365 mm

ULCOPRAZ 10 / 20
PM04268501

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

ULCOPRAZ 10
Rabeprazole sodium 10 mg (equivalent to rabeprazole)
Contains sugar (7 mg of mannitol)

ULCOPRAZ 20
Rabeprazole sodium 20 mg (equivalent to rabeprazole)
Contains sugar (14 mg of mannitol)

Read all of this leaflet carefully before you start taking ULCOPRAZ
- 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.
- **ULCOPRAZ** 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 **ULCOPRAZ** is and what it is used for
2. What you need to know before you take **ULCOPRAZ**
3. How to take **ULCOPRAZ**
4. Possible side effects
5. How to store **ULCOPRAZ**
6. Contents of the pack and other information

1. What ULCOPRAZ is and what it is used for

ULCOPRAZ contain rabeprazole sodium.

It belongs to a group of medicines called 'Proton Pump Inhibitors' (PPIs). They work by lowering the amount of acid that your stomach produces.

ULCOPRAZ are used to treat the following conditions:
- 'Gastro-oesophageal reflux disease' (GORD), which can include heartburn. GORD is caused when acid and food from your stomach escapes into your food pipe (oesophagus).
- Ulcers in your stomach or the upper part of your gut (intestine). If these ulcers are infected with bacteria called '*Helicobacter pylori*' (*H. Pylori*), you will also be given antibiotics.
- Using **ULCOPRAZ** and antibiotics together gets rid of the infection and makes the ulcer heal. It also stops the infection and ulcer from coming back.
- Zollinger-Ellison Syndrome where your stomach produces too much acid.

2. What you need to know before you take ULCOPRAZ

Do not take ULCOPRAZ:
- If you are allergic to rabeprazole sodium or any of the other ingredients of this medicine, listed in section 6.
- If you are pregnant or breastfeeding.
- You are taking medicine such as atazanavir and nelfinavir for HIV infection.

Warnings and precautions
Talk to your doctor before taking **ULCOPRAZ** You are allergic to other proton pump inhibitor medicines or 'substituted benzimidazoles'. Blood and liver problems have been seen in some patients but often get better when **ULCOPRAZ** is stopped.
You have a stomach tumour.
You have ever had liver problems
If you are taking atazanavir- for HIV infection,
If you have reduced body stores or risk factors for reduced vitamin B12 and receive long term treatment with rabeprazole sodium. As with all acid reducing agents, rabeprazole sodium may lead to a reduced absorption of vitamin B12.
If you have ever had a skin reaction after treatment with a medicine similar to **ULCOPRAZ** that reduces stomach acid.
If you get a rash on your skin, especially in areas exposed to the sun tell your doctor as soon as you can, as you may need to stop your treatment with **ULCOPRAZ**. Remember to also mention any other ill-effects like pain in your joints.
You are due to have a specific blood test (Chromogranin A).
- If you have fever, rash and joint pain, which may be signs of systemic lupus erythematosus (SLE, a so-called autoimmune disease).
- Blood problems have been seen in some patients but often gets better when **ULCOPRAZ** is stopped
- Using medicines like **ULCOPRAZ** for a long period of time may cause a growth in your stomach (polyp). This can lead to intestinal blockage or bleeding. Talk to your doctor if you experience nausea or stomach pain while you are taking **ULCOPRAZ**.
- Talk with your doctor if you have a type of kidney problem (acute tubulointerstitial nephritis). Some people who take proton pump inhibitor (PPI) medicines, including **ULCOPRAZ**, may develop a kidney problem called acute tubulointerstitial nephritis that can happen at any time during treatment with **ULCOPRAZ**. Call your doctor right away if you have a decrease in the amount that you urinate or if you have blood in your urine.

Use in children and adolescents
The use of **ULCOPRAZ** in children and adolescents (below the age of 18 years) is not recommended.

Other medicines and ULCOPRAZ
Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines.) Tell your doctor or pharmacist if you are taking any of the following medicines:
- Ketoconazole or itraconazole – used to treat infections caused by a fungus. **ULCOPRAZ** may lower the amount of this type of medicine in your blood. Your doctor may need to adjust your dose.
- Atazanavir – used to treat HIV-infection. **ULCOPRAZ** may lower the amount of this type of medicine in your blood and they should not be used together.
- Methotrexate (a chemotherapy medicine used in high doses to treat cancer) – if you are taking a high dose of methotrexate, your doctor may temporarily stop your **ULCOPRAZ** treatment.
- Ciclosporin - used in the prophylaxis of organ rejection in kidney, liver, and heart allogeneic transplants. Using **ULCOPRAZ** together with ciclosporin may cause a condition called hypomagnesaemia, or low blood magnesium.
- Digoxin – used to treat mild to moderate heart failure. In the short-term, **ULCOPRAZ** may cause an increase in the blood levels of digoxin. You should seek immediate medical attention if you experience signs and symptoms that may indicate excessive effects of digoxin, such as nausea, vomiting, diarrhoea, loss of appetite, visual disturbances (blurred vision; light halos around objects; green or yellow vision), or an abnormally fast or slow or uneven heartbeat. You may need a dose adjustment or more frequent monitoring by your doctor to safely use both medications.

ULCOPRAZ with food and drink:
ULCOPRAZ may be taken with or without food.

Pregnancy, breastfeeding and fertility
If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking **ULCOPRAZ.**

Do not take **ULCOPRAZ** if you are pregnant, are considering becoming pregnant or are breastfeeding.

Driving and using machines
You may feel sleepy while taking **ULCOPRAZ**. If this happens, do not drive or use any tools or machines.

3. How to take ULCOPRAZ

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

Always take **ULCOPRAZ** exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are not sure.

Swallow your tablets whole with a drink of water. Do not chew or crush the tablets.
- Your doctor will tell you how many tablets to take and how long to take them for. This will depend on your condition.
- If you are taking this medicine for a long time, your doctor will want to monitor you.

You can take **ULCOPRAZ** with or without food.

The recommended dose is:
For 'gastro-oesophageal reflux disease' (GORD)

Treatment of moderate to severe symptoms (symptomatic GORD)
- The usual dose is one **ULCOPRAZ 10** once a day for up to 4 weeks.
- Take the tablet in the morning before eating.
- If your condition returns after 4 weeks treatment, your doctor may tell you to take one **ULCOPRAZ** as and when you require it.

Treatment of more severe symptoms (erosive or ulcerative GORD)
- The usual dose is one **ULCOPRAZ 20** once a day for 4 to 8 weeks.
- Take the tablet in the morning before eating.

Long-term treatment of symptoms (GORD maintenance)
- The usual dose is one **ULCOPRAZ** 10 or 20 mg tablet once a day for as long as your doctor has told you.
- Take the tablet in the morning before eating.
- Your doctor will want to see you at regular intervals to check your symptoms and dosage.

For ulcers of the stomach (peptic ulcers)
- The usual dose is one **ULCOPRAZ 20** tablet once a day for 6 weeks.
- Take the tablet in the morning before eating.
- Your doctor may tell you to take **ULCOPRAZ** for another 6 weeks if your condition does not improve.

For ulcers of the intestine (duodenal ulcers)
- The usual dose is one **ULCOPRAZ 20** tablet once a day for 4 weeks.
- Take the tablet in the morning before eating.
- Your doctor may tell you to take **ULCOPRAZ** for another 4 weeks if your condition does not improve.

For ulcers caused by *H. Pylori* infection and to stop them coming back
- Your doctor will advise on the dose that should be taken.

Zollinger-Ellison Syndrome where excess acid is produced in the stomach
- The usual dose is three **ULCOPRAZ 20** tablets once a day to start with.
- The dose may then be adjusted by your doctor depending on how you respond to the treatment.
- If you are on long-term treatment you will need to see your doctor at regular intervals for review of your tablets and symptoms.

If you have the impression that the effect of **ULCOPRAZ** is too strong or too weak, talk to your doctor or pharmacist.

If you take more ULCOPRAZ than you should
In the event of over dosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you forget to take ULCOPRAZ
It is important to take your **ULCOPRAZ** regularly at the same time each day. If you forget to take a dose, take it as soon as you remember unless it is time for your next dose. Do not take two doses at the same time, to make up for a missed dose.

If you stop taking ULCOPRAZ
If **ULCOPRAZ** is stopped earlier than your doctor has prescribed, your symptoms may return or worsen. Always take **ULCOPRAZ** for as long as your doctor has prescribed.

4. Possible side effects

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

If any of the following happens, stop taking ULCOPRAZ and tell your doctor immediately or go to the casualty department at your nearest hospital:
- Allergic reactions – the signs may include: sudden swelling of your face, difficulty breathing or low blood pressure which may cause fainting or collapse.

These are all very serious side effects. If you have them, you may have had a serious reaction to **ULCOPRAZ.** 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:
- Severe skin blistering, or soreness or ulcers in your mouth and throat.
- Frequent infections, such as a sore throat or high temperature (fever), or ulcers in your mouth or throat.

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

Tell your doctor if you notice any of the following:
Frequent
- Infections
- Difficulty sleeping
- Headache or feeling dizzy
- Cough, runny nose or sore throat (pharyngitis)
- Effects on your stomach or gut such as stomach pain, diarrhoea, wind (flatulence), feeling sick (nausea),
- being sick (vomiting) or constipation
- Aches or back pain
- Weakness or flu-like symptoms
- Benign polyps in the stomach. These are small clumps of cells that forms on the lining of the stomach.

Less frequent:
- Changes in white blood cells (shown in blood tests) which may result in frequent infection
- Reduction in blood platelets resulting in bleeding or bruising more easily than normal
- Loss of appetite (Anorexia)
- Depression
- Hypersensitivity (includes allergic reactions)
- Feeling nervous or depression
- Visual disturbance
- Chest infection (bronchitis)
- Painful and blocked sinuses (sinusitis)
- Dry mouth
- Indigestion or belching
- Sore mouth (stomatitis) or taste disturbance
- Upset stomach or stomach pain
- Liver problems including yellowing of your skin and whites of your eyes (jaundice)
- Skin rash or redness
- Itchy rash or blistering skin
- Sweating
- Muscle, leg or joint pain
- Fractures of the hip, wrist and spine
- Bladder infection (urinary tract infection)
- Kidney problems
- Chest pain
- Chills or fever
- Changes in how your liver is working (shown in blood tests)
- Weight gain

Frequency unknown
- Breast swelling in men
- Fluid retention
- Inflammation of the gut (leading to diarrhoea)
- Low blood levels of sodium which can cause tiredness and confusion, muscle twitching, fits and coma
- Patients who have previously had liver problems may very rarely get encephalopathy (a brain disease)"
- Rash, possibly with pain in the joints

If you are on **ULCOPRAZ** for more than three months it is possible that the levels of magnesium in your blood may fall. Low levels of magnesium can be seen as fatigue, involuntary muscle contractions, disorientation, convulsions, dizziness, increased heart rate. If you get any of these symptoms, please tell your doctor promptly. Low levels of magnesium can also lead to a reduction in potassium or calcium levels in the blood. Your doctor may decide to perform regular blood tests to monitor your levels of magnesium.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist. Should your general health worsen or if you experience any untoward effects while taking **ULCOPRAZ**, please consult your healthcare provider for advice.

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/8. By reporting side effects, you can help provide more information on the safety of ULCOPRAZ.

5. How to store ULCOPRAZ

Store at or below 25 °C.
Protect from moisture.
Store in the original package / container.
Do not store in a refrigerator.
KEEP OUT OF THE REACH OF CHILDREN.
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 ULCOPRAZ contains
The active ingredient is rabeprazole sodium.
Contains mannitol
Other ingredients are:
Tablet core contains
Low substituted hydroxypropyl cellulose, magnesium oxide, magnesium stearate mannitol, sodium hydroxide, povidone, purified talc.

Coating material contains:
ULCOPRAZ 10
Ethyl cellulose, magnesium oxide, ferric oxide red, titanium dioxide, methacrylic acid copolymer dispersion (Eudragit L 30 D-55), triethylcitrate, purified talc.
ULCOPRAZ 20
Ethyl cellulose, magnesium oxide, ferric oxide yellow, titanium dioxide, methacrylic acid copolymer dispersion (Eudragit L 30 D-55), triethylcitrate, purified talc.

What ULCOPRAZ looks like and contents of the pack
ULCOPRAZ 10
Pink coloured, circular, biconvex, enteric coated tablet plain on the other side.
ULCOPRAZ 20
Yellow coloured, circular, biconvex, enteric coated tablet plain on other side.

Contents of the pack:
HDPE container
Tablets are packed in a round white HDPE container closed with child resistant closure with pulp and heat seal liner.
Pack sizes include 28's, 30's tablets and 90's tablets.

Blister pack
Tablets are packed in cold form laminate OPA/aluminium foil/PVC as forming material and aluminium foil as lidding material.
Pack size include 14's, 28's, 30's and 90's tablets

Blister pack with desiccant
Tablets are packed in cold form with desiccant layer and HDPE sealant layer as forming material and aluminium foil with HDPE sealant layer as lidding material.
Pack size include 14's, 28's, 30's and 90's tablets
Not all pack sizes are necessarily marketed.

Holder of Certificate of Registration
MACLEODS PHARMACEUTICALS SA (PTY) LTD
Ground Floor, Block 1, Bassonia Estate Office Park (East),
1 Cussonia Drive, Bassonia Rock Ext 12 Alberton Gauteng

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Registration numbers
ULCOPRAZ 10 : 56/11.4.3/0623,621
ULCOPRAZ 20 : 56/11.4.3/0624,622

Access to the corresponding Professional Information
The corresponding professional information can be accessed at https://www.macleodspharma.com or email macleodsrsa@macleodspharma.com or contact 011 682 1169

335 mm

PASIËNTINLIGTINGSBLAD

SKEDULERINGSTATUS: 84

ULCOPRAZ 10
Natriumrabeprasool 10 mg (ekwivalent aan rabeprasool)
Bevat suiker (7 mg van mannitol)

ULCOPRAZ 20
Natriumrabeprasool 20 mg (ekwivalent aan rabeprasool)
Bevat suiker (14 mg van mannitol)

Lees hierdie inligtingstuk sorgvuldig deur voordat jy ULCOPRAZ begin gebruik
- Hou hierdie inligtingstuk. Dit mag nodig wees om dit weer te lees.
- Indien jy verdere vrae het, vra asseblief jou dokter, apteker, verpleegkundige of ander gesondheidsorgverskaffer
- **ULCOPRAZ** is vir jou persoonlik voorgeskryf, en jy moet nie jou medisyne met ander persone deel nie. Dit mag skadelik vir hulle wees, selfs al is hul simptome dieselfde as joune.

Wat is in hierdie inligtingstuk

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

1. Wat ULCOPRAZ is en waarvoor dit gebruik word

ULCOPRAZ bevat natriumrabeprasool.

Dit behoort aan 'n groep medisyne genaamd 'Protonpomp-Inhibeerders' (PPI's). Hulle werk deur die hoeveelheid suur wat jou maag produseer, te verlaag.

ULCOPRAZ word gebruik om die volgende toestande te behandel:
- Gastro-esofagesale refluksiekte' (GERS), wat sooibrand kan insluit. GERS word veroorsaak wanneer suur en kos vanuit jou maag in jou slukderm (esofagus) opstoot.
- Ulkusse in jou maag of die boonste gedeelte van jou ingewande (derm). Indien hierdie ulkusse geïnfekteerd is met bakterieë genaamd *'Helicobacter pylori'* (*H. Pylori*), sal jy ook antiblotika gegee word.
- Die gesamentlike gebruik van **ULCOPRAZ** en antiblotika raak ontslae van die infeksie en laat die ulkus genees. Dit verhoed ook dat die infeksie en ulkus weer terugkeer.
- Zollinger-Ellison-sindroom waar jou maag te veel suur produseer.

2. Wat jy behoort te weet voordat jy ULCOPRAZ neem

Moet nie ULCOPRAZ neem nie:
- Indien jy allergies vir natriumrabeprasool of enige van die ander bestanddele van hierdie medisyne, soos gelys in afdeling 6.
- Indien jy swanger is of borsvoed
- Indien jy medisyne neem soos atasanavir en nelfinavir vir MIV-infeksie.

Waarskuwings en voorsorgmaatreëls
Praat met jou dokter voordat jy **ULCOPRAZ** neem.
Jy allergies is vir ander protonpomp-inhibeerder medisyne of 'gesubstitueerde bensimidasole'.
Bloed- en lewerprobleme is in sommige pasiënte gesien, maar word dikwels beter wanneer **ULCOPRAZ** gestaak word.
Jy 'n maaggewas het.
Jy al ooit lewerprobleme gehad het.
Indien jy atasanavir gebruik- vir MIV-infeksie.
Indien jy verlaagde liggaamstore of risikofaktore vir verlaagde vitamien B12 het en langtermynbehandeling met natriumrabeprasool ontvang. Soos met alle suurverminderende middels, kan natriumrabeprasool lei tot 'n verminderde absorpsie van vitamien B12.
Indien jy al ooit 'n velreaksie gehad het na behandeling met 'n medisyne soortgelyk aan **ULCOPRAZ**, wat maagsuur verminder.
Indien jy 'n uitslag op jou vel kry, veral in areas wat aan die son blootgestel is, vertel jou dokter so gou as wat jy kan, aangesien jy dalk jou behandeling met **ULCOPRAZ** sal moet staak. Onthou om ook enige ander ongewenste effekte, soos pyn in jou gewrigte, te noem.

Jy moet 'n spesifieke bloedtoets (Chromogranien A) ondergaan.
- indien jy koors, uitslag en gewrigspyn het, wat tekens van sistemiese lupus eritematause (SLE, 'n sogenaamde outo-immuun siekte) kan wees.
- Bloedprobleme is in sommige pasiënte gesien, maar word dikwels beter wanneer **ULCOPRAZ** gestaak word
- Die gebruik van medisyne soos **ULCOPRAZ** vir 'n lang tydperk kan 'n vergroeisel (poliep) in jou maag veroorsaak. Dit kan lei tot intestinale blokkasie of bloeding. Praat met jou dokter as jy naarheid of maagpyn ervaar terwyl jy **ULCOPRAZ** gebruik.
- Praat met jou dokter as jy 'n lipe nierprobleem het (akute tubulo-interstisiële nefritis). Sommige mense wat protonpomp-inhibeerder (PPI) medisyne gebruik, insluitend **ULCOPRAZ**, kan 'n nierprobleem ontwikkel wat akute tubulo-interstisiële nefritis genoem word, wat te eniger tyd tydens behandeling met **ULCOPRAZ** kan gebeur. Kontak onmiddellik jou dokter wanneer jy 'n afname het in die hoeveelheid wat jy urineer, of as jy bloed in jou urine het.

Gebruik in kinders en adolessente
Die gebruik van **ULCOPRAZ** in kinders en adolessente (onder die ouderdom van 18 jaar) word nie aanbeveel nie.

Ander medisyne en ULCOPRAZ
Vertel altyd vir jou professionele gesondheidsorgwerker indien jy enige ander medisyne neem. (Dit sluit komplementêre of tradisionele medisyne in.)

Vertel jou dokter of apteker as jy enige van die volgende medisyne gebruik:
- Ketokonasool of itrakonasool – word gebruik om infeksies wat deur 'n swam veroorsaak word, te behandel. **ULCOPRAZ** kan die hoeveelheid van hierdie soort medisyne in jou bloed verlaag. Jou dokter sal dalk jou dosis moet aanpas.
- Atasanavir- wat gebruik word om MIV-infeksie te behandel. **ULCOPRAZ** kan die hoeveelheid van hierdie soort medisyne in jou bloed verlaag en hulle moet nie saam gebruik word nie.
- Metotreksaat ('n chemoterapie middel wat in hoë dosisse gebruik word om kanker te behandel) – as jy 'n hoë dosis van metotreksaat neem, kan jou dokter jou **ULCOPRAZ**- behandeling tydelik stop.
- Siklosporien - gebruik in die profilakse van orgaanverwerping in nier-, lewer- en hart allogeneïese oorplantings. Die gebruik van **ULCOPRAZ** saam met siklosporien kan 'n toestand naamlik hipomagnesemie, of lae bloedmagnesium veroorsaak.
- Digoksien – gebruik om ligte tot matige hartversaking te behandel. Op die kort termyn kan **ULCOPRAZ** 'n toename in die bloedvlakke van digoksien veroorsaak. Jy moet onmiddellike mediese hulp soek indien jy tekens en simptome ervaar wat kan dui op oormatige effekte van digoksien, soos naarheid, braking, diarree, verlies aan eetlus, visuele steurnisse (dowwe visie; ligkrans rondom voorwerpe; groen of geel visie), of 'n abnormaal vinnige of stadige of onreëlmatige hartklop. Jy benodig dalk 'n dosisaanpassing of meer gereelde monitering deur jou dokter om beide medikasies veilig te gebruik.

ULCOPRAZ met voedsel en drank:
ULCOPRAZ kan met of sonder kos geneem word.

Swangerskap, borsvoeding en fertiliteit
Indien jy swanger is of jou baba borsvoed, raadpleeg asseblief jou dokter, apteker of ander professionele gesondheidsorgwerker vir advies voordat jy **ULCOPRAZ** neem.

Moet nie **ULCOPRAZ** neem indien jy swanger is, dit oorweeg om swanger te raak of borsvoed nie.

Bestuur en gebruik van masjinerie
Jy kan slaperig voel terwyl jy **ULCOPRAZ** neem. Indien dit gebeur, moet nie bestuur of enige gereedskap of masjiene gebruik nie.

3. Hoe om ULCOPRAZ te neem

Moet nie medisyne wat vir jou voorgeskryf is met enige ander persoon deel nie.

Neem altyd **ULCOPRAZ** presies soos wat jou dokter dit vir jou voorgeskryf het. Bevestig met jou dokter of apteker indien jy onseker is.

Sluk jou tablette heel met 'n glas water. Moet nie die tablette kou of fyn druk nie.
- Jou dokter sal vir jou sê hoeveel tablette om te neem en vir hoe lank dit geneem moet word. Dit sal afhang van jou toestand.
- Indien jy hierdie medisyne vir 'n lang ruk gebruik, sal jou dokter jou wil monitor.

Jy kan **ULCOPRAZ** met of sonder kos neem.
Die aanbevole dosis is:
Vir 'gastro-esofageale refluksiekte' (GERS),
Behandeling van matige tot ernstige simptome (simptomatiese GERS)
- Die gewone dosis is een **ULCOPRAZ 10** een keer per dag vir tot 4 weke.
- Neem die tablet soggens voordat jy eet.
- Indien jou toestand terugkeer, na 4 weke se behandeling, kan jou dokter vir jou sê om een **ULCOPRAZ** te neem soos, en wanneer jy dit benodig.

Behandeling van meer ernstige simptome (wegvretende of ulseratiewe GERS)
- Die gewone dosis is een **ULCOPRAZ 20** een keer per dag vir 4 tot 8 weke.
- Neem die tablet soggens voordat jy eet.

Langtermyn behandeling van simptome (GORD instandhouding)
- Die gewone dosis is een **ULCOPRAZ** 10 of 20 mg tablet een keer per dag vir so lank as wat jou dokter jou aangeseë het.
- Neem die tablet soggens voordat jy eet.
- Jou dokter sal jou met gereelde tussenposes wil sien om jou simptome en dosering na te gaan.

Vir maagsere (peptiese ulkusse)
- Die gewone dosis is een **ULCOPRAZ 20** tablet een keer per dag vir 6 weke.
- Neem die tablet soggens voordat jy eet.
- Jou dokter kan vir jou sê om **ULCOPRAZ** vir nog 6 weke te neem indien jou toestand nie verbeter nie.

Vir ulkusse veroorsaak deur *H. Pylori*-infeksie en om te verhoed dat hulle terugkeer
- Jou dokter sal jou adviseer oor die dosis wat geneem moet word.

Zollinger-Ellison-sindroom waar oortollige suur in die maag geproduseer word
- Die gewone dosis om mee te begin is drie **ULCOPRAZ 20** tablette, een keer per dag.
- Die dosis kan dan deur jou dokter aangepas word afhangende van hoe jy op die behandeling reageer.
- Indien jy op langtermynbehandeling is, sal jy jou dokter met gereelde tussenposes moet sien vir kontrolering van jou tablette en simptome.

Indien jy onder die indruk is dat die effek van **ULCOPRAZ** te sterk of te swak is, praat met jou dokter of apteker.

Indien jy meer ULCOPRAZ neem as wat jy behoort te neem
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 ULCOPRAZ te neem
Dit is belangrik om jou **ULCOPRAZ** elke dag gereeld op dieselfde tyd, te neem. Indien jy vergeet om 'n dosis te neem, neem dit sodra jy daarvan onthou, tensy dit tyd is vir jou volgende dosis. Moet nie twee dosisse gelyktydig neem om vir 'n oorgeslane dosis op te maak nie

Indien jy ophou om ULCOPRAZ te neem
Indien **ULCOPRAZ** vroeër gestop word as wat jou dokter voorgeskryf het, kan jou simptome terugkeer of vererger. Neem altyd **ULCOPRAZ** vir so lank as wat jou dokter dit voorgeskryf het.

4. Moontlike newe-effekte

ULCOPRAZ kan newe-effekte hê.
Nie al die newe-effekte wat vir **ULCOPRAZ** gerapporteer is, is in hierdie inligtingstuk ingesluit nie. Sou jou algemene gesondheid agteruitgaan of indien jy enige ongewenste effekte ervaar terwyl jy **ULCOPRAZ** gebruik, raadpleeg asseblief jou dokter, apteker of ander professionele gesondheidsorgwerker vir advies.

Indien enige van die volgende gebeur, hou op om ULCOPRAZ te neem en kontak onmiddellik jou dokter of gaan na die ongevalle afdeling van jou naaste hospitaal:
- Allergiese reaksies – die tekens kan insluit: skielike swelling van jou gesig, probleme met asemhaling of lae bloeddruk wat floute of ineenstorting kan veroorsaak.

Hierdie is almal baie ernstige newe-effekte. Indien jy dit ervaar, het jy dalk 'n ernstige reaksie teen **ULCOPRAZ** gehad. Jy mag dringende mediese aandag of hospitalisering nodig hê.

Vertel onmiddellik jou dokter of gaan na die ongevalle afdeling van jou naaste hospitaal indien jy enige van die volgende waarneem:
- Erge blaasvorming op die vel, of oop sere of ulkusse in jou mond en keel.
- Gereelde infeksies, soos 'n seer keel of hoë temperatuur (koors), of ulkusse in jou mond of keel.

Hierdie is alles ernstige newe-effekte. Jy mag dringende mediese aandag nodig hê.

Sê vir jou dokter indien jy enige van die volgende waarneem:
Gereeld
- Infeksies
- Sukkel om te slaap
- Hoofpyn of duiselig voel
- Hoes, loopneus of seer keel (faringitis)
- Effekte op jou maag of ingewande soos maagpyn, diarree, winde (winderigheid), slek voel (naarheid),
- Slek wees (braking) of hardlywigheid
- Pyne of rugpyn
- Swakheid of griepagtige simptome
- Goedaardige poliepe in die maag. Dit is klein klompe selle wat op die voering van die maag vorm.

Minder gereeld
- Veranderinge in witbloedselle (aangedui in bloedtoetse) wat tot gereelde infeksie kan lei
- Vermindering in bloedplaatjies wat makliker as normaal, bloeding of kneusing tot gevolg kan hê
- Verlies aan eetlus (Anoreksie)
- Depressie
- Hipersensitiwiteit (sluit allergiese reaksies in)
- Voel senuweeagtig of depressief
- Visuele versteuring
- Borskas ontsteking (brongitis)
- Pynlike en geblokkeerde sinusse (sinusitis)
- Droë mond
- Swak spysvertering of winde opbreek
- Seer mond (stomatitis) of smaakversteuring
- Omgekrapte maag- of maagpyn
- Lewerprobleme insluitend geel verkleuring van jou vel en die wit van jou oë (geelsug)
- Veluitslag of rooiheid
- Jeukerige uitslag of blase op vel
- Sweet
- Spier-, been- of gewrigspyn
- Frakture van die heup, pols en ruggraat
- Blaasinfeksie (urienweginfeksie)
- Nierprobleme
- Borskaspyn
- Koue rillings of koors
- Veranderinge in hoe jou lewer werk (aangedui in bloedtoetse)
- Gewigstoename

Frekwensie onbekend
- Swelling van borste in mans
- Vloeistof retensie
- Ontsteking van die ingewande (wat lei tot diarree)
- Lae bloedvlakke van natrium wat moegheid en verwarring, spiertrekkings, stuipe en koma kan veroorsaak
- Pasiënte wat voorheen lewerprobleme gehad het, kan baie selde enkefalopatie ('n breinsiekte) opdoen."
- Uitslag, moontlik met pyn in die gewrigte

Indien jy langer as drie maande op **ULCOPRAZ** is, is dit moontlik dat die vlakke van magnesium in jou bloed kan daal. Lae vlakke van magnesium kan gesien word as moegheid, onwillekeurige spierkontraksies, disoriëntasie, stuiptrekkings, duiseligheid, verhoogde harttempo. Indien jy enige van hierdie simptome kry, vertel asseblief onmiddellik jou dokter. Lae vlakke van magnesium kan ook lei tot 'n afname in kalium- of kalsiumvlakke in die bloed. Jou dokter kan besluit om gereelde bloedtoetse uit te voer om jou magnesiumvlakke te monitor.

Stel asseblief jou dokter of apteker in kennis, indien jy enige newe-effekte opmerk wat nie in hierdie inligtingstuk genoem word nie.
Indien jou algemene gesondheid agteruitgaan of indien jy enige ongewenste effekte ervaar terwyl jy **ULCOPRAZ** gebruik, raadpleeg asseblief jou gesondheidsorgverskaffer vir advies.

Aanmelding van newe-effekte
Indien jy newe-effekte kry, praat met jou dokter, apteker of verpleegkundige. Dit sluit enige moontlike newe-effekte in wat nie in hierdie inligtingstuk genoem is 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/Index/8.
Deur newe-effekte aan te meld kan jy help om meer inligting beskikbaar te stel aangaande die veiligheid van **ULCOPRAZ**.

5. Hoe om ULCOPRAZ te bewaar

Bewaar by of benede 25°C.
Beskerm teen vog.
Berg in die oorspronklike verpakking / houer.
Moet nie in 'n yskas bêre nie.
HOU BUITE DIE BEREIK VAN KINDERS.
Moet nie in die badkamer bêre nie
Moet nie gebruik na die vervaldatum wat op die stulpe / etiket /karton / bottel aangedui is nie.
Neem alle ongebruikte medisyne terug na jou apteker.
Moet nie ongebruikte medisyne in dreine of rioolstelsels (bv. toilette) weggooi nie.

6. Inhoud van die pak en ander inligting

Wat ULCOPRAZ bevat
Die aktiewe bestanddeel is natriumrabeprasool.
Bevat mannitol.
Ander bestanddele is:
Tabletkern bevat
Lae gesubstitueerde hidroksipropielsellulose, magnesiumoksied, magnesiumstearaat mannitol, natriumhidroksied, povidoon, gesuiwerde talk.
Bedekkingsmateriaal bevat:
ULCOPRAZ 10
Etielsellulose, magnesiumoksied, rooi yteroksied, titaandioksied, metakrielsuur kopolimeer dispersie (Eudragit L 30 D-55), trietielsitraat, gesuiwerde talk.
ULCOPRAZ 20
Etielsellulose, magnesiumoksied, geel yteroksied, titaandioksied, metakrielsuur kopolimeer dispersie (Eudragit L 30 D-55), trietielsitraat, gesuiwerde talk.

Hoe ULCOPRAZ lyk en inhoud van die pak
ULCOPRAZ 10
Pienk gekleurde, sirkelvormige, bikonvekse, enteriesbedekte tablet glad aan die ander kant.
ULCOPRAZ 20
Geel gekleurde, sirkelvormige, bikonvekse, enteriesbedekte tablet glad aan die ander kant.

Inhoud van die pak:
HDPE-houer
Tablette word verpak in 'n ronde wit HDPE-houer gesluit met kinderbestande sluiting met pulp en hitte seëlvoering.
Pakgroottes sluit 28's, 30's tablette en 90's tablette in.

Stulpverpakking
Tablette word verpak in koue vorm laminaat OPA / aluminiumfoelie / PVC as vormingsmateriaal en aluminiumfoelie as dekmateriaal.
Pakgrootte sluit 14's, 28's, 30's en 90's tablette in.

Stulpverpakking met droogmiddel
Tablette word verpak in koue vorm met droogmiddel en HDPE-seëlaar laag as vormingsmateriaal en aluminiumfoelie met HDPE-seëlaar laag as dekmateriaal.
Pakgrootte sluit 14's, 28's, 30's en 90's tablette in
Nie alle pakgroottes word noodwendig bemark nie.

Houer van die Registrasiesertifikaat
MACLEODS PHARMACEUTICALS SA (EDMS) BPK
Grondvloer, Blok 1, Bassonia Estate Kantoorpark (Oos),
Cussonia-rylaan 1, Bassonia Rock, Uitbr. 12, Alberton Gauteng

Hierdie inligtingstuk was hersien in

Registrasienommers
ULCOPRAZ 10 : 56/11.4.3/0623.621
ULCOPRAZ 20 : 56/11.4.3/0624.622

Toegang tot die ooreenstemmende Professionele Inligting
Die ooreenstemmende professionele inligting kan verkry word by https://www.macleodspharma.com of e-pos macleodsrsa@macleodspharma.com of kontak 011 682 1169

365 mm

335 mm

MASTER COPY

MACLEODS

Restricted Circulation

PACKAGING RESEARCH & DEVELOPMENT

(Front Page)

ARTWORK / PRINTPROOF APPROVAL FORM

1. Product: ULCOPRAZ (RABEPRAZOLE DR TABLETS 10/20 mg)	
2. Country: South Africa (Private Market)	3. Packaging component: Patient Information
4. No. of Colours: 1 Colour	5. Pantone Shade No.: Black
6. Specification: 40 gsm bible paper	
7. Machine Layout No.: NA	8. Dimensions: 365(L) X 335(W) mm
9. Design / Style: Booklet type	10. Item code No.: PM04268501
11. Artwork has been made: Actual Size	12. Pharma code No.: 33411 mini
13. Barcode/NDC no: NA	14. Supersedes Item code No: NA
15. Revision no: 00	16. AW File name:Z:\Rabeprazole\01\Rabeprazole Sodium 10-20 mg PIL - PM04268501.cdr
Approved By:	17. Location: Baddi

PRD	M.A. HOLDER	RAD	QC	PRODN	QA
12/12/23	Vanita Rajool	14/12/23	19-12-23		26/12/23

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 26/12/23

FRM/CQA/021/04-02

Reason for revision :	Item code	Artwork Send for Printing Date	Artwork Implementation Date
1) New Artwork for South Africa - Private Market	PM04268501		

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