

Indien jy nie seker is of jy **KYRIZ** moet neem of nie, kontak jou dokter.

Waarskuwings en voorsorgmaatreëls
Praat met jou dokter of apteker voordat jy **KYRIZ** neem
Vertel jou dokter:
- oor enige vorige of huidige mediese probleme.
- indien jy onregsmatige hartklop het, of al ooit gehad het.
- indien jy 'n aktiewe maagseer het, of al ooit gehad het.
- indien jy probleme het om te urineer, of al ooit gehad het.
- indien jy aanvalle kry, of al ooit gekry het.
- indien jy asma of ernstige respiratoriese siekte het, of al ooit gehad het.
- indien jy 'n ingekorte nierfunksie het, of ooit gehad het.
- indien jy 'n ingekorte lewerfunksie het, of ooit gehad het.
- indien jy aan bewing ly.
- indien jy 'n lae liggaamsgewig het.
- indien jy gastrointestinale reaksies het soos siek voel (naarheid), siek wees (braking) en diaree. Jy kan gedehidreer word (te veel vloeistof verloor) indien braking of diaree aanhou.

Indien enige van hierdie op jou van toepassing is, sal jou dokter jou dalk meer noukeurig moet monitor terwyl jy hierdie medisyne gebruik.
Indien jy vir 'n paar dae nie **KYRIZ** geneem het nie, moet nie die volgende dosis neem, voordat jy nie eers met jou dokter gepraat het nie.

Terwyl jy KRYIZ neem:
- Medisyne van hierdie tipe kan maarheid en braking veroorsaak, veral wanneer behandeling begin word en/of die dosis verhoog word. Hierdie newe-effekte kom meer algemeen in vrouens voor.
- Gewigsverlies is gesien in pasiënte wat **KYRIZ** neem. Jy en jou dokter moet gereeld jou gewig nagaan.

Ander medisyne en KYRIZ
Vertel altyd jou gesondheidsorgverskaffer indien jy enige ander medisyne neem. (Dit sluit komplementêre of tradisionele medisyne in.)
Dit is veral belangrik om jou dokter in te lig indien jy ander medisyne op 'n gereelde basis gebruik, insluitend komplementêre of tradisionele medisyne, die gebruik van **KYRIZ** saam met hierdie medisyne kan ongewenste interaksies veroorsaak.
- **KYRIZ** moet nie op dieselfde tyd saam met ander medisyne met soortgelyke effekte as **KYRIZ** geneem word nie.
- **KYRIZ** kan dalk inmeng met anticholinergiese middels (medisyne wat gebruik word om maagkrampe of spasmas te verlig, om Parkinson se siekte te behandel of om reissiekte te voorkom).
- Indien jy chirurgie moet ondergaan terwyl jy **KYRIZ** neem, vertel jou dokter voordat enige narkose aan jou gegee word, want **KYRIZ** kan die effekte van sommige spierverslappers tydens narkose vererger.
- Vertel jou dokter dat jy 'n beta-blokker neem vir die behandeling van onreelmatige hartklop, angina (borshaspyn) en hoë bloeddruk (bv. atenolol). Die gekombineerde gebruik van 'n beta-blokker met **KYRIZ** kan lei tot 'n baie stadige harttempo wat kan lei tot floute.
- Vertel jou dokter indien jy ander medisyne gebruik om die harttempo te vertraag (bv. amiodaroon, sotalol, dofetilied, verapamil, diltiasem, digitalis en pilokarpien).
- Vertel jou dokter indien jy die volgende medisyne neem wat tot abnormale hartritmes kan lei:
  - chloorpromasien, levomepromasien, sulpiried, sultopried, amisulpried, tiapried, veralipried, pimosied, haloperidol, droperidol (vir geestesongesteldheid)
  - sisapried (vir gastriese refluks)
  - sitalopram (vir depressie)
  - difemaniel (anti-spasmodies)
  - halofantrien (vir malaria)
  - misolastien (antihistamien)
  - metadoon (vir herofenverslawing)
  - eritromisien IV, pentamidien en moksifloksasien (vir infeksies)

KYRIZ met voedsel en vloeistof:
KYRIZ moet saam met kos geneem word.

Swangerskap, borsvoeding en fertiliteit
Dit is nie bekend of **KYRIZ** skadelik is vir 'n ongebore baba wanneer dit deur in swanger vrou geneem word nie.
Indien jy:
- swanger is of beplan om swanger te raak.
- borsvoed of beplan om jou baba te borsvoed, raadpleeg asseblief jou dokter, apteker of ander professionele gesondheidsorgwerker vir advies voordat **KYRIZ** geneem word.

Bestuur en gebruik van masjinerie
Duiseligheid en lomerigheid is gerapporteer in pasiënte wat **KYRIZ** ontvang. Dit is nie altyd moontlik om te voorspel tot watter mate **KYRIZ** kan inmeng met die daaglikse aktiwiteite van 'n pasiënt nie. Pasiënte moet seker maak dat hulle nie in die bogenoemde aktiwiteite betrokke raak, totdat hulle bewus is van die mate waarin **KYRIZ** hulle affekteer nie.

3. Hoe om KYRIZ te neem

Moet nie medisyne wat vir jou voorgeskryf is met enige ander persoon deel nie.
Neem altyd **KYRIZ** presies soos jou dokter jou beveel het. Vra vir jou dokter of apteker indien jy nie seker is nie.
Neem **KYRIZ** per mond.
Die gewone dosis is:
1,5 mg twee keer per dag.
Jou dokter sal vir jou sê hoeveel **KYRIZ** om te neem en hoe lank jy moet aanhou om dit te neem. **KYRIZ** word twee keer per dag geneem.
Behandeling begin gewoonlik met 'n lae dosering.
- Jou dokter sal jou dosis stadig verhoog, afhangende van hoe jy op behandeling reageer.
- Die hoogste dosis wat geneem moet word, is 6,0 mg twee keer per dag.

Jou dokter sal gereeld bevestig of **KYRIZ** vir jou werk. Jou dokter sal ook jou gewig monitor terwyl jy hierdie medisyne neem.
Indien jy vir 'n paar dae nie **KYRIZ** geneem het nie, moet nie die volgende dosis neem voordat jy nie met jou dokter gepraat het nie.
Raadpleeg jou dokter indien jou simptome terugkeer, maar moet nie ophou om **KYRIZ** te neem nie, tensy jou dokter jou beveel om dit te doen.

Indien jy meer KYRIZ neem as wat jy behoort te neem
Indien jy per ongeluk meer **KYRIZ** neem as wat jy moet, stel jou dokter in kennis. Jy mag dalk mediese hulp benodig. Sommige mense wat per ongeluk te veel **KYRIZ** geneem het, het siek gevoel (naarheid), siek geword (braking), diaree, hoë bloeddruk en hallusinasies ervaar. Stadige hartklop en floute kan ook voorkom. In die geval van oordosering raadpleeg jou dokter of apteker. Indien nie een beskikbaar is nie, kontak die naaste hospitaal of gifbeheersentrum.

Indien jy vergeet om KYRIZ te neem:
Indien jy vergeet om **KYRIZ** te neem, neem 'n dosis sodra jy daarvan onthou, en gaan dan aan om jou kapsule op die gewone tye te neem. Moet nie 'n dubbele dosis neem om vir vergete kapsule op te maak nie.

Indien jy ophou om KYRIZ te neem:
Moet nie ophou om jou kapsule te neem net omdat jy beter voel nie. Dit is belangrik dat jy aanhou om **KYRIZ** te neem vir so lank as wat jou dokter jou beveel.

4. Moontlike newe-effekte

KYRIZ kan newe-effekte hê.
Nie alle newe-effekte wat vir KYRIX aangemeld is, is in hierdie inligtingstuk ingesluit nie. Sou jou algemene gesondheid verslag of jy enige ongewenste effekte ondervind terwyl jy KYRIZ neem, kontak asseblief jou dokter, apteker, and ander professionele gesondheidsorgwerker vir advies.
Indien enige van die volgende gebeur, hou op om KYRIZ te neem en vertel onmiddellik vir jou dokter of gaan na die ongevalle afdeling van jou naaste hospitaal.
Al hierdie newe-effekte is ernstig en jy het moontlik dringende mediese aandag nodig:
Allergiese reaksie. Simptome van 'n ernstige allergiese reaksie soos:
- Swelling van gesig, tong of keel
- Probleme om te sluk
- Galbulte en probleme met asemhaling
- Ernstige velreaksies wat blase op die vel kan insluit.

Vertel jou dokter onmiddellik van hierdie of enige ander ongewone simptome.
Indien die simptome aanhou of vererger, soek mediese hulp.
Gereelde newe-effekte kan die volgende insluit:
- Verlies aan eetlus
- Rusteloosheid, verwarring, angs, nagmerries
- Voel duiselig, hoofpyn, slaperigheid, bewerasie
- Naarheid, braking, diaree, maagpyn, suur reflüks of sooibrand
- Oormatige sweet
- Moegheid swakheid
- Gewigsverlies

Minder gereelde newe-effekte
- Urineweginfeksie
- Sukkel om te slaap, voel depressief, hallusineer (sien dinge wat nie daar is nie)
- Floutes, aanvalle, Die tekens van Parkinson se siekte vererger of kry soortgelyke tekens – soos stywe spiere, sukkel om bewegings uit te voer
- Borskaspyn, onreëlmatige hartklop, vinnige hartklop
- Hoë bloeddruk
- Uitbrase wat in jou maag of ingewande bloei, bloeding in die derm– wys as bloed in stoelgang, swelling van die pankreas – die tekens sluit ernstige boonste maagpyn, dikwels met siek voel (naarheid) of siek wees (braking) in.
- Abnormale lewerfunksietoets
- Uitslag
- Val

Frekwensie onbekend
- Dehidrasie
- Aggressie, rusteloosheid
- Onreelmatige hartritmes
- Erge braking met die stukderm wat skeur
- Lewer versteurings (geel vel, vergeling van die wit van oë, abnormale verdonkering van die urisne of onverklaarbare naarheid, braking, moegheid en verlies aan eetlus)

Indien jy demensie met Parkinson se siekte het, kan jy die bykomende newe-effekte hieronder ervaar:
Gereelde newe-effekte:
- Verminderde eetlus, dehidrasie
- Sukkel om te slaap, angs, rusteloosheid, hallusinasies, depressie
- Bewe, duiseligheid, voel slaperig, hoofpyn, die tekens van Parkinson se siekte vererger of kry soortgelyke tekens – soos stywe spiere, sukkel om bewegings uit te voer, stadige bewegings en onbeheerde onwillekeurige bewegings
- Stadige hartklop
- Hoë bloeddruk
- Naarheid, braking, diaree, maagpyn, terugvloei van suur, toename in speeksel
- Toename in sweet
- Val, moegheid en swakheid, verandering in normale loop

Minder gereelde newe-effekte:
- Bewegings versteuring met spiere wat onbeheerbaar saamtrek
- Onreëlmatige hartklop
- Lae bloeddruk

Frekwensie onbekend:
- Aggressie
- Onreëlmatige hartklop
- Geswelde lewer
- Uitslag en jeukerige vel.

Indien jy enige newe-effekte waarneem wat nie in hierdie inligtingstuk genoem word nie, lig asseblief jou dokter of apteker in.

Aanmelding van newe-effekte
Indien jy newe-effekte kry praat met jou dokter of apteker of verpleegkundige. Dit sluit enige moontlike newe-effekte in wat nie in hierdie inligtingstuk gelys word nie. Jy kan ook newe-effekte aan SAHPRA rapporteer deur middel van die **"6.04 Adverse Drug Reaction Reporting Form"**, wat aanlyn gevind kan word onder SAHPRA se publikasies: https://www.sahpra.org.za/Publications/IndexSt.
Deur newe-effekte aan te meld kan jy help om meer inligting beskikbaar te stel aangaande die veiligheid van **KYRIZ**.

5. Hoe om KYRIZ te bewaar

Bewaar by of benede 25°C (kamertemperatuur). Beskerm teen lig
Hou die stulpstroke in die buitenste karton totdat dit benodig word vir gebruik.
Hou die HDPE houers dig toe.
Stoor in die oorspronklike houer om sodanig van lig en vog te beskerm.
Moet nie in 'n badkamer bêre nie.
Moet nie gebruik na die vervaldatum wat aangebring is op die stulpstrook/etiket/karton/bottel nie.
Neem alle ongebruikte medisyne terug na jou apteker.
Moet nie ongebruikte medisyne in dreine of dooltelsels (bv. toilette) gooi nie.

6. Inhoud van die pak en ander inligting

Wat KYRIZ bevat
Elke kapsule bevat rivastigmienartarzaat gelykstaande aan 1,50 mg, 3,0 mg, 4,50 mg of 6,0 mg rivastigmienbasis. Suikervry.

Die ander bestanddele sluit in:
Hulpstowwe: Mikrokristallyne sellulose, hipromellose, kolloïdale silikondioksied, magnesiumstearaat, gelatien, natriumlaurielsulfaat, titaandioksied (C.I. no. 77891).
Daarbenewens bevat **KYRIZ 1,5 MG** CAPSULES geel ysteroksied (C.I. no. 77492) en **KYRIZ 3 MG, KYRIZ 4,5 MG** en **KYRIZ 6 MG** CAPSULES bevat geel ysteroksied geel (C.I. no. 77492) en rooi ysteroksied (C.I. No. 77491).
Hoe KYRIZ lyk en Inhoud van die pak
KYRIZ 1,5 MG CAPSULES: Geel/Geel grootte '2' harde gelatienkapsules wat wit tot naaswit poeier bevat. met "CL7" op die doppie en "1.5 mg" op die lyf ingedruk met rooi ink.
KYRIZ 3 MG CAPSULES: Oranje/Oranje grootte '2' harde gelatienkapsules wat wit tot naaswit poeier bevat, met "CL8" op die doppie en "3 mg" op die lyf ingedruk in rooi ink.
KYRIZ 4,5 MG CAPSULES: Rooi/rooi grootte '2' harde gelatienkapsules wat wit tot naaswit poeier bevat, met "CL9" op die doppie en "4.5 mg" op die lyf ingedruk met wit ink.
KYRIZ 6 MG CAPSULES: Rooi/Oranje grootte '2' harde gelatienkapsules wat wit tot naaswit poeier bevat, met "CL10" op die doppie en "6 mg" op die lyf ingedruk met wit ink.

Stulpverpakking:
Koue vorm laminaat (saamgestel uit 25 mikron OPA/45 mikron aluminiumfoelie/50 mikron PVC) en gewone 30 mikron aluminiumfoelie met 6-8 GSM hittesëellak.
Verpakkingsgrootte:
10's - Elke karton bevat **1** stulpstroke van 10 kapsules elk.
60's - Elke karton bevat 6 stulpstroke van 10 kapsules elk.

HDPE houer verpakking:
60 ml, ronde wit HDPE bottel met 33-400 nekafwerking toegemaak met 'n wit 33 mm kinderbestande sluiting met pulp- en hitteseël sluiting.
Verpakkingsgrootte: 60's - Een HDPE houer bevat 60 kapsules
Nie alle verpakkingsgroottes sal bemark word nie.

Houer van Sertifikaat van Registrasie en Vervaardiger
MACLEODS PHARMACEUTICALS SA (EDMS) BPK
Kantoorblok 1, Bassonia Estate Kantoorpark (Oos),
Cussonia-rylaan 1, Bassonia Rock, Uitbr. 12,
Alberton, Suid-Afrika.

Hierdie inligtingstuk was hersien in
24 Mei 2022

Registrasienommer
KYRIZ 1,5 MG CAPSULES : 47/5.3/0210
KYRIZ 3 MG CAPSULES : 47/5.3/0211
KYRIZ 4,5 MG CAPSULES : 47/5.3/0212
KYRIZ 6 MG CAPSULES : 47/5.3/0213

Vir die goereinstemmende Professionele Inligting
Die goereinstemmende professionele inligting kan by https://macleodssaproducts.co.za/ verkry word of deur 011 682 1169 te kontak

MACLEODS

PACKAGING RESEARCH & DEVELOPMENT

Restricted Circulation

(Front Page)

ARTWORK / PRINTPROOF APPROVAL FORM

Note : Exclude Professional Information.

1. Product: KYRIZ 1,5 MG, 3 MG, 4,5 MG and 6 MG (Rivastigmine 1.5 mg, 3 mg, 4.5 mg and 6 mg Capsules)	
2. Country: South Africa - Private Market	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: 340 (L) x 330 (W) mm
9. Design / Style: Booklet	10. Item code No.: PM03918802
11. Artwork has been made: Actual Size	12. Pharma code No.: 32972 mini
13. Barcode/NDC no: NA	14. Supersedes Item code No: PM03918801
15. Revision no: 01	16. A/W File name:Y:\RIVASTIGMINE\SA Private market\Rivastigmine PI & PIL - PM03918801.cdr
Approved By:	17. Location: Daman

PRD	M.A. HOLDER	MEDICAL/RAD	QC	PRODN	QA
01/07/23	Vanita Rajool	03/07/23	03/07/23	04/07/23	05/07/23

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.

FRM/CQA/021/04-02

Reason for revision :	Item code	Artwork Release Date	Artwork Implementation Date
1) New Artwork for South Africa Private Market	PM03918801	01/10/22	18/11/2022
2) Exclude Professional Information.	PM03918802		