PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S2

RAPACID 20, 20 mg**,** capsule
Omeprazole

Contains sugar: 116,30 mg sucrose
Contains mannitol: 7,91 mg

Read all of this leaflet carefully before you start taking RAPACID 20
RAPACID 20 is available without a doctor's prescription, for you to treat a mild illness. Nevertheless, you still need to use RAPACID 20 carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share RAPACID 20 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 20 is and what it is used for

RAPACID 20 is a proton pump inhibitor (PPI) and works by reducing the amount of acid that your stomach produces.
RAPACID 20 is indicated for the temporary, short-term relief of heartburn and hyperacidity (excessive acid).

2. What you need to know before you take RAPACID 20

Do not take RAPACID 20:

- if you are hypersensitive (allergic) to omeprazole or any of the other ingredients of RAPACID 20 (listed in section 6),
- if you are pregnant or breastfeeding; safety has not been established.
- if you are taking atazanavir or nelfinavir, used in the management of HIV.

Warnings and precautions

Take special care with RAPACID 20**:**

- if you have any liver damage or disease.
- if you experience severe or persistent diarrhoea, as RAPACID 20 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 20**.**

- 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, if you look pale or and feel weak (anaemia) 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 20 also alleviates the symptoms of cancer and could cause delay in diagnosing it.
- 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 20 and seek medical attention immediately.
- if you get stomach pain or indigestion.
- as using RAPACID 20 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 20, 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 20 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 20. 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 20 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 20 treatment as the active ingredient in RAPACID 20 can interfere with these results.
- long-term safety of RAPACID 20 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 20 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 20 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 20.

Other medicines and RAPACID 20
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 20 treatment.

RAPACID 20 with food and drink
RAPACID 20 can be taken with or without food. Take RAPACID 20 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 20’).
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 20 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 20 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 20 affects them.

RAPACID 20 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 20

Do not share your medicines with any other person. Always take RAPACID 20 exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.
RAPACID 20 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 20 mg (one capsule) daily.
The maximum daily dose is 20 mg (one 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 20 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 20.

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 20 to make up for forgotten individual doses.

4. Possible side effects

RAPACID 20 can have side effects.
Not all side effects reported for RAPACID 20 are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking RAPACID 20, please

consult your doctor, pharmacist or other health care professional for advice.

If any of the following happens, stop taking RAPACID 20 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 20. 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 polyps in the stomach).

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 20**.**

5. How to store RAPACID 20

- 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).

Contents of the pack and other information

What RAPACID 20 contains
The active substance is omeprazole.
RAPACID 20 contains 20 mg omeprazole.
The other ingredients are disodium phosphate, 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 20 looks like and contents of the pack
Opaque, yellow cap and body, no. 2 hard gelatin capsules, containing off-white (ivory) to cream-white spherical pellets.

RAPACID 20 is packed into an opaque white HDPE piljar (container) with a white polypropylene cap containing a desiccant capsule and sealed with a tamper-evident ring or into an aluminium/aluminium thermoformed blister pack.
Pack size: 14 capsules

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PASIËNTINLIGTINGSVOUBILJET

SKEDULERINGSTATUS: S2

RAPACID 20, 20 mg**,** kapsule
Omeprasool

Bevat suiker: 116,30 mg sukrose
Bevat mannitol: 7,91mg

Lees die hele voubiljet noukeurig voordat u begin om RAPACID 20 te gebruik
RAPACID 20 is beskikbaar sonder 'n dokter se voorskrif, vir u om 'n ligte siekte te behandel. U moet egter steeds RAPACID 20 versigtig gebruik om die beste resultate daaruit te kry.

- Hou hierdie voubiljet U mag dit weer moet lees
- Moet nie RAPACID 20 met enige ander persoon deel nie.
- Vra u gesondheidsorgverskaffer of apteker as u meer inligting of advies nodig het.
- Raadpleeg u dokter as u simptome na 14 dae vererger of nie verbeter nie.

Wat is in hierdie voubiljet

1. Wat RAPACID 20 is en waarvoor dit gebruik word.

RAPACID 20 is 'n protonpomp-inhibeerder (PPI) en werk deur die hoeveelheid suur wat u maag produseer te verminder.
RAPACID 20 word aangedui vir tydelike, kort-termyn verligting van sooibrand en hiperasiditeit (oormatige suur).

2. Wat u moet weet voordat u RAPACID 20 gebruik.

Moet nie RAPACID 20 gebruik:

- as u allergies is (hipersensitief) vir omeprazool of enige van die ander bestanddele van RAPACID 20 (wat in afdeling 6 gelys word),
- as u swanger of borsvoedend is; veiligheid is nie vasgestel nie.
- as u atazanavir of nelfinavir neem, wat gebruik word in die behandeling van MIV.

Waarskuwings en voorsorgmaatreëls
Neem spesiale sorg met RAPACID 20:

- as u lewerskade of -siekte het.
- as u erge of aanhoudende diarree ervaar, aangesien RAPACID 20 geassosieer word met 'n klein toename in aansteeklike diarree. U moet onmiddellik hulp van 'n gesondheidswerker aanvra indien u waterige stoelgang, buikpyn en koors ervaar terwyl u

RAPACID 20 gebruik.

- as u 'n spesifieke bloedtoets (Chromogranien A) moet ondergaan, moet u onmiddellik sorg inwin as u onbedoelde gewigsverlies, herhaalde braking, probleme met sluk, braking van bloed, as u bleek lyk en of swak voel (anemie) of as u bloed in u stoelgang opmerk of u stoelgang swart lyk (bloedbevlekte ontlasting). U dokter kan besluit dat u toetse benodig om kwaadaardige siektes uit te sluit, omdat RAPACID 20 ook die simptome van kanker verlig en vertraging in die diagnose daarvan kan veroorsaak.
- as u erge velreaksies insluitend blaasvroming en skilvering van die vel ervaar wat mag voorkom as gevolg van Stevens-Johnson-sindroom (SJS), Toksiese Epidermale Nekrolise (TEN), Geneesmiddelreaksie met Eosinofilie en sistemiese simptome (DRESS) en snelle voorkoms van areas met rooi vel uitgevoer met speldekop-grootte sterile pustules (AGEP); hou op om RAPACID 20 te gebruik en soek onmiddelik mediese hulp.
- as u maagpyn of indigestie kry.
- siende dat die gebruik van RAPACID 20 u risiko van fraktuur in die heup, gewrig of ruggraat kan verhoog. Stel u dokter in kennis as u osteoporose het of as u kortikosteroïede neem (wat die risiko van osteoporose kan verhoog).
- omeprasool, soos in RAPACID 20, word op groot skaal in die lewer gemetaboliseer en dit word aanbeveel dat die dosis by lewerskade verminder moet word.

Die volgende moet in aanmerking geneem word:

- RAPACID 20 kan die opname van vitamien B12 (sianokobalamien) verminder. Dit moet in ag geneem word by pasiënte met verminderde liggaamstore of risikofaktore vir verminderde vitamien B12-absorpsie op langtermynterapie.
- as letsels voorkom, veral in sonblootgestelde dele van die vel, en as dit gepaard gaan met pyn in 'n gewrig, moet u dadelik mediese hulp soek en die gesondheidsorgverskaffer moet dit oorweeg om RAPACID 20 te staak. Subakute kutane lupus eritematose (SCLE) (dit is abnormale velgroeisel wat droog is en ontwikkel as ringvormige velgroeisels) na vorige behandeling met 'n protonpomp inhibeerder kan die risiko van SCLE met ander protonpomp inhibeerders verhoog.
- as u langer as drie maande op RAPACID 20 is, is dit moontlik dat die vlakke van magnesium in u bloed kan daal. Lae vlakke van magnesium kan gesien word as moegheid, onwillekeurige spierkontraksies, disoriëntasie, stuiptrekkings, duiseligheid of verhoogde harttempo. As u enige van hierdie simptome kry, vertel onmiddellik u dokter. Lae vlakke van magnesium kan ook lei tot 'n afname in kalium- of kalsiumvlakke in die bloed. U dokter kan besluit om gereelde bloedtoetse uit te voer om u magnesiumvlakke te monitor.
- as u nodig het om te gaan vir toetse vir senuweestelselgewasse sal u dokter u inlig om u RAPACID 20 behandeling te staak 20 omdat die aktiewe bestanddeel in RAPACID 20 met hierdie resultate kan inmeng.
- langtermynveiligheid van RAPACID 20 by pasiënte met nier- en lewerprobleme is nie vasgestel nie.
- mede-toediening met atazanavir en nelfinavir (gebruik in die behandeling van MIV-infeksie) word nie aanbeveel nie.

- die langtermyn gebruik van RAPACID 20 is geassosieer met die vorming van maagklier siste (vloeistof gevulde, geslote sakke), maar dit blyk nie kankeragtig te wees nie en blyk omkeerbaar te wees by die beëindiging van terapie.
- RAPACID 20 kan 'n verhoogde risiko van niersiekte veroorsaak wat lei tot nierversaking. Dit word tubulointerstisiële nefritis genoem en u mag verhoogde urinering, bloed in u urine of donker urine, verandering in gemoedstoestand, soos lomerigheid of verwardheid, swelling van enige area van u liggaam hê.

Kinders en tieners
Daar is beperkte ervaring in kinders met RAPACID 20.

Ander medisyne en RAPACID 20
Vergewis altyd u gesondheidswerker as u enige ander medisyne gebruik. (Dit sluit komplementêre of tradisionele medisyne in.)
Vertel u dokter as u enige van die volgende medikasie gebruik:

- Ketokonasool, itrakonasool, posakonasool or vorikonasool (gebruik om infeksies wat deur 'n fungus veroorsaak word te behandel).
- Erlotinib (gebruik om kanker te behandel).
- Warfarien (gebruik om u bloed te verdun en om bloedklontvorming te verhoed).
- Diazepam (gebruik om angstigheid te behandel).
- Phenytoin (gebruik om epilepsie te behandel).
- Digoxien (gebruik om hartversaking en vinnige hartklop te behandel).
- Rifampicin (gebruik om tuberkulose te behandel).
- Saquinavir (gebruik om MIV-infeksie te behandel).
- Tacrolimus (in gevalle van orgaanoorplanting).
- Clopidogrel en cilostazol (gebruik om bloedklontvorming (trombi) te voorkom).
- Methotrexate (gebruik in die behandeling van sekere kankers en outo-immuunsiektes) indien u hoë dosisse van methotrexate neem, mag u dokter tydelik u RAPACID 20 behandeling staak.

RAPACID 20 met kos en drank
RAPACID 20 kan met of sonder kos geneem word. Neem RAPACID 20 met ten minste 'n halwe glas vloeistof.

Swangerskap en borsvoeding
Die veiligheid in swanerskap en borsvoeding is nie vasgestel nie (sien afdeling: ‘Moet nie RAPACID 20 neem’).
As u swanger is of borsvoed, dink u is dalk swanger of beplan om 'n baba te hê, raadpleeg asseblief u dokter, apteker of ander gesondheidsorgverskaffer vir advies voordat u hierdie medisyne gebruik.

Bestuur en gebruik van masjinerie
Moet nie bestuur of enige gereerdskap of masjinerie gebruik nie, veral aan die begin van

terapie omdat RAPACID 20 mag lei tot lomerigheid en verswakte konsentrasie wat vererger kan word deur gelyktydige inname van alkohol of ander sentrale senuweestelsel-onderdrukkers.
Dit is nie altyd moontlik om te voorspel tot watter mate RAPACID 20 met die daaglikse aktiwiteite van 'n pasiënt kan inmeng nie. Pasiënte moet seker maak dat hulle nie aan die bogenoemde aktiwiteite deelneem totdat hulle bewus is van die mate waartoe RAPACID 20 hulle affekteer nie.

RAPACID 20 bevat sukrose en mannitol
Indien u deur u dokter in kennis gestel is dat u onverdraagsaamheid het teenoor sommige suikers, kontak u dokter voordat u hierdie mediese produk gebruik.
Mannitol mag 'n ligte lakseermiddeleffek hê.

3. Hoe om RAPACID 20 te neem

Moet nie u medikasie met enige ander persoon deel nie. Neem altyd RAPACID 20 presies soos u dokter u aangesê het. Kontroleer met u dokter of apteker as u onseker is.
Dit word aanbeveel om RAPACID 20 in die oggend te neem en heel in te sluk saam met ;n halwe glas vloeistof. Die kapsule moet nie gekou of fyngedruk word nie.

Volwassenes:
Die algemene dosis is 20 mg (een kapsule) daagliks.
Die maksimum daaglikse dosis is 20 mg (een kapsule) en die maksimum behandelingsperiode is 14 dae.
Indien u simptome nie onder beheer is na 14 dae se behandeling nie, raadpleeg u dokter.
As u die indruk het dat die effek van RAPACID 20 te sterk of te swak is, praat met u dokter of apteker.

As u meer RAPACID neem as wat u moet
Dowwe visie, verwardheid, oormatige sweet, rooiheid van die gesig en nek, hoofpyn, omgekrapde maag, algemene gevoel van ongemak, vomering, duiseligheid, gebrek aan belangstelling of begeerte, algemene gevoel van hartseer en verhoogde harttempo of hartklop is aangemeld as gevolg van oordosering met RAPACID 20.

In die geval van oordosering, raadpleeg u dokter of apteker. As geen een beskikbaar is nie, kontak die naaste hospitaal of gifsentrum.

As u vergeet om RAPACID te neem
As u 'n dosis mis, neem dit so gou as moontlik. As dit egter amper tyd is vir u volgende dosis, slaan die gemiste dosis oor en gaan terug na u gewone skedule. Moet nie 'n dubbeldosis of RAPACID 20 neem om vergete individuele dosisse in te haal nie.

4. Moontlike newe-effekte

RAPACID 20 kan newe-effekte hê.

Nie alle newe-effekte wat aangemeld word vir RAPACID 20 word in hierdie voubiljet ingesluit nie. Indien u algemene gesondheid vererger of as u enige ongunstige effekte ervaar terwyl u RAPACID 20 gebruik, raadpleeg asseblief u dokter, apteker of ander gesondheidsorgverskaffer vir advies.

Indien enige van die volgende plaasvind, hou op om RAPACID 20 te neem en sê 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 moeilike sluk of asemhaling mag veroorsaak.
- Uitslag of jeuk.
- Floute.
- Blaasvorming van die vel, mond, oë, en geslagsdele, aangesien dit as gevolg van 'n ernstige allergiese reaksie kan wees bekend as Stevens-Johnson-sindroom (SJS), Toksiese Epidermale Nekrolise (TEN), Geneesmiddelreaksie met Eosinofilie en Sistemiese Simptome (DRESS) of Akute Veralgemeende Eksantematiese Pustulose (AGEP).

Al hierdie is uiters ernstige newe-effekte. Indien u hulle het, mag u moontlik 'n enstige allergiese reaksie op RAPACID 20 gehad het. U mag dringende mediese aandag of hospitalisering nodig hê.

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

- Lewerprobleme, insluitend geelsug, wat geel vel, donker urine, en moegheid kan veroorsaak,
- waterige stoelgang, abdominale pyn en koors, omdat hierdie tekens kan wees van ernstige maaginfeksie,
- as u vir geen rede gewig verloor en moeilike sluk ervaar,
- as u maagpyn of indigestie kry,
- as u begin om kos of bloed te vomeer,
- as u swart stoelgang (bloedbevlekte ontlasting) het,
- fraktuur van die heup, gewrigte of ruggraat,
- pynlike urinering en lae rugpyn omdat hierdie simptome mag wees van ernstige nierprobleme, insluitend nierversaking, (interstisiële nefritis),
- verandering in bloedtelling insluitend agranulositose (tekort aan witbloedselle). Indien u 'n infeksie het met simptome soos koors met ernstige verswakte algemene toestand of koors met simptome van 'n lokale infeksie soos pyn in die nek, keel of mond of moeilike urinering,
- moet u, u dokter so gou as moontlik besoek sodat 'n tekort aan witbloedselle (agranulositose) uitgesksakel kan word deur 'n bloedtoets,
- enstige lewerprobleme wat lei tot lewerversaking en inflammasie van die brein.

Al hierdie is ernstige newe-effekte. U mag dringende mediese aandag nodig hê.

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

- Hoofpyn,

- naar voel (naarheid) of opgooi (vomering),
- maagpyn of koliek (wat benigne poliepe in die maag kan wees).

Aanmeld van newe-effekte
As u newe-effekte ervaar, praat met u dokter of apteker. U kan ook newe-effekte aan SAHPRA rapporteer via die "6.04 Adverse Drug Reaction Reporting Form", wat aanlyn gevind 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 20 **te verskaf.**

5. Hoe om RAPACID 20 te bêre
- Bêre alle medisyne buite bereik van kinders
- Bêre teen of laer as 30 °C
- Bêre in die oorspronklike verpakking om teen vogtigheid te beskerm.
- Moet nie na die vervaldatum, soos gedruk op die etiket, gebruik nie.
- Besorg alle ongebruikte medisyne terug aan u apteker.
- Moet nie ongebruikte medisyne in dreine of rioolstelsels (bv. toilette) weggooi nie.

Inhoud van die pak en ander inligting
Wat RAPACID 20 bevat
Die aktiewe bestanddeel is omeprasool.
RAPACID 20 bevat 20 mg omeprasool.
Die ander bestanddele is dinatriumfosfaat, gelatien, hipromellose, makrogol 6000, mieliestysel, mannitol, metakrielsuur-etielakrilaatkopolimeer, polisorbaat 80, gesuiwerde water, kinoliengeel (E104), natriumlaurielsulfaat, sukrose, talk, titaandioksied (E171).

Hoe RAPACID 20 lyk en die inhoud van die pak:
Ondeursigtige, geel dop en liggaam, no. 2 harde gelatienkapsules, wat naaswit (ivoor) tot roomwit sferiese korrels bevat.

RAPACID 20 word verpak in 'n ondeursigtige wit HDPE pillebottel (houer) met 'n wit polipropileen dop wat 'n droogmiddel kapsule bevat en verseël is met 'n peuter-duidelike ring of in 'n aluminium/aluminium-termogevormde drukblasieverpakking.
Pak grootte: 14 kapsules

Houer van registrasiesertifikaat
Adcock Ingram Beperk
1 New Road
Erand Gardens
Midrand, 1685
Klantediens: 0860 ADCOCK / 232625

PASIËNTINLIGTINGSVOUBILJET

Laaste hersiening van die voubiljet
13 Februarie 2024

Registrasienommer:
37/11.4.3/0228

adcock ingram

916791-01 & 916792-01
01/2025

Datum van goedkeuring: 13 Februarie 2024