SCHEDULING STATUS: S4

RAPACID MR 10, 10 mg hard gelatine capsules
Contains sugar (sucrose): 5,75 mg per capsule
Contains mannitol: 2,5 mg per capsule

RAPACID MR 20, 20 mg hard gelatine capsules
Contains sugar (sucrose): 11,49 mg per capsule
Contains mannitol: 5 mg per capsule

RAPACID MR 40, 40 mg hard gelatine capsules
Contains sugar (sucrose): 22,98 mg per capsule
Contains mannitol: 10 mg per capsule

Omeprazole

Read all of this leaflet carefully before you start taking RAPACID MR

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

1. What RAPACID MR is and what it is used for

RAPACID MR contains the active substance omeprazole. It belongs to a group of medicines called ‘proton pump inhibitors’. They work by reducing the amount of acid that your stomach produces.

RAPACID MR is used to treat the following conditions:

In adults:

- Ulcers in the upper part of the intestine (duodenal ulcer) or stomach (gastric ulcer).
- ‘Gastro-oesophageal reflux disease’ (GORD). This is where acid from the stomach escapes into the gullet (the tube which connects your throat to your stomach) causing pain,

inflammation and heartburn.
- Ulcers which are infected with bacteria called 'Helicobacter pylori'. If you have this condition, your doctor may also prescribe antibiotics to treat the infection and allow the ulcer to heal.
- Ulcers caused by medicines called NSAIDs (Non-Steroidal Anti-Inflammatory Drugs). RAPACID MR can also be used to stop ulcers from forming if you are taking NSAIDs.
- Too much acid in the stomach caused by a growth in the pancreas (Zollinger-Ellison syndrome).

In children
Short term (up to 3 months) treatment of severe ulcerative reflux oesophagitis. This is where acid from the stomach escapes into the gullet (the tube which connects your throat to your stomach) causing pain, inflammation and heartburn.

2. What you need to know before you take RAPACID MR
Do not take RAPACID MR
- If you are hypersensitive (allergic) to omeprazole or any of the other ingredients of RAPACID MR (listed in section 6).
- If you are taking a medicine containing nelfinavir (used for HIV infection).
- If you are pregnant or breastfeeding.

Warnings and precautions
Talk to your doctor or pharmacist before taking RAPACID MR.
RAPACID MR may hide the symptoms of other diseases. Therefore, if any of the following happen to you before you start taking RAPACID MR or while you are taking it, talk to your doctor straight away:
- If you suffer nervous dyspepsia (symptoms of indigestion that have no obvious cause),
- if you lose a lot of weight for no reason and have problems swallowing,
- if you begin to vomit blood and food,
- if you pass black stools (blood-stained faeces),
- if you suffer from low levels of vitamin B_{12}, also called cyanocobalamin,
- if you are taking the clopidogrel to prevent blood clots,
- if you are planning to take RAPACID MR for a prolonged time or if you are using medications that may cause low levels of magnesium (such as diuretics or digoxin),
- if you experience severe or persistent diarrhoea, as omeprazole has been associated with a small increase in infectious diarrhoea,
- if you have ever had a skin reaction after treatment with a medicine similar to RAPACID MR that reduces stomach acid.

You should not take RAPACID MR with atazanavir (used for HIV infection). Your doctor will decide when the combination is important and some additional tests (e.g. virus load) will be done.

If you take RAPACID MR on a long-term basis (longer than 1 year) your doctor will probably keep you under regular surveillance.
You should report any new and exceptional symptoms and circumstances whenever you see your doctor.

Taking a proton pump inhibitor like RAPACID MR, especially over a period of more than one year, may slightly increase your risk of fracture in the hip, wrist or spine. Tell your doctor if you have osteoporosis or if you are taking corticosteroids (which can increase the risk of osteoporosis).

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 RAPACID MR. Remember to also mention any other ill-effects like pain in your joints.

If you need to go for laboratory tests, tell you doctor that you are taking RAPACID MR. Your doctor might advise you to stop taking RAPACID MR for some time before the tests are done.

If any of the following happens, stop using RAPACID MR and tell your doctor or pharmacist:
Blood in the urine, fever, swelling in any part of the body, difficulty breathing, rash, feeling tired, unwell, nausea, vomiting, eating disorder. All these symptoms may be indicative of inflammation of the kidneys which possibly may lead to kidney failure.

Children
Some children with chronic illnesses may require long-term treatment although it is not recommended. There is limited experience with use of omeprazole in children.

Other medicines and RAPACID MR
Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)
Tell your doctor or pharmacist if you are taking any of the following medicines:
- Nelfinavir and atazanavir (used to treat HIV infection).
- Ketoconazole, itraconazole, posaconazole or voriconazole (used to treat infections caused by a fungus).
- Digoxin (used to treat heart problems).
- Clopidogrel (used to prevent blood clots).
- Erlotinib (used to treat cancer).
- Medicines that are used to thin your blood, such as warfarin or other vitamin K blockers. Your doctor may need to monitor you when you start or stop taking RAPACID MR.
- Cilostazol (used to treat intermittent claudication).
- Diazepam (used to treat anxiety, relax muscles or in epilepsy).

- Phenytoin (used in epilepsy). If you are taking phenytoin, your doctor will need to monitor you when you start or stop taking RAPACID MR.
- Saquinavir (used to treat HIV infection).
- 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 RAPACID MR treatment.
- Tacrolimus (in cases of organ transplantation).
- Antibiotics that are metabolised (broken down) by the liver (enzymes
- CYP2C19 and CYP3A4) such as clarithromycin and voriconazole (especially if you have liver problems).
- St John's wort (Hypericum perforatum) (used to treat mild depression).
- Rifampicin (used to treat tuberculosis).

Pregnancy, breastfeeding and fertility
If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking this medicine.
Do not take RAPACID MR if you are pregnant or breastfeeding.

Driving and using machines
Side effects such as dizziness and visual disturbances may occur (see section 4).
It is not always possible to predict to what extent RAPACID MR may interfere with your daily activities. You should ensure that you do not engage in activities requiring mental alertness, judgment and/or sound coordination and vision e.g. driving, riding, flying, sailing or operating machines/equipment until you are aware of the measure to which RAPACID MR affects you.

RAPACID MR contains sucrose
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

RAPACID MR contains sodium
RAPACID MR contains less than 1 mmol sodium (23 mg) per capsule, that is to say essentially 'sodium-free'.

RAPACID MR contains mannitol
RAPACID MR contains less than 10 g per capsule, that is to say essentially 'mannitol-free'.
May have a mild laxative effect.

3. How to take RAPACID MR
Do not share medicines prescribed for you with any other person.
Always take RAPACID MR exactly as your doctor, or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Depending on the condition you are suffering from, your doctor will tell you what strength of RAPACID MR to take, how many capsules to take and for how long.

Taking this medicine:

- It is recommended that you take your capsules in the morning.
- Swallow your capsules whole with half a glass of water. Do not chew or crush the capsules. This is because the capsules contain coated pellets which stop the medicine from being broken down by the acid in your stomach. It is important not to damage the pellets.
- If you or your child have trouble swallowing the capsules:
    - Open the capsules and swallow the contents directly with half a glass of water or put the contents into a glass of still (non-fizzy) water, any acidic fruit juice (e.g. apple, orange or pineapple) or apple sauce.
    - Always stir the mixture just before drinking it (the mixture will not be
    - clear). Then drink the mixture straight away or within 30 minutes.
    - To make sure that you have drunk all of the medicine, rinse the glass very well with half a glass of water and drink it. The solid pieces contain the medicine - do not chew or crush them.

Your doctor will tell you how long your treatment with RAPACID MR will last. Do not stop RAPACID MR without first talking to your doctor or pharmacist. If you have the impression that the effect of RAPCID MR is too strong or too weak, tell your doctor or pharmacist.

If you take more RAPACID MR than you should
In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

Nausea, vomiting, dizziness, stomach pain, diarrhoea, headache, apathy (lack of interest or enthusiasm), depression and confusion have been reported from overdosage with omeprazole. Treatment is symptomatic and supportive.

If you forget to take RAPACID MR
If you miss a dose, take it as soon as possible. However, if it is almost time for the next dose, skip the missed dose and go back to your regular dosing schedule. Do not take a double dose to make up for forgotten individual doses.

If you stop taking RAPACID MR
Do not stop taking RAPACID MR without talking to your doctor or pharmacist first.

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

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

- Sudden wheezing, swelling of your lips, tongue and throat or body, rash, fainting or difficulties in swallowing (severe allergic reaction).
- Reddening of the skin with blisters or peeling. There may also be severe blisters and bleeding in the lips, eyes, mouth, nose and genitals. This could be 'Stevens-Johnson syndrome' or 'toxic epidermal necrolysis'.
- Yellow skin or eyes, dark urine and tiredness which can be symptoms of liver problems.
- Muscle cramps, fits, dizziness and pounding heart with chest pain. These may indicate a severe lack of magnesium in your body.
- Blood in the urine, fever, swelling in any part of the body, difficulty breathing, rash, feeling tired, unwell, nausea, vomiting, eating disorder. All these symptoms may indicate inflammation of the kidneys which may lead to kidney failure.

These are all very serious side effects. If you have them, you may have had a serious reaction to RAPACID MR. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:
Frequent side effects:

- Headache
- Stomach pain or tenderness, constipation, diarrhoea, wind (flatulence), nausea/vomiting,

Less frequent side effects:

- Blood problems such as a reduced number of white cells or platelets.
- This can cause weakness, unexplained bleeding, bruising or make infections more likely.
- Low levels of sodium in the blood. This may cause weakness, being sick (vomiting) and cramps.
- Disturbed sleep (insomnia), feeling agitated, confused, aggressive or depressed, seeing, feeling or hearing things that are not there (hallucinations).
- Dizziness, tingling feelings such as "pins and needles", feeling sleepy,
- Taste disturbance.
- Blurred vision.
- Spinning feeling (vertigo).
- Suddenly feeling wheezy or short of breath (bronchospasm).
- Dry mouth, inflammation in the mouth – red patches, blisters, swelling.
- Skin rash, lumpy rash (hives) and itchy skin, hair loss (alopecia), sudden onset of a severe rash or blistering or peeling skin.
- Fracture of the hip, wrist or spine, joint pains (arthralgia) or muscle pains (myalgia), muscular weakness.
- Severe kidney problems (interstitial nephritis). Hypersensitivity reactions, non-specific symptoms of decreased kidney function such as a general sense of being unwell, nausea, eating disorder, fever, diarrhoea, stomach pain, dark-coloured urine and yellowing of the

eyes and skin etc. All these symptoms may be indicative of inflammation of the kidneys which possibly may lead to kidney failure.
- Enlarged breasts in men (gynaecomastia).
- Generally feeling unwell and lacking energy (malaise), swelling of legs and arms (peripheral oedema), increased sweating.

Side effects of unknown frequency:
- If you are on RAPACID MR 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 or 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.
- Microscopic colitis (inflammation of the large intestine that causes persistent watery diarrhoea).
- Subacute cutaneous lupus erythematosus (skin rash on exposure to sunshine)

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. 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 RAPACID MR.

5. How to store RAPACID MR
- Store all medicines out of reach of children.
- Store at or below 25 °C.
- Store in the original package / container.
- Keep the blisters in the outer carton.
- Keep the bottle tightly closed
- Protect from 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 RAPACID MR contains

The active substance is omeprazole.
The other ingredients are: Disodium phosphate; Hypromellose type 2910; Macrogol 6000, Magnesium hydroxide; Mannitol; Methacrylic Acid-Ethyl Acrylate Copolymer (1:1); Polysorbate 80; Sodium lauryl sulphate; Sodium starch glycolate (Type A); Sugar spheres (sucrose and maize starch); Talc; and Titanium dioxide.

Capsule shell (10 mg) contains: Brilliant blue FCF - FD&C Blue 1 (E133); Gelatine; Titanium dioxide (E-171); and Yellow iron oxide (E172).

Capsule shell (20 mg) contains: Gelatine; Indigotine-FD&C Blue2 (E132);
and Titanium Dioxide (E171).

Capsule shell (40 mg) contains: Black iron oxide; Gelatine; and Titanium dioxide (E171).

What RAPACID MR looks like and contents of the pack

RAPACID MR 10:

- Hard gelatine capsule size “4”, with green cap and white body, containing white to off-white cream spherical pellets.

RAPACID MR 20:

- Hard gelatine capsule size “4”, with blue cap and white body, containing white to off-white cream spherical pellets.

RAPACID MR 40:

- Hard gelatine capsule size “3”, with white cap and grey body, containing white to off-white cream spherical pellets.

RAPACID MR hard gelatine capsules are packed in:

- High density polyethylene (HDPE) bottle with silica gel desiccant container in the cap.

RAPACID MR 10:
Bottles 35 mL: 7; 14; 15; 28; 30; 50; 56; 60 and 90 capsules.
Bottles 50 mL: 98; 100 and 120 capsules.
Bottles 100 mL: 250 capsules.

RAPACID MR 20:
Bottles 35 mL: 7; 14; 15; 28; 30; 50; 56; 60 to 90 capsules.
Bottles 50 mL: 98; 100 and 120 capsules.
Bottles 100 mL: 250 capsules.

RAPACID MR 40:
Bottles 35 mL: 7; 14; 15; 28; 30; 50; 56 to 60 capsules.
Bottles 50 mL: 90 capsules.
Bottles 100 mL: 98; 100 and 120 capsules.

- PVC-PE-PVDC/Aluminium thermoformed blisters. The blister strips will be packed in an outer carton.

Blister packs of 10 hard gelatine capsules: 1 blister, 10 capsules per pack; 2 blisters, 20 capsules per pack; 3 blisters, 30 capsules per pack; 5 blisters, 50 capsules per pack; 6 blisters, 60 capsules per pack; 9 blisters, 90 capsules per pack and 10 blisters, 100 capsules per pack.

Blister packs of 14 hard gelatine capsules: 1 blister, 14 capsules per pack; 2 blisters, 28 capsules per pack; 3 blisters, 42 capsules per pack; 4 blisters, 56 capsules per pack; and 7 blister, 98 capsules per pack.

Blister packs of 15 hard gelatine capsules: 1 blister, 15 capsules per pack; 2 blister, 30 capsules per pack.

Not all pack sizes may be marketed.

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This leaflet was last revised in
25 September 2025

Registration number
RAPACID MR 10: 56/11.4.3/0913
RAPACID MR 20: 56/11.4.3/0914
RAPACID MR 40: 56/11.4.3/0915

PASIËNT INLIGTINGSBILJET

SKEDULERINGSTATUS: S4

RAPACID MR 10, 10 mg harde gelatien kapsules
Bevat suiker (sukrose): 5,75 mg per kapsule
Bevat mannitol: 2,5 mg per kapsule

RAPACID MR 20, 20 mg harde gelatien kapsules
Bevat suiker (sukrose): 11,49 mg per kapsule
Bevat mannitol: 5 mg per kapsule

RAPACID MR 40, 40 mg harde gelatien kapsules
Bevat suiker (sukrose): 22,98 mg per kapsule
Bevat mannitol: 10 mg per kapsule

Omeprasool

Lees die hele voubiljet noukeurig voordat u RAPACID MR begin gebruik
- Hou hierdie voubiljet. U mag dit weer moet lees.
- Indien u enige verdere vrae het, raadpleeg asseblief u dokter, apteker, verpleegkundige of ander gesondheidsorgverskaffer.
- RAPACID MR is aan u persoonlik voorgeskryf en u moet nie u medisyne met enige ander persoon deel nie. Dit kan hulle benadeel, al ervaar hulle dieselfde simptome as u.

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

1. Wat RAPACID MR is en waarvoor dit gebruik word
RAPACID MR bevat die aktiewe bestanddeel omeprasool. Dit behoort aan ’n groep medisynes wat ‘protonpomp-inhibeerders’ genoem word. Hulle werk deur die hoeveelheid suur wat u maag vervaardig, te verminder.

RAPACID MR word gebruik vir die behandeling van die volgende toestande:
By volwassenes:
- Maagsere in die boonste deel van die derms (duodenale seer) of maag (gastriese seer).
- ‘Gastro-esofageale reflukssiekte’ (GERS). Dit is waar suur van die maag na die slukderm (die buis wat die keel met die maag verbind) deurdruk wat pyn, inflammasie en sooibrand veroorsaak.
- Sere wat met bakterieë besmet is, genoem ‘*Helicobacter pylori*’. Indien u hierdie toestand het

kan u dokter ook antibiotika voorskryf om die infeksie te behandel, wat die seer toelaat om te genees.
- Sere wat deur medisyne wat NSAIMs (Nie-Steroïed Anti-Inflammatoriese Middels) veroorsaak word. RAPACID MR kan ook gebruik word om seervorming te voorkom indien u NSAIMs gebruik.
- Te veel suur in die maag wat deur 'n groeisel in die pankreas (Zollinger-Ellison sindroom) veroorsaak word.

By kinders
Korttermyn (tot 3 maande) behandeling van ernstige ulseratiewe refluks-esofagitis. Dit is waar suur van die maag na die slukderm (die buis wat die keel en die maag verbind) deurdruk wat pyn, inflammasie en sooibrand veroorsaak.

2. Wat u moet weet voordat u RAPACID MR gebruik
Moenie RAPACID MR gebruik nie
- Indien u hipersensitief (allergies) vir omeprasool of enige van die ander bestanddele van RAPACID MR is (gelys in afdeling 6).
- Indien u medisyne gebruik wat nelfinavir bevat (wat vir MIV-infeksie gebruik word).
- Indien u swanger is of borsvoed.

Waarskuwings en voorsorgmaatreëls
Raadpleeg u dokter of apteker voordat u RAPACID MR gebruik.
RAPACID MR kan die simptome van ander siektes verdoesel. Raadpleeg dus onmiddellik u dokter indien enige van die volgende met u gebeur voordat u RAPACID MR begin gebruik, of tydens gebruik:
- Indien u aan senuwee-dispepsie (simptome van slegte spysvertering met geen ooglopende oorsaak) ly,
- indien u baie gewig vir geen rede verloor en u sukkel om te sluk,
- indien u begin om bloed en kos te braak,
- indien u swart stoelgange het (bloederige ontlasting),
- indien u lae vlakke van vitamien B_{12} het, wat ook sianokobalamien genoem word,
- indien u klopidogrel gebruik om bloedklonte te voorkom,
- indien u beplan om RAPACID MR vir 'n langdurige periode te gebruik of u gebruik medikasie wat lae magnesiumvlakke kan veroorsaak (soos diuretika of digoksien),
- indien u ernstige of aanhoudende diarree ervaar, want omeprasool hou verband met 'n effense toename van aansteeklike diarree,
- indien u ooit 'n velreaksie gehad het ná behandeling met medisyne soortgelyk aan RAPACID MR, wat maagsuur verminder.

U moet nie RAPACID MR saam met atazanavir (wat vir MIV-infeksie gebruik word) gebruik nie. U dokter sal besluit wanneer die kombinasie belangrik is en bykomende toetse (bv. viruslading) sal gedoen word.

Indien u RAPACID MR op ’n langtermyn-basis (langer indien 1 jaar) gebruik sal u dokter u heel waarskynlik gereeld monitor.

U moet enige nuwe en buitengewone simptome en omstandighede aanmeld wanneer u die dokter besoek.

Indien u ’n protonpomp-inhibeerder soos RAPACID MR gebruik, veral oor ’n tydperk van langer as een jaar, kan u risiko om ’n heup, gewrig of ruggraat te breek verhoog. Lig u dokter in indien u osteoporose het of indien u kortikosteroïede (wat die risiko van osteoporose kan verhoog), gebruik.

Lig u dokter in so gou as moontlik indien u ’n uitslag op u vel kry, veral op dele wat aan die son blootgestel is, want u mag u behandeling met RAPACID MR moet staak. Onthou om ook ander nadelige gevolge soos pyn in die gewrigte te noem.

Indien u vir laboratoriumtoetse moet gaan, lig u dokter in dat u RAPACID MR gebruik. U dokter kan aanbeveel dat u die gebruik van RAPACID MR vir ’n tydperk voor die toetse gedoen word, moet staak.

Indien enige van die volgende gebeur, staak die gebruik van RAPACID MR en lig u dokter of apteker in:
Bloed in die urien, koors, swelling van enige deel van die liggaam, moeite om asem te haal, veluitslag, moegheid, onwel gevoel, naarheid, braking, eetversteuring. Al hierdie simptome kan aanduidend wees van inflammasie van die niere wat moontlik tot nierversaking kan lei.

Kinders
Sommige kinders met chroniese siektes kan langtermyn behandeling nodig hê alhoewel dit nie aanbeveel word nie. Daar is beperkte ondervinding met die gebruik van omeprasool vir kinders.

Ander medisyne en RAPACID MR
Lig altyd u gesondheidsorgverskaffer in indien u enige ander medisyne gebruik. (Dit sluit alle komplementêre of tradisionele medisyne in.)
Lig u dokter of apteker in indien u enige van die volgende medisynes gebruik:
- Nelfinavir en atazanavir (gebruik vir die behandeling van MIV-infeksie).
- Ketokonasool, itrakonasool, posakonasool of vorikonasool (word vir behandeling van swaminfeksies gebruik).
- Digoksien (word gebruik om hartprobleme te behandel).
- Klopidogrel (word gebruik om bloedklonte te voorkom).
- Erlotinib (word gebruik om kanker te behandel).
- Medisyne wat gebruik word om u bloed te verdun, soos warfarien of ander vitamien K-blokkers. U dokter kan u moet monitor wanneer u RAPACID MR begin gebruik of staak.
- Silostasool (word gebruik vir behandeling van afwisselende *claudicasio*).

- Diasepaam (word gebruik vir die behandeling van angstigheid, spierverslapping of vir epilepsie).
- Fenitoïen (word vir epilepsie gebruik). Indien u fenitoïen gebruik, kan u dokter monitor wanneer u RAPACID MR moet begin gebruik of staak.
- Saquinavir (word gebruik om MIV-infeksie te behandel).
- Metotreksaat ('n chemoterapie medisyne wat in hoë dosisse gebruik word om kanker te behandel) – u dokter kan u behandeling met RAPACID MR tydelik staak indien u 'n hoë dosis metotreksaat gebruik.
- Takrolimus (in gevalle van orgaanoorplanting).
- Antibiotika wat deur die lewer (ensieme CYP2C19 en CYP3A4) afgebreek word soos klaritromisien en vorikonasool (veral indien u lewerprobleme het).
- "St John's wort" (*Hypericum perforatum*) (wat gebruik word om minder ernstige depressie te behandel).
- Rifampisien (wat gebruik word om tuberkulose te behandel).

Swangerskap, borsvoeding en vrugbaarheid
Indien u swanger is of borsvoed, dink u kan dalk swanger wees of beplan om 'n baba te hê, raadpleeg asseblief u dokter, apteker of ander gesondheidsorgverskaffer vir advies voor u hierdie medisyne gebruik
Moenie RAPACID MR gebruik indien u swanger is of borsvoed nie.

Bestuur en hantering van masjinerie
Newe-effekte soos duiseligheid en versteurde visie kan voorkom (sien afdeling 4).
Dit is nie altyd moontlik om te voorspel tot watter mate RAPACID MR by u daaglikse aktiwiteite kan inmeng nie. U moet verseker dat u nie enige aktiwiteite wat verstandelike waaksaamheid, oordeel en/of goeie koördinasie en sig, bv. bestuur, ry, vlieg, seil of hantering van masjinerie/ toerusting uitvoer nie totdat u bewus is van die mate waartoe RAPACID MR u beïnvloed nie.

RAPACID MR bevat sukrose
Indien u dokter u ingelig het dat u 'n onverdraagsaamheid teenoor sekere suikers het, raadpleeg u dokter voordat u hierdie medisyne gebruik

RAPACID MR bevat natrium
RAPACID MR bevat minder as 1 mmol natrium (23 mg) per kapsule, dit is so te sê essensieel 'natrium-vry'.

RAPACID MR bevat mannitol
RAPACID MR bevat minder as 10 g per kapsule, dit is so te sê essensieel 'mannitol-vry'.
Mag 'n matige lakserende uitwerking hê.

3. Hoe om RAPACID MR te gebruik
Moenie medisyne wat aan u voorgeskryf is met enige ander persoon deel nie

Gebruik RAPACID MR altyd presies soos u dokter of apteker vir u voorgeskryf het. Bevestig met u dokter of apteker indien u nie seker is nie.

Afhangende van die toestand waaraan u ly, sal u dokter vir u sê watter sterkte van RAPACID MR om te gebruik, hoeveel kapsules om te neem en vir hoe lank.

Gebruik van hierdie medisyne:

- Dit word aanbeveel dat u die kapsules in die oggend neem.
- Sluk die kapsule heel met ’n halwe glas water. Moenie die kapsule kou of fyndruk nie. Dit is omdat die kapsule bedekte korrels bevat wat voorkom dat die medisyne deur die suur in u maag afgebreek word. Dit is belangrik om nie die korrels te beskadig nie.
- Indien u of u kind probleme het om kapsules te sluk:
    - Maak die kapsules oop en sluk die inhoud direk met ’n halwe glas water, of gooi die inhoud in ’n glas gewone (nie-bruisende) water, enige suur vrugtesap (bv. appel, lemoen of pynappel) of appelsous.
    - Roer die mengsel altyd net voor u dit drink (die mengsel sal nie helder wees nie). Drink die mengsel dan dadelik of binne 30 minute.
    - Spoel die glas goed met ’n halwe glas water en drink dit om seker te maak dat u al die medisyne gedrink het. Dit soliede deeltjies bevat die medisyne – moenie hulle kou of fyn druk nie.

U dokter sal u inlig hoe lank u behandeling met RAPACID MR sal duur. Moenie gebruik van RAPACID MR staak sonder om eers met u dokter of apteker te praat nie. Lig u dokter of apteker in indien u die indruk kry dat die uitwerking van RAPCID MR te sterk of te swak is.

Indien u meer RAPACID MR gebruik as wat u moes
Raadpleeg u dokter of apteker in die geval van oordosering. Kontak u naaste hospitaal of gifhulpsentrum indien nie een van hulle beskikbaar is nie.

Naarheid, braking, duiseligheid, maagpyn, diarree, hoofpyn, apatie (tekort aan belangstelling of entoesiasme), depressie en verwarring is by oordosering van omeprasool aangemeld. Behandeling is simptomaties en ondersteunend.

Indien u vergeet om RAPACID MR te gebruik
Indien u ’n dosis oorslaan, neem dit so gou as moontlik. Indien dit egter amper tyd vir die volgende dosis is, slaan die vergete dosis oor en gaan voort met die normale skedule. Moenie ’n dubbele dosis neem om op te maak vir vergete individuele dosisse nie.

Indien u die gebruik van RAPACID MR staak
Moenie die gebruik van RAPACID MR staak sonder om eers met u dokter of apteker te praat nie.

4. Moontlike newe-effekte

RAPACID MR kan newe-effekte hê.
Nie alle newe-effekte wat vir RAPACID MR aangemeld is word in hierdie voubiljet ingesluit nie. Raadpleeg asseblief u gesondheidsorgverskaffer vir advies indien u algemene gesondheid verswak of u enige nadelige gevolge ervaar terwyl u RAPACID MR gebruik.
Staak die gebruik van RAPACID MR en lig u dokter onmiddellik in, of gaan na die ongevalle afdeling by u naaste hospitaal indien enige van die volgende gebeur:

- Skielike hyging, swelling van u lippe, tong en keel of liggaam, veluitslag, floute of moeite om te sluk (ernstige allergiese reaksie).
- Rooi word van die vel met blaasvorming of afskilfering. Daar kan ook erge blase en bloeding binne die lippe, oë, mond, neus en geslagsdele wees. Dit kan 'Stevens-Johnson-sindroom' of 'toksiese epidermale nekrolise' wees.
- Geel vel of oë, donker urien en moegheid, wat simptome van lewerprobleme kan wees.
- Spierkrampe, stuiptrekkings, duiseligheid en hart wat hard klop met borspyn. Hierdie kan 'n teken van 'n ernstige tekort aan magnesium in die liggaam wees.
- Bloed in die urien, koors, swelling in enige deel van die liggaam, moeite om asem te haal, veluitslag, moegheid, onwel gevoel, naarheid, braking, eetversteuring. Al hierdie simptome kan inflammasie van die niere aandui, wat tot nierversaking kan lei.

Hierdie is alles baie ernstige newe-effekte. Indien u dit ervaar kan u 'n ernstige reaksie teen RAPACID MR gehad het. U mag dringende mediese aandag of hospitalisasie benodig.

Lig u dokter in indien u enige van die volgende opmerk:
Algemene newe-effekte:

- Hoofpyn
- Maagpyn of gevoeligheid, hardlywigheid, diarree, wind (winderigheid), naarheid/braking,

Minder algemene newe-effekte:

- Bloedprobleme soos verminderde aantal wit bloedselle of plaatjies.
- Dit kan swakheid, onverklaarbare bloeding of kneusing veroorsaak of infeksie meer waarskynlik maak.
- Lae vlakke van natrium in die bloed. Dit kan swakheid, naar wees (braking) en krampe veroorsaak.
- Versteurde slaap (insomnia), geïrriteerd voel, verward, aggressief of depressief, sien, voel of hoor goed wat nie daar is nie (hallusinasies).
- Duiseligheid, tintelende gevoel soos "naalde en spelde", slaperig voel.
- Versteurde smaak.
- Versteurde sig.
- Draaiende gevoel (vertigo).
- Skielike hygend voel of kortasem (bronchospasma).
- Droë mond, inflammasie in die mond – rooi kolle, blase, swelling.
- Veluitslag, knopperige uitslag (galbulte) en jeukende vel, haarverlies (alopesie), vinnige verskyning van ernstige veluitslag of blaasvorming of skilferende vel.

- Fraktuur van die heup, gewrig of ruggraat, gewrigspyne (artralgie) of spierpyne (mialgie), spierswakheid.
- Ernstige nierprobleme (interstisiële nefritis). Hipersensitiwiteitsreaksies, nie-spesifieke simptome van verminderde nierfunksie soos 'n algemene gevoel van onwel wees, naarheid, eetversteuring, koors, diarree, maagpyn, donker urien en vergeling van die oë en vel, ens. Al hierdie simptome kan 'n teken wees van inflammasie van die niere wat moontlik tot nierversaking kan lei.
- Vergroting van borste in mans (ginekomastie).
- Algemene onwel gevoel en tekort aan energie (malaise), swelling van bene en arms (perifere edeem), verhoogde sweet.

Newe-effekte van onbekende frekwensie:

- Indien u RAPACID MR vir langer as drie maande gebruik, is dit moontlik dat die magnesiumvlakke in u bloed kan daal. Lae magnesiumvlakke vertoon as moegheid, onwillekeurige spiersametrekkings, disoriëntasie, stuiptrekkings, duiseligheid of versnelde hartklop. Lig u dokter dadelik in indien u enige van hierdie simptome ervaar. Lae magnesiumvlakke kan ook tot vermindering van kalium of kalsium vlakke in u bloed lei. U dokter kan besluit om gereelde bloedtoetse uit te voer om u magnesiumvlakke te monitor.
- Mikroskopiese kolitis (inflammasie van die dikderm wat aanhoudende waterige diarree veroorsaak).
- Sub-akute kutane lupus eritematose (veluitslag by blootstelling aan sonlig).

Stel asseblief u dokter of apteker in kennis indien u enige newe-effekte wat nie in hierdie voubiljet genoem word nie, opmerk.

Aanmelding van newe-effekte

Indien u newe-effekte ervaar, raadpleeg u dokter, apteker of verpleegkundige. Dit sluit enige moontlike newe-effekte in wat nie in hierdie voubiljet genoem word nie. U kan newe-effekte ook by SAHPRA aanmeld via die vorm "**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 u help om meer inligting oor die veiligheid van RAPACID MR te verskaf.

5. Hoe om RAPACID MR te bêre

- Bêre alle medisyne buite bereik van kinders.
- Bêre teen of benede 25 °C.
- Bêre in die oorspronklike verpakking/houer.
- Hou die stulpstroke in die buitenste kartonboksie.
- Hou die bottel dig toe.
- Beskerm teen vog.
- Moenie in 'n badkamer bêre nie.
- Moenie ná die vervaldatum, soos op die etiket/kartonboksie/bottel aangedui, gebruik nie

- Neem alle ongebruikte medisyne na u apteker terug.
- Moenie ongebruikte medisyne in afvoerpype of rioolstelsels (bv. toilette) afspoel nie.

6. Inhoud van die verpakking en ander inligting

Wat RAPACID MR bevat

Die aktiewe bestanddeel is omeprasool.

Die ander bestanddele is: Dinatriumfosfaat; Hipromellose tipe 2910; Makrogol 6000, Magnesiumhidroksied; Mannitol; Metakriliese Suuretielakrilaatkopolimeer (1:1); Polisorbaat 80; Natriumlourielsulfaat; Natriumstyselglikolaat (Tipe A); Suikersfere (sukrose en mieliestysel); Talk; en Titaandioksied.

Kapsule dop (10 mg) bevat: “Brilliant” blou FCF - FD&C Blou 1 (E133); Gelatien; Titaandioksied (E-171); en Geel ysteroksied (E172).

Kapsule dop (20 mg) bevat: Gelatien; “Indigotine-FD&C” Blou 2 (E132); en Titaandioksied (E171).

Kapsule dop (40 mg) bevat: Swart ysteroksied; Gelatien; en Titaandioksied(E171).

Hoe RAPACID MR lyk en inhoud van die verpakking

RAPACID MR 10:

- Harde gelatien kapsule grootte “4”, met groen dop en wit basis, wat wit tot naaswit roomkleurige sferiese korrels bevat.

RAPACID MR 20:

- Harde gelatien kapsule grootte “4”, met blou dop en wit basis, wat wit tot naaswit roomkleurige sferiese korrels bevat.

RAPACID MR 40:

- Harde gelatien kapsule grootte “3”, met wit dop en grys basis, wat wit tot naaswit roomkleurige sferiese korrels bevat.

RAPACID MR harde gelatien kapsules word verpak in:

- Hoë digtheid poliëtileen (HDPE) bottel met silikoonjel droogmiddel-houer in die prop.

RAPACID MR 10:
Bottels 35 mL: 7; 14; 15; 28; 30; 50; 56; 60 en 90 kapsules.
Bottels 50 mL: 98; 100 en 120 kapsules.
Bottels 100 mL: 250 kapsules.

RAPACID MR 20:
Bottels 35 mL: 7; 14; 15; 28; 30; 50; 56; 60 tot 90 kapsules.
Bottels 50 mL: 98; 100 en 120 kapsules.

Bottels 100 mL: 250 kapsules.

RAPACID MR 40:
Bottels 35 mL: 7; 14; 15; 28; 30; 50; 56 tot 60 kapsules.
Bottels 50 mL: 90 kapsules.
Bottels 100 mL: 98; 100 en 120 kapsules.

- PVC-PE-PVDC/Aluminium hitte-gevormde stulpstroke. Die stulpstroke sal in ’n buitenste kartonboksie verpak word.

Stulpstroke met 10 harde gelatien kapsules: 1 stulpstrook, 10 kapsules per pak; 2 stulpstroke, 20 kapsules per pak; 3 stulpstroke, 30 kapsules per pak; 5 stulpstroke, 50 kapsules per pak; 6 stulpstroke, 60 kapsules per pak; 9 stulpstroke, 90 kapsules per pak en 10 stulpstroke, 100 kapsules per pak.

Stulpstroke met 14 harde gelatien kapsules: 1 stulpstrook, 14 kapsules per pak; 2 stulpstroke, 28 kapsules per pak; 3 stulpstroke, 42 kapsules per pak; 4 stulpstroke, 56 kapsules per pak; en 7 stulpstroke, 98 kapsules per pak.

Stulpstroke met 15 harde gelatien kapsules: 1 stulpstrook, 15 kapsules per pak; 2 stulpstroke, 30 kapsules per pak.

Nie alle verpakkingsgroottes word noodwendig bemark nie.

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Hierdie voubiljet is mees onlangs hersien op
25 September 2025

Registrasienommer
RAPACID MR 10: 56/11.4.3/0913
RAPACID MR 20: 56/11.4.3/0914
RAPACID MR 40: 56/11.4.3/0915

adcock ingram
925260-01 11/2025