SCHEDULING STATUS
S3

MYPRODOL CAPSULES, **10 mg/200 mg/250 mg, capsules**
Codeine phosphate, ibuprofen, paracetamol

Each capsule contains 10 mg Codeine phosphate, 200 mg ibuprofen and 250 mg paracetamol.
Sugar free

Read all of this leaflet carefully before you start taking MYPRODOL CAPSULES

- 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.
- MYPRODOL CAPSULES have 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.
- You must see a doctor if your symptoms worsen or do not improve after three days.

What is in this leaflet

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

1. What MYPRODOL CAPSULES is and what it is used for

This medicine contains Codeine. Codeine belongs to a group of medicines called opioid analgesics which act to relieve pain.
This medicine also contains Ibuprofen. Ibuprofen, a non-steroidal anti-inflammatory medicine (NSAID), also acts to reduce swelling (inflammation).
This medicine also contains paracetamol. Paracetamol, an analgesic, acts to relieve pain.

This medicine can be used for the short-term treatment of mild to moderate pain (with or without fever).

2. What you need to know before you take MYPRODOL CAPSULES

Do not take MYPRODOL CAPSULES

- If you are hypersensitive (allergic) to codeine, ibuprofen or paracetamol or any of the other ingredients of MYPRODOL CAPSULES (listed in section 6).
- If you have liver or kidney problems.
- If you have heart failure.
- If you have had a bleeding stomach ulcer after taking a non-steroidal anti-inflammatory

medicine (NSAID) (you may have been sick and it contained blood or dark particles that look like coffee grounds, passed blood in your stools or passed black tarry stools).
- If you have a stomach ulcer, perforation or bleeding from the ulcer, or have had an ulcer in the past.
- If you have had a condition called cardiovascular disease (you may have had chest pain, or tightness, or discomfort, shortness of breath; or pain, numbness, weakness or coldness in your legs or arms if the blood vessels in those parts of your body are narrowed; or you might have had a blood clot).
- If you have difficulty breathing or breathing problems.
- If you have had an operation on the biliary tract.
- If you regularly drink large quantities of alcohol.
- If you have had head injuries or have a condition where the pressure inside your skull is high.
- If you are taking medicines to treat depression or bipolar disorder called monoamine oxidase inhibitors or have stopped taking these medicines within the last 14 days.
- If you are taking medicine known as blood thinners.
- If you have had an allergic-type reaction after taking aspirin.
- If you are pregnant, avoid use of NSAIDs, including MYPRODOL CAPSULES at 30 weeks or later in your pregnancy, because these medicines may cause problems in your unborn baby.

Warnings and precautions

Do not use continuously for more than 10 days without consulting a doctor.

Note that the safety of continuous use of MYPRODOL CAPSULES for more than four weeks has not been proven and is therefore seen as unsafe to use it for longer than four weeks.

Take special care with MYPRODOL CAPSULES:
Codeine
- If you use more than what you should or for longer periods, as it can cause dependence and addiction to MYPRODOL CAPSULES.

Ibuprofen
- If you have a history of high blood pressure and/or heart failure as MYPRODOL CAPSULES may cause water retention and swelling, and may also cause heart failure if you are prone to water retention.
- If you are an elderly person, as you have an increased chance to experience adverse reactions to NSAIDs including MYPRODOL CAPSULES, especially sores on the inside lining of your stomach and intestine and bleeding that can be life threatening.
- If you have had an ulcer, perforation or bleeding of the gastrointestinal tract as you are at the risk of this to happen again with increasing doses of MYPRODOL CAPSULES. When gastrointestinal bleeding or ulceration occurs in patients receiving MYPRODOL CAPSULES, stop taking MYPRODOL CAPSULES and go to your doctor, pharmacist or other health care provider.

- If you have had gastrointestinal disease (e.g. ulcerative colitis, (inflammation and sores in your digestive tract), Crohn's disease (inflammation of your digestive track), hiatus hernia (stomach pushing through an opening in the diaphragm), gastroesophageal reflux disease (stomach acid flows back into the tube connecting your mouth and stomach)), as MYPRODOL CAPSULES can cause these conditions to worsen.
- If you have severe cutaneous adverse reactions (SCARS) or serious skin reaction, including peeling and blistering of the skin. The peeling may progress quickly, resulting in large raw areas that may ooze or weep (e.g. Stevens-Johnson syndrome). Stop taking MYPRODOL CAPSULES at the first appearance of skin rash, or any other sign of hypersensitivity and go to your doctor or nearest hospital.
- Tell your doctor or health care provider if you are pregnant or plan to become pregnant. Taking NSAIDs at around 20 weeks of pregnancy or later may harm your unborn baby. If you need to take NSAIDs when you are between 20 and 30 weeks of your pregnancy, your healthcare provider may need to monitor the amount of fluid in your womb around your baby. You should not take NSAIDs around 30 weeks of pregnancy or later.
- If you develop a fever, skin rash, swelling of the lymph nodes and/or swelling of the face. This is known as Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS). Stop taking MYPRODOL CAPSULES and go to your doctor or nearest hospital, as this can be life threatening.

Paracetamol

- MYPRODOL CAPSULES contains paracetamol which may be fatal if you take a higher dose than you should. In the event of overdosage or if you suspect that you have taken more than you should, even if you do not have any symptoms of an overdose, go to your nearest doctor, hospital or Poison Centre must immediately.
- If you take more paracetamol as in MYPRODOL CAPSULES, you may cause your liver to be severely damaged.
- Serious skin reactions such as toxic epidermal necrolysis (TEN), Stevens-Johnson syndrome (SJS), acute generalised exanthematous pustulosis (AGEP), eosinophilia and systemic (DRESS)/Drug-induced hypersensitivity syndrome (DIHS) and fixed drug eruptions (FDE), have been reported in patients receiving paracetamol. If you experience any signs of serious skin reactions such as swelling, itching, red severe rash, stop using MYPRODOL CAPSULES immediately and contact your doctor (see Section 4).
- Do not use continuously for more than 10 days without consulting a doctor

Children and adolescents

Do not give MYPRODOL CAPSULES to children under the ages of 12 years.

Other medicines and MYPRODOL CAPSULES

Always tell your health care provider if you are taking any other medicine.
(This includes all complementary or traditional medicines.)

- NSAIDs and the use of two or more NSAIDs together with MYPRODOL CAPSULES could result in you having more side effects.
- Corticosteroids (medicines that lower inflammation in your body) as

MYPRODOL CAPSULES together with these medicines can increase your risk to have peptic ulcers (open sores that develop on the inside lining of your **stomach** and the upper portion of your small intestine) and bleeding.

- Anticoagulants (medicines that help to prevent blood clots, e.g. apixaban, dabigatran, edoxaban, rivaroxaban, warfarin. MYPRODOL CAPSULES may make the effects of these medicines stronger.
- Antiplatelet medicines (e.g., clopidogrel, ticagrelor, prasugrel dipyridamole or aspirin to name a few) and selective serotonin reuptake inhibitors (SSRIs) (used to treat depression, e.g., escitalopram, fluoxetine, paroxetine to name a few) as it might increase your risk of gastrointestinal bleeding.

MYPRODOL CAPSULES with food, drink and alcohol
Do not drink alcohol (wine, beer, spirits) whilst taking this medicine.

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 MYPRODOL CAPSULES.
You should not take MYPRODOL CAPSULES when you are pregnant or breastfeeding.
Use of NSAIDs (as in MYPRODOL CAPSULES) during the third trimester of pregnancy may result in breathing problems of your newborn child.

Fertility
No data on male and female fertility are available

Driving and using machines
It is not always possible to predict to what extent MYPRODOL CAPSULES may interfere with your daily activities. MYPRODOL CAPSULES may make you feel dizzy or sleepy. 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 MYPRODOL CAPSULES affects you.

MYPRODOL CAPSULES contain colourants which may cause allergic reactions see section 6.

3. How to take MYPRODOL CAPSULES
Do not share medicines prescribed for you with any other person.
Always take MYPRODOL CAPSULES exactly as your doctor or pharmacist has told you.
Check with your doctor or pharmacist if you are not sure
DO NOT EXCEED THE RECOMMENDED DOSE.

The usual dose for adults and children over the age of 12 years is:
One to two capsules four hourly and not more than twelve capsules per twenty-four hours.
Start with the lowest effective dose for the shortest possible time. Swallow each capsule with water.
Talk to your doctor if you do not feel better with the recommended dosage.

If you take more MYPRODOL CAPSULES than you should
In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.
Immediate medical attention is critical. Even if you do not show symptoms of an overdose, go immediately to your nearest hospital or Poison Centre.
MYPRODOL CAPSULES contains paracetamol and an overdose, can be fatal.
The symptoms of an overdose can include nausea, stomach pain, loss of appetite, vomiting (may be blood streaked), ringing in the ears, excitement, convulsions (mainly in children), and breathing problems.

If you forget to take MYPRODOL CAPSULES
It is important to take MYPRODOL CAPSULES as your doctor has prescribed. If you miss a dose, resume your usual schedule the following day. Do not take a double dose to make up for forgotten individual doses.

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

If any of the following happens, stop taking MYPRODOL CAPSULES and tell your doctor immediately or go to the casualty department at your nearest hospital:
- Rashes, including peeling and blistering of the skin. The peeling may progress quickly, resulting in large raw areas that may ooze or weep (e.g. Stevens-Johnson syndrome).
- Swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing.
- Bronchospasm (difficult to breath and cause wheezing).
- Fever, skin rash, swelling of the lymph nodes and/or swelling of the face (also known as DRESS).

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

Codeine
- Mood changes, restlessness, confusion,
- Drowsiness,
- Feeling dizzy (vertigo),
- Small pupils (miosis),
- Irregular heartbeat (palpitations) and slow heartbeat,
- A sudden drop in blood pressure when you stand up (orthostatic hypotension),
- Pressure in your skull,
- Facial flushing,
- Low body temperature,
- Nausea, vomiting, constipation, dry mouth,
- Sweating, hives (urticaria), itching,
- Pain in your liver and/or gallbladder (biliary spasm),

- Difficulty in emptying your bladder.

Ibuprofen

- Hypersensitivity (e.g., fever, swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallow or breathing),
- Dizziness,
- Nausea, vomiting, ulcers in the stomach or intestine, bleeding in the gastrointestinal tract, diarrhoea, passing of wind, constipation, indigestion, blood in your stools, vomiting of blood, gastritis and pain in the abdomen.
- Low blood cells, may cause tiredness, easy bruising, frequent nose bleeds and increased risk of infections,
- Nervousness, depression, drowsiness, sleeplessness (insomnia),
- Change in your vision,
- Ringing in your ears (tinnitus),
- Oedema, high blood pressure, heart failure,
- Abnormal liver function tests,
- Blistering of the skin, severe skin reaction can occur including Stevens-Johnson syndrome and toxic epidermal necrolysis. Symptoms includes skin rash, blistering and peeling of the skin,
- Drug Reaction with Eosinophilia and Systemic Symptoms (DRESS) (for details on this condition, please refer to serious side effects above and section 2, ‘Warnings and precautions’),
- Reduction of kidney function.

Paracetamol

- Changes in your blood counts and cells.
- Sensitivity reactions, usually in the form of skin rashes (which will disappear if you stop using MYPRODOL CAPSULES).
- Mouth ulcers, cold sores and ulcers or soreness of your tongue
- Skin lumps or hives (raised, red or white, itchy patches of skin)
- Blisters on your skin or inside your mouth, nose, vagina or bottom
- The appearance of a rash or sunburn when you have been outside (even on a cloudy day)
- swelling of the eyelids, face, tongue or lips
- severe dizziness
- difficulty in breathing
- Serious skin reactions such as swelling, itching, red severe rash especially those covering your whole body (appearing as allergic wheals), stop giving MYPRODOL CAPSULES immediately and contact your doctor (see Section 2).

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 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 MYPRODOL CAPSULES.

5. How to store MYPRODOL CAPSULES

Store all medicines out of reach of children.

- Store at or below 25 °C in a well-closed container.
- Do not use after the expiry date stated on the label/carton/blister.
- 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 MYPRODOL CAPSULES contains

The active substances are codeine phosphate 10 mg, ibuprofen 200 mg and paracetamol 250 mg.
The other ingredients are colloidal silica, magnesium stearate, maize starch, potassium sorbate, hard gelatin capsule (capsule shell: opaque green cap, opaque red body, printing ink).
Capsule shell colourants are brilliant blue FCF (E133), erythrosine (E127), quinoline yellow (E104), sunset yellow (E110) and titanium dioxide (E171).

What MYPRODOL CAPSULES looks like and contents of the pack

Hard gelatin capsule of size '0'. The cap is opaque green and the body is opaque red. "RIO" is printed in black on both the cap and body. Contents of the capsule are fine white granular powder.

Content of the packaging

- A white polypropylene securitainer with a low-density polyethylene (LDPE) lid or a white high density polyethylene container with a high-density polyethylene (HDPE) screw cap containing 30 capsules.
- Push through clear PVC and aluminium blister packs of 10 capsules in unit cartons of 10, 30, 60 or 100 capsules.
- Not all pack sizes may be marketed

Holder of Certificate of Registration

Adcock Ingram Limited
1 New Road, Erand Gardens
Midrand
1685

Customer Care: 0860 ADCOCK / 232625

This leaflet was last revised in

18 October 2024

Registration number
T/2.8/244

Botswana (S3): BOT2404232/A/B/C
Namibia (NS2): 90/2.8/00146

SKEDULERINGSTATUS
S3

MYPRODOL CAPSULES, **10 mg/200 mg/250 mg, kapsules**
Kodeïenfosfaat, ibuprofeen, parasetamol

Elke kapsule bevat 10 mg kodeïenfosfaat, 200 mg ibuprofeen en 250 mg parasetamol.
Suikervry

Lees hierdie hele biljet noukeurig deur voordat u MYPRODOL CAPSULES begin neem

- Hou hierdie biljet. U sal dit dalk weer moet lees.
- Indien u verdere vrae het, raadpleeg asseblief u dokter, apteker, verpleegkundige of ander gesondheidsorgverskaffer.
- MYPRODOL CAPSULES is aan u persoonlik voorgeskryf en u moet nie u medisyne met ander mense deel nie. Dit kan hulle benadeel, selfs al ervaar hul dieselfde simptome as u.
- U moet 'n dokter spreek indien u simptome vererger, of nie na drie dae verbeter nie.

Wat in hierdie biljet is

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

1. Wat MYPRODOL KAPSULES is en waarvoor dit gebruik word

Hierdie medisyne bevat kodeïen. Kodeïen behoort tot 'n groep medisyne genaamd opioïed-analgetika wat gebruik word om pyn te verlig.
Hierdie medisyne bevat ook ibuprofeen. Ibuprofeen, 'n nie-steroïed anti-inflammatoriese medisyne (NSAIM), werk ook deur swelling (inflammasie) te verminder.
Hierdie medisyne bevat ook parasetamol. Parasetamol, 'n analgetikum, werk om pyn te verlig.

Hierdie medisyne kan gebruik word vir die korttermyn-behandeling van ligte tot matige pyn (met of sonder koors).

2. Wat u moet weet voordat u MYPRODOL CAPSULES neem

Moenie MYPRODOL CAPSULES neem nie

- Indien u hipersensitief (allergies) is vir kodeïen, ibuprofeen of parasetamol, of enige van die ander bestanddele van MYPRODOL CAPSULES (gelys in afdeling 6).
- Indien u lewer- of nierprobleme het.
- Indien u hartversaking het.
- Indien u 'n bloeiende maagseer gehad het nadat u 'n nie-steroïed anti-inflammatoriese medisyne (NSAIM) geneem het (u was dalk naar en dit het bloed of donker deeltjies bevat

wat soos gemaalde koffie lyk, daar was bloed in u stoelgang of swart teeragtige stoelgang).
- Indien u 'n maagseer, perforasie of bloeding van die maagseer het, of in die verlede 'n maagseer gehad het.
- Indien u 'n toestand gehad het wat kardiovaskulêre siekte genoem word (u het dalk borspyn gehad, of benoudheid, of ongemak, kortasem; of pyn, gevoelloosheid, swakheid of koue in u bene of arms as die bloedvate in daardie dele van u liggaam vernou is; of u het dalk 'n bloedklont gehad).
- Indien u sukkel om asem te haal, of asemhalingsprobleme het.
- Indien u 'n operasie aan die galweg gehad het.
- Indien u gereeld groot hoeveelhede alkohol drink.
- Indien u kopbeserings gehad het of 'n toestand het waar die druk in u skedel hoog is.
- Indien u medisyne neem om depressie of bipolêre versteuring, genaamd monoamienoksidase-remmers, te behandel, of opgehou het om hierdie medisyne te neem gedurende die afgelope 14 dae.
- Indien u medisyne gebruik wat bekend staan as bloedverdunners.
- Indien u 'n allergiese tipe reaksie gehad het nadat u aspirien geneem het.
- Indien u swanger is, vermy die gebruik van NSAIM's, insluitend MYPRODOL CAPSULES teen 30 weke of later in u swangerskap, aangesien hierdie medisyne probleme by u ongebore baba kan veroorsaak.

Waarskuwings en voorsorgmaatreëls

Moenie langer as 10 dae aaneenlopend gebruik sonder om 'n dokter te raadpleeg nie.

Let daarop dat die veiligheid van deurlopende gebruik van MYPRODOL CAPSULES vir meer as vier weke nie bewys is nie, en gebruik vir langer as vier weke word dus as onveilig beskou.

Wees veral versigtig met MYPRODOL CAPSULES:
Kodeïen
- Indien u meer gebruik as wat u moet, of vir langer tydperke, aangesien dit afhanklikheid en verslawing aan MYPRODOL CAPSULES kan veroorsaak.

Ibuprofeen
- Indien u 'n geskiedenis van hoë bloeddruk en/of hartversaking het, kan MYPRODOL CAPSULES waterretensie en swelling veroorsaak, en kan ook hartversaking veroorsaak indien u geneig is tot waterretensie.
- Indien u 'n bejaarde persoon is, aangesien u 'n groter kans het om nadelige reaksies op NSAIM's te ervaar, insluitend MYPRODOL CAPSULES, veral sere aan die binneste voering van u maag en ingewande, en bloeding wat lewensgevaarlik kan wees.
- Indien u 'n maagseer, perforasie of bloeding van die spysverteringskanaal gehad het, aangesien u die risiko loop dat dit weer sal gebeur met toenemende dosisse MYPRODOL CAPSULES. Wanneer gastro-intestinale bloeding of ulserasie voorkom by pasiënte wat MYPRODOL CAPSULES ontvang, staak die gebruik van MYPRODOL CAPSULES en gaan na u dokter, apteker of ander gesondheidsorgverskaffer.

- Indien u gastro-intestinale siekte gehad het (bv. ulseratiewe kolitis, (inflammasie en sere in u spysverteringskanaal), Crohn se siekte (inflammasie van u spysverteringskanaal), hiatusbreuk (maag wat deur 'n opening in die diafragma opdruk), gastro-esofageale refluksiekte (maagsuur vloei terug in die buis wat u mond en maag verbind)), aangesien MYPRODOL CAPSULES hierdie toestande kan vererger.
- Indien u ernstige kutaneuse nadelige reaksies (SCARS) of ernstige velreaksie het, insluitend afskilfering en blaasvorming van die vel. Die afskilfering kan vinnig vorder, wat lei tot groot rou areas wat mooontlik vog lek (bv. Stevens-Johson se sindroom). Staak die gebruik van MYPRODOL CAPSULES met die eerste verskyning van veluitslag, of enige ander teken van hipersensitiwiteit, en gaan na u dokter of naaste hospitaal.
- Lig u dokter of gesondheidsorgverskaffer in indien u swanger is of van plan is om swanger te raak. Indien u NSAIM's teen ongeveer 20 weke van swangerskap of later neem, kan dit u ongebore baba benadeel. Indien u NSAIM's moet neem tussen 20 en 30 weke van u swangerskap, moet u gesondheidsorgverskaffer dalk die hoeveelheid vloeistof in u baarmoeder rondom u baba monitor. U moet nie NSAIM's teen ongeveer 30 weke van swangerskap of later neem nie.
- Indien u koors, veluitslag, swelling van die limfknope en/of swelling van die gesig ontwikkel. Dit staan bekend as Geneesmiddelreaksie met Eosinofilie en Sistemiese Simptome (GRESS). Staak die gebruik van MYPRODOL CAPSULES, en gaan na u dokter of naaste hospitaal, aangesien dit lewensgevaarlik kan wees.

Parasetamol

- MYPRODOL CAPSULES bevat parasetamol wat dodelik kan wees indien u 'n hoër dosis neem as wat u moes. In die geval van oordosering of indien u vermoed dat u meer geneem het as wat u moes, selfs al het u geen simptome van 'n oordosis nie, moet u dadelik na u naaste dokter, hospitaal of gifhulpsentrum gaan.
- Indien u meer parasetamol neem, soos in MYPRODOL CAPSULES, kan dit ernstige skade aan u lewer veroorsaak.
- Ernstige velreaksies soos toksiese epidermale nekrolise (TEN), Stevens-Johnson se sindroom (SJS), akute algemene eksantematiese pustulose (AGEP), eosinofilie en sistemiese (GRESS)/Geneesmiddel-geïnduseerde hipersensitiwiteitsindroom (DIHS) en area-spesifieke geneesmiddel-uitslag (FDE), is aangemeld by pasiënte wat parasetamol ontvang. Indien u enige tekens van ernstige velreaksies soos swelling, jeukerigheid, rooi ernstige veluitslag ervaar, staak die gebruik van MYPRODOL CAPSULES onmiddellik en kontak u dokter (sien Afdeling 4).
- Moenie langer as 10 dae aaneenlopend gebruik sonder om 'n dokter te raadpleeg nie

Kinders en adolessente
Moenie MYPRODOL CAPSULES aan kinders onder die ouderdom van 12 jaar gee nie.

Ander medisyne en MYPRODOL CAPSULES
Lig altyd u gesondheidsorgverskaffer in indien u enige ander medisyne neem.
(Dit sluit alle komplementêre of tradisionele medisyne in.)

- NSAIM's en die gebruik van twee of meer NSAIM's saam met MYPRODOL CAPSULES kan daartoe lei dat u meer newe-effekte het.

- Kortikosteroïede (medisyne wat inflammasie in u liggaam verlaag), aangesien MYPRODOL CAPSULES saam met hierdie medisyne u risiko kan verhoog om maagsere (oop sere wat aan die binnekant van u maag en die boonste gedeelte van u dunderm ontwikkel) en bloeding te hê.
- Antikoagulante (medisyne wat help om bloedklonte te voorkom, bv. apiksaban, dabigatran, edoksaban, rivaroksaban, warfarien. MYPRODOL CAPSULES kan die effekte van hierdie medisyne verhoog.
- Antiplaatjiemedisyne (bv. klopidogrel, tikagrelor, prasugrel dipiridamool of aspirien, om 'n paar te noem) en selektiewe serotonienheropname inhibeerders (SSHI's) (wat gebruik word om depressie te behandel, bv. esitalopraam, fluoksetien, paroksetien, om 'n paar te noem) aangesien dit u risiko van gastro-intestinale bloeding kan verhoog.

MYPRODOL CAPSULES met kos, drank en alkohol
Moenie alkohol (wyn, bier, sterk drank) drink terwyl u hierdie medisyne gebruik nie.

Swangerskap, borsvoeding en vrugbaarheid
Indien u swanger is of borsvoed, dink u is dalk swanger of van plan is om 'n baba te hê, raadpleeg asseblief u dokter, apteker of ander gesondheidsorgverskaffer vir advies voordat u MYPRODOL CAPSULES neem.
U moenie MYPRODOL CAPSULES neem wanneer u swanger is of borsvoed nie.
Die gebruik van NSAIM's (soos in MYPRODOL CAPSULES) gedurende die derde trimester van swangerskap kan asemhalingsprobleme van u pasgebore kind tot gevolg hê.

Vrugbaarheid
Geen data oor manlike en vroulike vrugbaarheid is beskikbaar nie

Bestuur en gebruik van masjinerie
Dit is nie altyd moontlik om te voorspel in watter mate MYPRODOL CAPSULES met u daaglikse aktiwiteite kan inmeng nie. MYPRODOL CAPSULES kan u duiselig of slaperig laat voel. U moet seker maak dat u nie betrokke raak by aktiwiteite wat verstandelike waaksaamheid, oordeel en/of goeie koördinasie en visie vereis nie, bv. bestuur, ry, vlieg, vaar of masjinerie/toerusting hanteer totdat u bewus is van die mate waartoe MYPRODOL CAPSULES u beïnvloed nie.

MYPRODOL CAPSULES bevat kleurstowwe wat allergiese reaksies kan veroorsaak, sien afdeling 6.

3. Hoe om MYPRODOL CAPSULES te neem
Moenie medisyne wat aan u voorgeskryf is, met enige ander persoon deel nie.
Neem altyd MYPRODOL CAPSULES presies soos u dokter of apteker u ingelig het. Raadpleeg u dokter of apteker indien u nie seker is nie
MOENIE DIE AANBEVOLE DOSIS OORSKRY NIE.

Die algemene dosis vir volwassenes en kinders ouer as 12 jaar is:
Een tot twee kapsules vier-uurliks, en nie meer as twaalf kapsules per vier-en-twintig uur nie.

Begin met die laagste effektiewe dosis vir die kortste moontlike tyd. Sluk elke kapsule met water.
Raadpleeg u dokter indien u nie beter voel met die aanbevole dosis nie.

Indien u meer MYPRODOL CAPSULES neem as wat u moes
In die geval van oordosering, raadpleeg u dokter of apteker. Indien nie een beskikbaar is nie, kontak die naaste hospitaal of gifhulpsentrum.
Onmiddellike mediese hulp is van kritieke belang. Selfs indien u nie simptome van 'n oordosis toon nie, gaan dadelik na u naaste hospitaal of gifhulpsentrum.
MYPRODOL CAPSULES bevat parasetamol en 'n oordosis, kan dodelik wees.
Die simptome van 'n oordosis kan naarheid, maagpyn, verlies aan eetlus, braking (kan bloedstrepe in hê), gelui in die ore, opgewondenheid, stuiptrekkings (veral by kinders) en asemhalingsprobleme insluit.

Indien u vergeet om MYPRODOL CAPSULES te neem
Dit is belangrik om MYPRODOL CAPSULES te neem soos u dokter voorgeskryf het. Indien u 'n dosis mis, hervat u gewone skedule die volgende dag. Moenie 'n dubbele dosis neem om op te maak vir vergete individuele dosisse nie.

4. Moontlike newe-effekte
MYPRODOL CAPSULES kan newe-effekte hê.
Nie alle newe-effekte wat vir MYPRODOL CAPSULES aangemeld is, word in hierdie biljet ingesluit nie. Indien u algemene gesondheid verswak of u enige ongewenste gevolge ervaar terwyl u MYPRODOL CAPSULES neem, raadpleeg asseblief u gesondheidsorgverskaffer vir advies.

Indien enige van die volgende gebeur, staak die gebruik van MYPRODOL CAPSULES en lig u dokter dadelik in, of gaan na die ongevalle-afdeling by u naaste hospitaal:
- Veluitslag, insluitend afskilfering en blaasvorming van die vel. Die afskilfering kan vinnig vorder, wat lei tot groot rou areas wat kan vog lek (bv. Stevens-Johnson se sindroom).
- Swelling van die hande, voete, enkels, gesig, lippe en mond of keel, wat probleme kan veroorsaak om te sluk of asem te haal.
- Bronchospasma (moeite om asem te haal en veroorsaak hyging).
- Koors, veluitslag, swelling van die limfknope en/of swelling van die gesig (ook bekend as GRESS).

Hierdie is alles baie ernstige newe-effekte. Indien u dit ervaar, het u dalk 'n ernstige reaksie op MYPRODOL CAPSULES gehad. U sal dalk dringende mediese hulp of hospitalisasie benodig.

Kodeïen
- Gemoedsveranderinge, rusteloosheid, verwarring,
- Lomerigheid,
- Voel duiselig (vertigo),
- Klein pupille (miose),
- Onreëlmatige hartklop (hartkloppings) en stadige hartklop,
- 'n Skielike daling in bloeddruk as u opstaan (ortostatiese hipotensie),

- Drukking in u skedel,
- Gesigblosing,
- Lae liggaamstemperatuur,
- Naarheid, braking, hardlywigheid, droë mond,
- Sweet, galbulte (urtikaria), jeukerigheid,
- Pyn in u lewer en / of galblaas (galspasma),
- Sukkel om u blaas leeg te maak.

Ibuprofeen

- Hipersensitiwiteit (bv. koors, swelling van die hande, voete, enkels, gesig, lippe en mond of keel, wat probleme met sluk of asemhaling kan veroorsaak),
- Duiseligheid
- Naarheid, braking, sere in die maag of ingewande, bloeding in die spysverteringskanaal, diarree, winde laat, hardlywigheid, slegte spysvertering, bloed in u stoelgang, braking van bloed, gastritis en pyn in die buik.
- Lae bloedseltellings kan moegheid, maklike kneusing, gereelde neusbloeding en verhoogde risiko van infeksies veroorsaak,
- Senuweeagtigheid, depressie, slaperigheid, slapeloosheid,
- Verandering in u visie,
- Gelui in u ore (tinnitus),
- Edeem, hoë bloeddruk, hartversaking,
- Abnormale lewerfunksietoetse,
- Blaasvorming van die vel, ernstige velreaksie kan voorkom, insluitend Stevens-Johnson se sindroom en toksiese epidermale nekrolise. Simptome sluit veluitslag, blaasvorming en afskilfering van die vel in,
- Geneesmiddelreaksie met eosinofilie en sistemiese simptome (GRESS) (vir besonderhede oor hierdie toestand, verwys asseblief na ernstige newe-effekte hierbo, en afdeling 2, 'Waarskuwings en voorsorgmaatreëls'),
- Verlaging van nierfunksie.

Parasetamol

- Veranderinge in u bloedtellings en selle.
- Sensitiwiteitsreaksies, gewoonlik in die vorm van veluitslag (wat sal verdwyn indien u ophou om MYPRODOL CAPSULES te gebruik).
- Mondsere, koorsblare en maagsere of seerheid van u tong
- Velknoppe of galbulte (opgehewe, rooi of wit, jeukerige kolle van die vel)
- Blase op u vel of binne-in u mond, neus, vagina of boude
- Die voorkoms van 'n uitslag of sonbrand indien u buite was (selfs op 'n bewolkte dag)
- swelling van die ooglede, gesig, tong of lippe
- erge duiseligheid
- moeilike asemhaling
- Ernstige velreaksies soos swelling, jeukerigheid, rooi erge uitslag, veral dié wat u hele liggaam bedek (wat as allergiese swelsels voorkom); staak die gebruik van MYPRODOL CAPSULES onmiddellik en kontak u dokter (sien Afdeling 2).

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

Aanmelding van newe-effekte
Indien u newe-effekte ervaar, raadpleeg u dokter of apteker of verpleegkundige. Dit sluit enige moontlike newe-effekte in wat nie in hierdie biljet gelys word nie. U kan ook newe-effekte by die SAHPRA aanmeld via die vorm **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 om meer inligting oor die veiligheid van MYPRODOL CAPSULES te verskaf.

5. Hoe om MYPRODOL CAPSULES te bêre

Bêre alle medisyne buite bereik van kinders.

- Bêre teen of benede 25 °C in 'n diggeslote houer.
- Moenie gebruik ná die vervaldatum wat op die etiket/kartonhouer/stuplverpakking aangedui word nie.
- Neem alle ongebruikte medisyne terug na u apteker.
- Moenie ongebruikte medisyne in afvoerpype of rioolstelsels (bv. toilette) weggooi nie.

6. Inhoud van die verpakking en ander inligting

Wat MYPRODOL CAPSULES bevat
Die aktiewe bestanddele is kodeïenfosfaat 10 mg, ibuprofeen 200 mg en parasetamol 250 mg.
Die ander bestanddele is kolloïdale silika, magnesiumstearaat, mieliestysel, kaliumsorbaat, harde gelatienkapsule (kapsuledop: ondeursigtige groen dop, ondeursigtige rooi lyf, drukkers-ink).
Kapsule-dop kleurstowwe is helderblou FCF (E133), eritrosien (E127), kinoliengeel (E104), sonsonderganggeel (E110) en titaandioksied (E171).

Hoe MYPRODOL CAPSULES lyk en die inhoud van die verpakking
Harde gelatienkapsule van grootte '0'. Die dop is ondeursigtig groen en die lyf is ondeursigtig rooi. "RIO" is in swart op beide die dop en lyf gedruk. Die inhoud van die kapsule is fyn korrelrige wit poeier.

Inhoud van die verpakking

- 'n Wit polipropileen-veiligheidshouer met 'n lae-digtheid poliëtileen (LDPE) deksel of 'n wit hoëdigtheid poliëtileenhouer met 'n hoëdigtheid poliëtileen (HDPE) skroefdop, wat 30 kapsules bevat.
- Stulpstroke van deursigtige PVC en aluminium, waaruit kapsules gedruk kan word, met 10 kapsules, verpak in eenheidskartonhouers van 10, 30, 60 of 100 kapsules.
- Nie alle verpakkingsgroottes mag dalk bemark word nie.

Houer van Sertifikaat van Registrasie
Adcock Ingram Limited
New Road 1,
Erand Gardens
Midrand

1685

Kliëntediens: 0860 ADCOCK / 232625

Hierdie biljet is mees onlangs hersien op
18 Oktober 2024

Registrasienommer
T/2.8/244

Botswana (S3): BOT2404232/A/B/C
Namibië (NS2): 90/2.8/00146

adcock ingram

1229229 09/2025 &
32008 08/2025