SCHEDULING STATUS: S2

RAPACID 10 mg capsule
Omeprazole

Contains sugar: 54,5 mg sucrose
Contains mannitol: 3,955 mg

Read all of this leaflet carefully before you start taking RAPACID
RAPACID is available without a doctor's prescription, for you to treat a mild illness. Nevertheless, you still need to use RAPACID carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share RAPACID with any other person.
- Ask your health care provider or pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve after 14 days.

What is in this leaflet

1. What RAPACID is and what it is used for
RAPACID is a proton pump inhibitor (PPI) and works by reducing the amount of acid that your stomach produces.
RAPACID is indicated for the temporary, short-term relief of heartburn and hyperacidity (excessive acid).

2. What you need to know before you take RAPACID
Do not take RAPACID:

- if you are hypersensitive (allergic) to omeprazole or any of the other ingredients of RAPACID (listed in section 6),
- if you are pregnant or breastfeeding; safety has not been established (see pregnancy and breastfeeding),
- if you are taking atazanavir or nelfinavir, used in the management of HIV.

Warnings and precautions
Take special care with RAPACID**:**

- if you have any liver damage or disease.
- if you experience severe or persistent diarrhoea, as RAPACID has been associated with a

small increase in infectious diarrhoea. You should seek immediate help from a health care professional if you experience watery stools, abdominal pain and fever whilst using RAPACID**.**

- if you are due to have a specific blood test (Chromogranin A),
- seek immediate care if you experience unintentional loss of weight, repeated vomiting, difficulty swallowing, vomiting of blood or if you notice blood in your stool or your stool appears black (blood-stained faeces). Your doctor may decide that you need some tests to rule out malignant disease because RAPACID also alleviates the symptoms of cancer and could cause delay in diagnosing it. If your symptoms continue in spite of your treatment, further investigations will be considered.
- if you experience serious skin reactions including blistering and peeling of the skin which may be due to Stevens-Johnson syndrome (SJS), Toxic Epidermal Necrolysis (TEN), Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS) and rapid appearance of areas of red skin studded with pinhead-sized sterile pustules (AGEP); stop using RAPACID and seek medical attention immediately.
- if you get stomach pain or indigestion.
- as using RAPACID may 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).
- omeprazole, as in RAPACID, is extensively metabolised in the liver and it is recommended that the dosage should be reduced in liver impairment.

The following should be considered:

- RAPACID may reduce the absorption of vitamin B12 (cyanocobalamin). This should be considered in patients with reduced body stores or risk factors for reduced vitamin B12 absorption on long-term therapy.
- if lesions occur, especially in sun-exposed areas of the skin, and if accompanied by pain in a joint, you should seek medical help promptly and the health care provider should consider stopping RAPACID. Subacute cutaneous lupus erythematosus (SCLE) (these are abnormal skin growths that are dry and evolve as ring shaped skin growths) after previous treatment with a proton pump inhibitor may increase the risk of SCLE with other proton pump inhibitors.
- if you are on RAPACID 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.
- if you need to go for tests for nervous system tumours your doctor will inform you to stop your RAPACID treatment as the active ingredient in RAPACID can interfere with these results.
- long-term safety of RAPACID in patients with kidney and liver problems has not been established.

- co-administration with atazanavir and nelfinavir (used in the treatment of HIV infection) is not recommended.
- long-term use of RAPACID has been associated with the formation of stomach glandular cysts (fluid-filled, closed sacs), but these appear to be non-cancerous and appear to be reversible on cessation of therapy.
- RAPACID can cause an increased risk of kidney disease leading to kidney failure. This is called tubulointerstitial nephritis and you may have increased urine output, blood in your urine or dark urine, changes in mental status, such as drowsiness or confusion, swelling of any area of your body.

Children and adolescents
There is limited experience in children with RAPACID.

Other medicines and RAPACID
Always tell your health care professional if you are taking any other medicine. (This includes complementary or traditional medicines.)
Tell your doctor if you are taking any of the following medicines:
- Ketoconazole, itraconazole, posaconazole or voriconazole (used to treat infections caused by a fungus).
- Erlotinib (used to treat cancer).
- Warfarin (used to thin your blood and prevent blood clots from forming).
- Diazepam (used to treat anxiety).
- Phenytoin (used to treat epilepsy).
- Digoxin (used to treat heart failure and a fast heartbeat).
- Rifampicin (used to treat tuberculosis).
- Saquinavir (used to treat HIV infection).
- Tacrolimus (in cases of organ transplantation).
- Clopidogrel and cilostazol (used to prevent blood clots (thrombi)).
- Methotrexate (used in the treatment of certain cancers and autoimmune diseases) if you are taking a high dose of methotrexate, your doctor may temporarily stop your RAPACID treatment.
- Nelfinavir, atazanavir

RAPACID with food and drink
RAPACID can be taken with or without food. Take RAPACID with at least half a glass of liquid.

Pregnancy and breastfeeding
Safety in pregnancy and breastfeeding has not been established (see section: ‘Do not take RAPACID’).
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.

Driving and using machines
Do not drive or operate any tools or machines, particularly at the start of therapy because RAPACID may lead to drowsiness and impaired concentration that may be aggravated by simultaneous intake of alcohol or other central nervous system depressants.
It is not always possible to predict to what extent RAPACID 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 RAPACID affects them.

RAPACID contains sucrose and mannitol
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.
Mannitol may have a mild laxative effect.

3. How to take RAPACID
Do not share medicines prescribed for you with any other person.
Always take RAPACID exactly as your doctor has instructed you. Check with your doctor or pharmacist if you are unsure.
RAPACID is recommended to be taken in the morning and swallowed whole with half a glass of liquid. The capsule should not be chewed or crushed.

Adults:
The usual dose is one or two 10 mg capsules daily. The maximum daily dose is 20 mg (2 x 10 mg capsules), and the maximum treatment period is 14 days. If your symptoms are not under control after 14 days of treatment, consult your doctor.
If you have the impression that the effect of RAPACID is too strong or too weak, talk to your doctor or pharmacist.

If you take more RAPACID than you should
Blurred vision, confusion, excessive sweating, redness of the face and neck, headache, unsettled stomach, general feeling of discomfort, vomiting, dizziness, lack of interest or desire, general feeling of sadness and increased rate of heartbeat have been reported from overdosage with RAPACID.
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 RAPACID
If you miss a dose, take it as soon as possible. However, if it is almost time for your next dose, skip the missed dose and go back to your regular schedule. Do not take a double dose of RAPACID to make up for forgotten individual doses.

4.Possible side effects
RAPACID can have side effects.
Not all side effects reported for RAPACID are included in this leaflet. Should your general health

worsen or if you experience any untoward effects while taking RAPACID, please consult your doctor, pharmacist or other health care professional for advice.

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

- Swelling of your hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing.
- Rash or itching.
- Fainting.
- Blistering of the skin, mouth, eyes, and genitals as these may be due to a serious allergic reaction known as Stevens-Johnson Syndrome (SJS), Toxic Epidermal Necrolysis (TEN), Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS) or Acute Generalized Exanthematous Pustulosis (AGEP).

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to RAPACID. 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*:*

- Liver problems, including jaundice, which can cause yellow skin, dark urine, and tiredness,
- Watery stools, abdominal pain and fever, as these can be signs of a serious stomach infection,
- If you lose weight for no reason and have problems swallowing,
- If you get stomach pain or indigestion,
- If you begin to vomit food or blood,
- If you pass black stools (blood-stained faeces),
- Fracture of the hip, wrists or spine,
- Painful urination and lower back pain as these may be symptoms of severe kidney problems, including kidney failure, (interstitial nephritis),
- Changes in blood count including agranulocytosis (lack of white blood cells). If you have an infection with symptoms such as fever with a severely reduced general condition or fever with symptoms of a local infection such as pain in the neck, throat or mouth or difficulties in urinating,
- You must consult your doctor as soon as possible so that a lack of white blood cells (agranulocytosis) can be ruled out by a blood test,
- Severe liver problems leading to liver failure and inflammation of the brain.

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

Tell your doctor if you notice any of the following:

Frequent side effects:

- Headache,
- feeling sick (nausea) or being sick (vomiting),
- stomach pain or colic (which could be benign polpys in the stomach).

Less frequent side effects:

- Blood problems, such as a reduced number of white cells or platelets. This can cause weakness, bruising or make infections more likely,
- feeling agitated, confused, or depressed,
- taste changes,
- dizziness, 'pins and needles' feeling on the skin, drowsiness, difficulty in sleeping,
- ringing in the ears,
- dry mouth,
- an inflammation on the inside of the mouth,
- an infection called "thrush", which can affect the gut and is caused by a fungus,
- hair loss (alopecia),
- skin rash on exposure to sunshine,
- joint pains (arthralgia) or muscle pains (myalgia),
- muscle weakness,
- increased sweating,
- sudden wheezing or shortness of breath (bronchospasm).
- inflammation in the gut (leading to diarrhoea),
- if you are on RAPACID 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,
- a feeling of general discomfort or uneasiness,
- the abnormal development of large breasts in males,
- swelling of the hands and feet due to water retention,
- spinning feeling (vertigo),
- eyesight problems,
- aggression,
- seeing, feeling or hearing things that are not there (hallucinations).

Frequency unknown:

- rash, possibly with pain in the joints.

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. 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**.**

5. How to store RAPACID

- Store all medicines out of reach of children.
- Store at or below 30 °C.
- Store in the original package to protect from moisture.
- Do not use after the expiry date printed on the label.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What RAPACID contains

The active substance is omeprazole.
RAPACID contains 10 mg omeprazole.

The other ingredients are disodium phosphate anhydrous, gelatin, hypromellose, macrogol 6000, maize starch, mannitol, methacrylic acid-ethyl acrylate copolymer, polysorbate 80, purified water, quinoline yellow (E104), sodium lauryl sulphate, sucrose, talc, titanium dioxide (E171).

What RAPACID looks like and contents of the pack

Opaque, yellow cap and body, No. 3 hard gelatin capsules, containing off-white (ivory) to cream-white spherical pellets.

RAPACID are packed in 14’s, and 28’s into either aluminium/aluminium thermoformed blister packs or opaque white HDPE piljars (containers) with white polypropylene caps containing a desiccant capsule and sealed with a tamper-evident ring.

Holder of Certificate of Registration

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SKEDULERINGSTATUS: S2

RAPACID 10 mg kapsule
Omeprazole

Bevat suiker: 54,5 mg sukrose
Bevat mannitol: 3,955 mg

Lees die hele voubiljet noukeurig voordat u begin om RAPACID te gebruik
RAPACID is beskikbaar sonder ’n doktersvoorskrif vir u om ’n matige toestand te behandel. U moet RAPACID nietemin steeds omsigtig gebruik om die beste resultate daaruit te kry.

- Hou hierdie voubiljet. U mag dit weer moet lees.
- Moenie RAPACID met enige ander persoon deel nie.
- Vra u gesondheidsorgverskaffer of apteker as u meer inligting of advies benodig.
- U moet ’n dokter raadpleeg as u simptome vererger of nie na 14 dae verbeter nie.

Wat in hierdie voubiljet is

1. Wat RAPACID is en waarvoor dit gebruik word

RAPACID is ’n protonpomp inhibeerder (PPI) en werk deur die hoeveelheid suur wat u maag produseer te verminder.
RAPACID word gebruik vir die tydelike, korttermyn verligting van sooibrand en hipersuurheid (oormatige suur).

2. Wat u moet weet voordat u RAPACID gebruik

Moenie RAPACID gebruik nie:

- as u hipersensitief (allergies) vir omeprazole of enige ander bestanddele van RAPACID (in afdeling 6 gelys) is,
- as u swanger is of borsvoed; veiligheid is nog nie vasgestel nie (sien swangerskap en borsvoeding),
- as u atazanavir of nelfinavir, wat vir die bestuur van MIV gebruik word, neem.

Waarskuwings en voorsorgmaatreëls

Neem spesiale sorg met RAPACID**:**

- as u lewerskade of -siekte het.
- as u erge of aanhoudende diarree ervaar, want RAPACID is met ’n effense toename in

aansteeklike diarree geassosieer. As u waterige stoelgang, maagpyn en koors ervaar terwyl u RAPACID gebruik moet u dadelik ’n gesondheidsorgverskaffer vir mediese bystand raadpleeg**.**

- as u ’n spesifieke bloedtoets (Chromogranin A) moet ondergaan,
- soek onmiddellike hulp as u onbeplande gewigsverlies, herhaaldelike braking, moeite om te sluk, braking van bloed of as u bloed in u stoelgang opmerk of u stoelgang is swart (bloederige ontlasting) ervaar. U dokter mag besluit dat u sekere toetse nodig het om kwaadaardige siekte uit te sluit want RAPACID verdoesel ook die simptome van kanker en kan vertraging van die diagnose veroorsaak. As u simptome aanhou ten spyte van u behandeling mag verdere ondersoeke oorweeg moet word.
- as u ernstige velreaksies wat blaasvorming en afskilfering as gevolg van Stevens-Johnson sindroom (SJS), Toksiese Epidermale Nekrolise (TEN), Geneesmiddelreaksie met Eosinofilie en Sistemiese Simptome (DRESS) en skielike voorkoms van rooi vel besaai met steriele pustules van speldekop-grootte (AGEP) ervaar; staak gebruik van RAPACID en soek onmiddellike mediese sorg.
- as u maagpyn of slegte spysvertering ervaar.
- vertel u dokter as u osteoporose het of kortikosteroïede (wat die risiko van osteoporose kan verhoog) gebruik aangesien die gebruik van RAPACID die risiko van fraktuur van die heup, gewrig of ruggraat kan verhoog.
- omeprazole, soos in RAPACID, word omvattend in die lewer gemetaboliseer en dit word aanbeveel dat die dosis verminder moet word in geval van lewerversaking.

Die volgende moet oorweeg word:

- RAPACID kan die opname van vitamien B12 (sianokobalamien) verminder. Dit moet oorweeg word by pasiënte met verminderde liggaamskapasiteit of risikofaktore vir verminderde vitamien B_{12}-opname tydens langtermyn-terapie.
- as letsels voorkom, veral in areas van die vel wat aan son blootgestel word, en as dit gepaard gaan met pyn in ’n gewrig, moet u dadelik mediese hulp soek en die gesondheidsorgverskaffer moet staking van gebruik van RAPACID oorweeg. Subakute kutane lupus eritematose (SCLE) (hierdie is abnormale velgroeisels wat droog is en as ringvormige velgroeisels ontwikkel) na vorige behandeling met ’n protonpomp-inhibeerder kan die risiko van SCLE met ander protonpomp-inhibeerders verhoog.
- as u RAPACID vir langer as drie maande gebruik is dit moontlik dat die vlakke van magnesium in u bloed kan daal. Lae vlakke van magnesium kan as moegheid, onwillekeurige spiersametrekking, disoriëntasie, stuiptrekkings, duiseligheid of vinniger hartklop ervaar word. Vertel asseblief dadelik u dokter as u enige van hierdie simptome ervaar. Lae vlakke van magnesium kan ook lei tot ’n verlaging van kalium- of kalsiumvlakke in dit bloed. U dokter kan besluit om gereelde bloedtoetse te doen om die magnesiumvlakke in u bloed te monitor.
- as u vir toetse vir senuweestelsel-gewasse moet gaan sal u dokter u beveel om behandeling met RAPACID te staak want die aktiewe bestanddeel van RAPACID kan met hierdie uitslae inmeng.

- langtermyn veiligheid van RAPACID in pasiënte met nier- en lewerprobleme is nie vasgestel nie.
- gesamentlike toediening met metatazanavir en nelfinavir (wat vir die behandeling van MIV-infeksie gebruik word) word nie aanbeveel nie.
- langtermyn gebruik van RAPACID word met die vorming van maagklier-siste (vloeistof-gevulde, toe sakke) geassosieer, maar dit blyk nie-kankeragtig te wees nie en is omkeerbaar met staking van behandeling.
- RAPACID kan die risiko van niersiekte wat tot nierversaking lei verhoog. Dit word tubulointerstisiële nefritis genoem en u kan verhoogde urinelating, bloed in u urine of donker urine, verandering in geestestoestand, soos lomerigheid of verwarring of swelling van enige area van u liggaam ervaar.

Kinders en adolessente
Daar is beperkte ondervinding met kinders en RAPACID.

Ander medisyne en RAPACID
Vertel altyd u gesondheidsorgverskaffer as u enige ander medisyne gebruik. (Dit sluit aanvullende en tradisionele medisyne in.)
Vertel u dokter as u enige van die volgende medisyne gebruik:
- Ketokonasool, itrakonasool, posakonasool of vorikonasool (wat vir die behandeling van swaminfeksies gebruik word).
- Erlotinib (wat vir kankerbehandeling gebruik word).
- Warfarin (wat gebruik word om u bloed te verdun en bloedklonte te voorkom).
- Diazepam (wat gebruik word om angstigheid te behandel).
- Phenytoin (wat vir behandeling van epilepsie gebruik word).
- Digoxin (wat gebruik word vir behandeling van hartversaking en vinnige hartklop).
- Rifampicin (wat gebruik word om tuberkulose te behandeling).
- Saquinavir (wat gebruik word om MIV-infeksie te behandeling).
- Tacrolimus (vir orgaanoorplanting-gevalle).
- Clopidogrel en cilostazol (om bloedklonte te voorkom).
- Methotrexate (wat vir die behandeling van sekere kankers en outo-imuunsiektes gebruik word). U dokter kan u behandeling met RAPACID tydelik staak as u ’n hoë dosis Methotrexate gebruik.
- Nelfinavir, atazanavir

RAPACID met kos en drank
RAPACID kan met of sonder kos geneem word. Neem RAPACID met ten minste ’n halwe glas vloeistof.

Swangerskap en borsvoeding
Veiligheid met swangerskap en borsvoeding is nie vasgestel nie (sien afdeling: ‘Moenie RAPACID gebruik nie’).
Raadpleeg asseblief u dokter, apteker of ander gesondheidsorgverskaffer as u swanger is of

borsvoed, dink u kan dalk swanger wees of beplan om ’n baba te hê.

Bestuur en bedryf van masjinerie
Moenie bestuur of enige gereedskap of masjiene bedryf nie, veral met aanvang van behandeling want RAPACID kan tot lomerigheid en verswakte konsentrasie lei wat met gelyktydige inname van alkohol of ander sentrale senuweestelsel-onderdrukkers vererger kan word.
Dit is nie altyd moontlik om te voorspel tot watter mate RAPACID met die pasiënt se daaglikse aktiwiteite kan inmeng nie. Pasiënte moet seker maak dat hulle nie aan die bogenoemde aktiwiteite deelneem tot hulle bewus is van die mate waartoe RAPACID hulle beïnvloed nie.

RAPACID bevat sukrose en mannitol
Kontak u dokter voor u hierdie medisinale produk gebruik as u dokter vir u gesê het dat u onverdraagsaamheid vir sommige suikers het.
Mannitol kan ’n lakseer-effek hê.

3. Hoe om RAPACID te gebruik
Moenie medisyne wat aan u voorgeskryf is met enige ander persoon deel nie.
Gebruik RAPACID altyd presies soos u dokter voorgeskryf het. Bevestig met u dokter of apteker as u onseker is.
Dit word aanbeveel dat RAPACID in die oggend gebruik word en heel met ’n halwe glas vloeistof gesluk word. Die kapsule moenie gekou of fyngedruk word nie.

Volwassenes:
Die gewone dosis is een of twee 10 mg kapsules per dag. Die maksimum daaglikse dosis is 20 mg (2 x 10 mg kapsules), en die maksimum behandelingstydperk is 14 dae. As u simptome nie na 14 dae onder beheer is nie, raadpleeg u dokter.
Praat met u dokter of apteker as u die indruk kry dat die uitwerking van RAPACID te sterk of te swak is.

As u meer RAPACID gebruik as wat u moet
Versteurde visie, verwarring, oormatige sweet, rooiheid van die gesig en nek, hoofpyn, omgekrapte maag, algemene gevoel van ongemak, braking, duiseligheid, gebrek aan belangstelling of begeerte, algemene gevoel van hartseer en verhoogde hartklop is aangemeld met oordosering van RAPACID.
Raadpleeg u dokter of apteker in die geval van oordosering. Kontak die naaste hospitaal of gifsentrum as nie een van hulle beskikbaar is nie.

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

4. Moontlike newe-effekte

RAPACID kan newe-effekte hê.
Nie alle newe-effekte wat vir RAPACID aangemeld is word in hierdie voubiljet ingesluit nie. As u algemene gesondheid versleg of u ervaar enige nadelige gevolge tydens gebruik van RAPACID, raadpleeg asseblief u dokter, apteker of ander gesondheidsorgverskaffer vir advies.

Staak gebruik van RAPACID as enige van die volgende gebeur en vertel u dokter onmiddellik of gaan na die ongevalle afdeling by u naaste hospitaal:

- Swelling van u hande, voete, enkels, gesig, lippe, mond of keel, wat dit moeilik maak om te sluk of asem te haal.
- Uitslag of jeuking.
- Floute.
- Blaasvorming van die vel, mond, oë en geslagsdele aangesien hierdie as gevolg van ’n ernstige allergiese reaksie bekend as Stevens-Johnson Sindroom (SJS), Toksiese Epidermale Nekrolise (TEN), Geneesmiddelreaksie met Eosinofilie en Sistemiese Simptome (DRESS) of Akute Veralgemeende Eksantematiese Pustulose (AGEP) kan wees.

Hierdie is almal baie ernstige newe-effekte. As u hulle ervaar kan u ’n baie ernstige allergiese reaksie vir RAPACID gehad het. U mag dringende mediese aandag of hospitalisasie benodig.

Vertel u dokter onmiddellik of gaan na die ongevalle afdeling by u naaste hospitaal as u enige van die volgende opmerk*:*

- Lewerprobleme, geelsug ingesluit, wat geel vel, donker urine en moegheid kan veroorsaak,
- Waterige stoelgange, maagpyn en koors, want hierdie kan tekens van ’n ernstige maaginfeksie wees.
- As u vir geen rede gewig verloor en u sluk moeilik.
- As u maagpyn of slegte spysvertering het.
- As u kos of bloed begin braak.
- As u swart stoelgange (bloederige ontlasting) passeer.
- Frakture van die heup, gewrigte of ruggraat.
- Pynlike urinering en lae-rugpyn, want hierdie kan simptome van ernstige nierprobleme, wat nierversaking insluit, (interstisiële nefritis) wees.
- Verandering in bloedtelling, insluitend agranulositose (tekort aan wit bloedselle). As u ’n infeksie met simptome soos koors met ’n erge verlies van algemene kondisie of koors met simptome van ’n plaaslike infeksie soos pyn in die nek, keel of mond het of moeite om te urineer ervaar.
- U moet u dokter so gou as moontlik raadpleeg sodat ’n tekort aan wit bloedselle (agranulositose) met ’n bloedtoets uitgeskakel kan word.
- Ernstige lewerprobleme wat tot lewerversaking lei, en inflammasie van die brein.

Hierdie is almal ernstige newe-effekte. U mag dringende mediese sorg nodig hê.

Vertel u dokter as u enige van die volgende opmerk:
Gereelde newe-effekte:

- Hoofpyn

- siek gevoel (naarheid) of siek wees (braking)
- maagpyn of koliek (wat nie-kwaadaardige poliepe in die maag kan wees)

Minder gereelde newe-effekte:

- bloedprobleme, soos 'n verminderde aantal wit bloedselle of plaatjies. Dit kan swakheid of kneusing veroorsaak of die moontlikheid van infeksies verhoog.
- gevoel van verontrusting, verwarring of depressie.
- verandering in smaak
- duiseligheid, 'naalde-en-spelde' gevoel op die vel, lomerigheid, moeite om te slaap.
- gesuis in die ore.
- droë mond.
- inflammasie aan die binnekant van die mond.
- 'n infeksie wat "sproei" genoem word, wat die derms kan beïnvloed en deur 'n swam veroorsaak word.
- haarverlies (alopesie).
- veluitslag by blootstelling tot sonlig.
- gewrigspyne (artralgie) of spierpyne (mialgie).
- spierswakheid.
- verhoging van sweet.
- skielike gehyg of kortasem (bronchospasma).
- Inflammasie in die derms (wat tot diarree lei).
- as u RAPACID vir langer as drie maande gebruik is dit moontlik dat die vlakke van magnesium in u bloed kan verlaag. Lae magnesium-vlakke kan as moegheid, onwillekeurige stuiptrekkings, duiseligheid, of vinniger hartklop voorkom. Vertel u dokter dadelik as u enige van hierdie simptome kry. Lae magnesiumvlakke kan ook tot 'n tekort aan kalium of kalsium in u bloed lei. U dokter kan besluit om gereelde bloedtoetse te doen om u magnesiumvlakke te monitor.
- 'n gevoel van algemene ongemak of onrustigheid.
- die abnormale ontwikkeling van groot borste in mans.
- swelling van die hande en voete as gevolg van waterretensie.
- dronk gevoel (vertigo).
- sigprobleme.
- aggressie.
- sien, voel en hoor goed wat nie daar is nie (hallusinasies).

Gereeldheid onbekend:

- uitslag, moontlik met pyn in die gewrigte.

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

Aanmeld van newe-effekte

Praat met u dokter of apteker as u newe-effekte ervaar. U kan newe-effekte ook by SAHPRA

aanmeld via die "**6.04 Adverse Drug Reaction Reporting Form**", aanlyn gevind onder SAHPRA se publikasies: https://www.sahpra.org.za/Publications/Index/8.
Deur newe-effekte aan te meld kan u help met meer inligting oor die veiligheid van RAPACID**.**

5. Hoe om RAPACID te bêre

- Bêre alle medisyne buite bereik van kinders.
- Bêre teen of laer as 30 °C.
- Bêre in die oorspronklike verpakking om teen vog te beskerm.
- Moenie na die vervaldatum soos op die etiket aangedui gebruik nie.
- Gee alle ongebruikte medisyne aan u apteker terug.
- Moenie ongebruikte medisyne in dreine en rioolstelsels (bv. toilette) afspoel nie.

6. Inhoud van die pak en ander inligting

Wat RAPACID bevat

Die aktiewe bestanddeel is omeprazole.
RAPACID bevat 10 mg omeprazole.

Die ander bestanddele is watervrye dinatriumfosfaat, gelatien, hipromellose, makrogool 6000, mieliestysel, mannitol, metakrielsuur-etielakrilaatkopolimee, polisorbaat 80, gesuiwerde water, kinolien geel (E104), natriumlaurielsulfaat, sukrose, talk, titaandioksied (E171).

Hoe RAPACID lyk en inhoud van die pak

Ondeursigtige, geel, No. 3 harde gelatien kapsules wat naaswit (ivoor) tot roomwit ronde korrels bevat.

RAPACID word verpak in 14's, en 28's in óf aluminium/aluminium-termovorm stulpverpakkings óf ondeursigtige wit HDPE buisies (houers) met wit polipropileen proppies, wat 'n droogmiddel kapsule bevat en met 'n peutervrye ring verseël is.

Houer van Registrasiesertifikaat

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Laaste hersiening van hierdie voubiljet

13 February 2024

Registrasienommer

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