

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

RAPACID MR 10, 10 mg hard gelatine capsules

Contains sugar (sucrose): 5,75 mg per capsule

Contains sugar (mannitol): 2,5 mg per capsule

RAPACID MR 20, 20 mg hard gelatine capsules

Contains sugar (sucrose): 11,49 mg per capsule

Contains sugar (mannitol): 5 mg per capsule

RAPACID MR 40, 40 mg hard gelatine capsules

Contains sugar (sucrose): 22,98 mg per capsule

Contains sugar (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 B₁₂, 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.

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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 your 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.

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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 RAPACID 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.

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- 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, anhydrous; 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 opaque green cap and opaque white body, containing white to off-white cream spherical regular pellets without detectable defects.

RAPACID MR 20:

- Hard gelatine capsule size “4”, with opaque blue cap and opaque white body, containing white to off-white cream spherical regular pellets without detectable defects.

RAPACID MR 40:

- Hard gelatine capsule size “3”, with opaque white cap and opaque grey body, containing white to off-white cream spherical regular pellets without detectable defects.

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.

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.

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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.

Holder of Certificate of Registration

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