SCHEDULING STATUS: S3

MYPRODOL® SUSPENSION, 10 mg/200 mg/250 mg, suspension
Codeine phosphate, ibuprofen, paracetamol
Sugar free
Contains sweetener: sodium cyclamate 90 mg/10 ml, sodium saccharin 12,4 mg/10 ml

Read all of this leaflet carefully before you start taking MYPRODOL® SUSPENSION

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or health care provider.
- MYPRODOL® SUSPENSION 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 MYPRODOL® SUSPENSION is and what it is used for
2. What you need to know before you take MYPRODOL® SUSPENSION
3. How to take MYPRODOL® SUSPENSION
4. Possible side effects
5. How to store MYPRODOL® SUSPENSION
6. Contents of the pack and other information

1. What MYPRODOL® SUSPENSION is and what it is used for

MYPRODOL® SUSPENSION contains paracetamol, ibuprofen and codeine phosphate and belongs to a group of medicines called pain-killers or analgesics.
It is used for mild to moderate pain, caused by inflammation, with or without fever.

2. What you need to know before you take MYPRODOL® SUSPENSION

Do not take MYPRODOL® SUSPENSION:

- if you are hypersensitive (allergic) to paracetamol, ibuprofen or codeine phosphate or any of the other ingredients of MYPRODOL® SUSPENSION (listed in section 6),
- if you have liver or kidney problems,
- if you have heart problems or heart failure,
- if you have or have had a stomach ulcer or a history of bleeding into, or preformation of, the intestine especially after previous treatment with NSAIDs (non-steroidal anti-inflammatory drugs, such as ibuprofen) or MYPRODOL® SUSPENSION.
- if you have breathing or lung problems (especially if you are turning blue due to low oxygen levels) and have an increased amount of mucus from your lungs,
- if you have had an operation involving the gallbladder,
- if you are drinking alcohol in large quantities,
- if you have a head injury or have a condition where the pressure inside your skull has

increased,
- if you currently have an asthma attack,
- if you have heart failure as a result of ongoing lung disease,
- if you are taking monoamine oxidase inhibitors (for the treatment of depression or anxiety) or if you have stopped treatment in the past 14 days,
- if you are using medicines known as blood thinners (coumarin anticoagulants),
- if you are sensitive (or allergic) to aspirin,
- if you have growths in your nose (nasal polyps) associated with aspirin induced breathing difficulty (bronchospasm),
- if you are in the third trimester of pregnancy (28 to 40 weeks),
- if you are breastfeeding your baby
- if your child is under 12 years old,
- For pain relief in children and adolescents (0-18 years of age) after removal of tonsils or adenoids due to obstructive sleep apnoea syndrome.
- if you have had allergic reactions such as runny nose, itchy skin, rash or swelling of the lips, face, tongue, or throat after you have taken medicines containing acetylsalicylic acid (such as aspirin) or other medicines for pain and inflammation (NSAIDs) (or if you are sensitive to aspirin or NSAIDs).
- if you have severe diarrhoea associated with pseudomembranous colitis.
- if you have any bleeding disorders.

Warnings and precautions

MYPRODOL® SUSPENSION contains paracetamol which may be fatal in overdose. In the event of overdosage or suspected overdose and notwithstanding the fact that the person may be asymptomatic, the nearest doctor, hospital or Poison Centre must be contacted immediately.

Take special care with MYPRODOL® SUSPENSION:
- if you are pregnant or breastfeeding your baby,
- 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 for more than 2 days when you are between 20 weeks of pregnancy and later your health care provider may need to monitor the amount of fluid in your womb around your baby.
- if you are using MYPRODOL® SUSPENSION for longer than four weeks, as it might be unsafe,
- go to the nearest hospital if an overdosage occurred or is suspected (even if the person looks alright),
- if you are using higher than normal dosages, as it may cause sever liver damage,
- if you have lower than normal kidney function,
- if you have a history of high blood pressure and/or heart failure, as your body may hold on to excess water (fluid retention) and cause swelling (oedema). The fluid retention may even cause heart failure, even if you don’t have heart problems,
- if you are an elderly person, as you may have a higher possibility to experience unwanted effects (such as gastrointestinal problems and bleeding which may be life threatening) whilst

using MYPRODOL® SUSPENSION,

- if you are using MYPRODOL® SUSPENSION more frequently or in higher the normal quantities, as you be at higher risk of experiencing gastrointestinal problems. If you are experiencing gastrointestinal problems, stop using MYPRODOL® SUSPENSION,
- if you have had previous gastrointestinal diseases such as ulcerative colitis (an inflammatory bowel disease that causes inflammation and sores) in your digestive tract, Crohn's disease (inflammation of your digestive tract), hiatus hernia (when your stomach bulges up into your chest through an opening in your diaphragm), gastroesophageal reflux disease (a type of heartburn) or angiodysplasia (abnormality with the blood vessels in the gastrointestinal (GI) tract),
- if you have a rash, as treatment MYPRODOL® SUSPENSION should be stopped immediately. You may have a serious allergic reaction (that can be life threatening),
- 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).
- if you are using ibuprofen (as in MYPRODOL® SUSPENSION) during the third trimester of pregnancy, as it may cause breathing problem is your newborn. It may also delay and increase the duration of labour (giving birth),
- if you are using MYPRODOL® SUSPENSION for a long time, as it contains codeine, which may cause dependency and addiction,
- if you have an underactive thyroid, problems with your adrenal glands (glands on top of the kidneys), liver problems, prostate problems or if you are in shock,
- if you have problems in your intestine (such as inflammation or an obstruction),
- if you are an elderly or weakened person, as you should use lower dosages,
- if you are using alcohol, painkillers, sleeping medication or medicines to treat psychosis (a mental disorder characterised by a disconnection from reality) with MYPRODOL® SUSPENSION, as the tranquilising effect (the effect of making you sleepy) of codeine (as in MYPRODOL® SUSPENSION) may be greater.
- if you suffer from allergies, hay fever, chronic swelling of nasal mucosa, respiratory impairment, or chronic obstructive disorders of the respiratory tract. The risk for developing narrowing of the airways with difficulty in breathing (bronchospasm) is greater, as MYPRODOL® SUSPENSION may decrease respiratory drive and increase resistance.
- if you or your child is dehydrated (if your body does not have enough water and other fluids to carry out its normal functions).
- if you have an infection, MYPRODOL® SUSPENSION may mask signs of infections such as fever and pain. It is therefore possible that MYPRODOL® SUSPENSION may delay appropriate treatment of infection, which may lead to an increased risk of complications. If you take this medicine while you have an infection and your symptoms of the infection persist or worsen, consult a doctor without delay.
- if you have a disorder of blood coagulation or bleeding, a decreased number of red blood cells (anaemia).
- if you have a stiff neck, headache, nausea, vomiting, fever or disorientation, as these may be symptoms of meningitis.
- if you suffer from lupus, mixed connective tissue diseases or a similar condition.
- if you have acute abdominal (stomach) conditions.

- if you have fits (convulsions) or history thereof, as this may be induced or exacerbated.
- if you have gallbladder disease or gallstones, as this may cause biliary tract spasm.
- if you have recent gastrointestinal tract surgery or any major surgery.
- if you have hypothyroidism (a condition where the thyroid gland does not produce sufficient thyroid hormone).
- if you have an enlarged prostrate or have had recent urinary tract surgery.
- if you have inflammatory or obstructive bowel disorders.
- serious skin reactions such as toxic epidermal necrolysis (TEN), Stevens-Johnson syndrome (SJS), acute generalized exanthematous pustulosis (AGEP), Drug reaction with eosinophilia and systemic symptoms (DRESS)/Drug-induced hypersensitivity syndrome (DIHS) and fixed drug eruptions (FDE) have been reported in patients receiving paracetamol. If your child experiences any signs of serious skin reactions such as swelling, itching, red severe rash, stop using MYPRODOL® SUSPENSION immediately and contact your doctor (see section 4),
- do not use continuously for more than 10 days without consulting a doctor.

Tolerance dependence, and addiction:
Increased risk of addiction in patients with personal or family history of substance abuse or mental health disorders

MYPRODOL® SUSPENSION contains codeine, which is an opioid medicine.
Repeated use of MYPRODOL® SUSPENSION may result in you becoming accustomed to it (needing to take higher doses). Repeated use of MYPRODOL® SUSPENSION may also lead to dependence, abuse and addiction, which may result in life-threatening overdose.
If you are taking MYPRODOL® SUSPENSION for longer than the recommended time or at higher than recommended doses you are at risk of serious harms. These include serious harms to the stomach/gut and kidneys, as well as very low levels of potassium in your blood. These can be fatal (see section 4).
If you experience any of the following signs whilst taking MYPRODOL® SUSPENSION, talk to your doctor or pharmacist as it could be an indication that you are dependent or addicted.
- You need to take this medicine for longer than advised
- You need to take more than the recommended dose
- You are using this medicine for reasons other than medical reasons, for instance, ‘to stay calm’ or to ‘help you sleep’
- You have made repeated, unsuccessful attempts to quit or control the use of this medicine
- When you stop taking this medicine you feel unwell, and you feel better once taking this medicine again (‘withdrawal effects’).

Opioid Induced Hyperalgesia
Taking opioid medications for too long can paradoxically induce or sensitise patients to acute pain this condition is called opioid-induced hyperalgesia. The type of pain experienced might be the same as or different from the original underlying pain, and in some cases, patients may experience pain from ordinarily non-painful stimuli (allodynia).

Children
Do not give MYPRODOL® SUSPENSION to children younger than 12 years of age.

Codeine is not recommended in children with breathing problems, since the symptoms of morphine toxicity may be worse in these children,

Other medicines and MYPRODOL® SUSPENSION:
Always tell your health care provider if you are taking any other medicine.
(This includes all complementary or traditional medicines.)

Tell your doctor if you are taking any of the following:

- Anticoagulants (blood-thinning tablets) such as aspirin, warfarin or heparin since the effect of the anticoagulant may be enhanced.
- Anti-platelets, platelet aggregation inhibitors (medicines used against clotting) such as ticlopidine or clopidogrel as there may be an increased risk of gastrointestinal bleeding.
- Antidiabetic medicines, such as sulfonylureas (medicines to treat diabetes) since your blood sugar levels can be affected.
- Anti-hypertensives, (used in lowering blood pressure) (e.g. ACE-inhibitors such as captopril; beta-blockers such as atenolol medicines; angiotensin-II receptor antagonists such as losartan).
- Diuretics (water tablets) since the risk of kidney toxicity may be increased.
- Aminoglycoside antibiotics used in certain infections e.g. amikacin, gentamycin, neomycin, tobramycin, since MYPRODOL® SUSPENSION may decrease excretion of aminoglycosides.
- Lithium (used to treat depression and mania) since the effect of lithium may be enhanced.
- Methotrexate (used for some inflammatory diseases and some cancers).
- Ciclosporin or tacrolimus (used to treat some inflammatory diseases and after transplants) since kidney damage may occur.
- Quinolone antibiotics (used for infections) since the risk of convulsions (fits) may be increased.
- Digoxin (used to treat heart problems) since the effect of digoxin may be enhanced.
- Oral corticosteroids (an anti-inflammatory medicine) since this may increase the risk of gastrointestinal ulcers or bleeding.
- Non-steroidal anti-inflammatory drugs (NSAIDs), including aspirin and COX-2 inhibitors, since the use of two or more NSAIDs concomitantly could result in an increase in side effects.
- Mifepristone (a medicine used to end pregnancy) since MYPRODOL® SUSPENSION can reduce the effect of mifepristone.
- Zidovudine (a medicine used in HIV-infection).
- Bisphosphonates (medicines used in osteoporosis and to reduce high blood calcium levels) as the risk of gastrointestinal perforation, ulceration and bleeding is increased.
- Oxpentifylline (medicines used in the treatment of blood circulation) as the risk of gastrointestinal perforation, ulceration and bleeding is increased.
- Bone marrow depressants e.g. azathioprine used in the treatment of certain autoimmune diseases and in the management of organ transplants.
- Enzyme-inducing and hepatotoxic medicines (medicines which cause chemical-driven liver damage).

- Metoclopramide (used as an antiemetic).
- Cholestyramine (used in reducing cholesterol levels in your blood).
- Selective serotonin reuptake inhibitors (SSRIs) (medicines used to treat depression) such as paroxetine, sertraline, citalopram as these may increase risk of gastrointestinal bleeding.
- Monoamine oxidase inhibitors (MAOIs), medicine used to treat depression: Sometimes fatal reactions may occur in patients taking MAOIs, and also within 14 days of stopping such treatment.
- Central nervous system depressants such as anaesthetics, hypnotics and sedatives.
- Medicines used to treat diarrhoea, as there is an increased risk of severe constipation.
- Anticholinergics, such as atropine, as there is an increased risk of severe constipation.
- Voriconazole and fluconazole (CYP2C9 inhibitors) (used for fungal infections), since the effect of MYPRODOL® SUSPENSION may increase.
- Ginkgo biloba (a herbal medicine) as there is a chance you may bleed more easily if you are taking this with MYPRODOL® SUSPENSION.

MYPRODOL® SUSPENSION with alcohol
MYPRODOL® SUSPENSION should not be used with the consumption of alcohol, as it may cause unwanted effects.

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® SUSPENSION.

Pregnancy
You should not use MYPRODOL® SUSPENSION during pregnancy, as it may be harmful to your unborn child. Please consult your doctor or pharmacist for advice.

Breastfeeding
You should not use MYPRODOL® SUSPENSION while you are breastfeeding your baby.

Fertility
MYPRODOL® SUSPENSION belongs to a group of medicines (NSAIDs) which may make it more difficult to become pregnant.

Driving and using machines
MYPRODOL® SUSPENSION has a moderate influence on your ability to drive and to operate machinery, as it may cause dizziness, drowsiness (feeling sleepy) and blurred vision (difficulty in your eyesight).
It is not always possible to predict to what extent MYPRODOL® SUSPENSION 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 MYPRODOL®

SUSPENSION affects you.

MYPRODOL® SUSPENSION contains sodium
This medicine contains 28,77 mg (main component of cooking/table salt) in each 10 ml. This is equivalent to 1,438 % of the recommended maximum daily dietary intake of sodium for an adult.

MYPRODOL® SUSPENSION contains sodium benzoate ~~(excipient)~~
This medicine contains 10 mg sodium benzoate in each 10 ml which is equivalent 0,1 % *m/v*.
Sodium benzoate may increase jaundice (yellowing of the skin and eyes) in newborn babies (up to 4 weeks old).

MYPRODOL® SUSPENSION contains sodium metabisulphite
MYPRODOL® SUSPENSION contains sodium metabisulphite which may rarely cause severe hypersensitivity reactions and bronchospasm.

3. How to take MYPRODOL® SUSPENSION
Do not share medicines prescribed for you with any other person.
Always use MYPRODOL® SUSPENSION exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.
Do not use more than the recommended dose below.

The usual dose is:
Adults
Two to four medicine measures (10 to 20 ml) four hourly and not more than twenty-four medicine measures in twenty-four hours.
You should use the lowest effective dose for the shortest possible duration of treatment.
You should contact your doctor if no relief is obtained with the recommended dosages.
Shake the bottle before use.

If you take more MYPRODOL® SUSPENSION than you should:
In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.
Prompt medical attention is critical. Even if you do not show symptoms of an overdose, go immediately to your nearest hospital or Poison Centre.
MYPRODOL® SUSPENSION contains paracetamol and an overdose, can be fatal.

The symptoms can include nausea, stomach pain, vomiting (may be blood streaked), or severe diarrhoea. In addition to these symptoms, headache, bleeding in the digestive tract, blurred vision, ringing in the ears, confusion, shaky eye movement, exacerbation of asthma in asthmatics may occur. At high doses, drowsiness, excitation, disorientation, chest pain, palpitations, loss of consciousness, convulsions (mainly in children), vertigo, weakness and dizziness, blood in urine, low blood pressure, changes in the blood clotting time, acute kidney failure, liver damage, respiratory depression, cold body feeling, and breathing problems have been reported.

If you forget to take MYPRODOL® SUSPENSION
Take your missed dose as soon as you remember, if within a few hours after missing a dose. Do not take a double dose to make up for forgotten individual doses.

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

If any of the following happens, stop taking MYPRODOL® SUSPENSION and tell your doctor immediately or go to the casualty department at your nearest hospital:
- Mouth ulcers, cold sores and ulcers or soreness of your tongue,
- skin lumps or hives (raised, red or white, itchy patches of skin),
- swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing,
- allergic reactions which can include flu-like symptoms along with a skin rash or sunburn when you have been outside (even on a cloudy day), itching, painful red areas, peeling or blistering on your skin or inside your mouth, nose, vagina, or bottom, swollen mouth, face, lips, tongue or throat (also known as Stevens-Johnson's syndrome),
- fever, skin rash, swelling of the lymph nodes and/or swelling of the face (also known as DRESS),
- fainting.

These are all very serious side effects. If you have them, you may have had a serious reaction to MYPRODOL® SUSPENSION. 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:
- Shortness of breath, fatigue, weakness, swelling in your legs, ankles and feet,
- changes in the way your heart beats, for example, if you notice it is beating faster or not rhythmic, heart failure, chest pain, changes in blood pressure; symptoms include palpitations, dizziness, fainting, shortness of breath and chest discomfort,
- high blood pressure which may cause a serious headache,
- stomach ulcers, ruptures or tears in your gastrointestinal tract (that may cause severe pain) or blood in your stools,
- vomiting of blood,
- stomach pain, indigestion, heartburn, wind, nausea (feeling sick), or vomiting (being sick) as you may be experiencing inflammation in your bowel, colon (colitis), or digestive tract (Crohn’s disease), or complications of the large bowel (perforation),
- yellowing of your skin or the whites of your eyes (jaundice),
- kidney failure or liver failure,
- severe fall in blood pressure,

- breathing disorders such as slow, ineffective or difficulty breathing which may cause wheezing or coughing, asthma attacks,
- increasing pressure inside your skull,
- aseptic meningitis with symptoms of stiff neck, headache, nausea, vomiting, fever or disorientation.

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:

- nausea (feeling sick),
- vomiting,
- diarrhoea,
- passing of wind,
- constipation,
- indigestion,
- abdominal pain,
- dizziness
- headache.

Less frequent side effects

- abdominal pain including risk of inflammation of pancreas, which causes severe pain in the abdomen and back,
- inflammation of the mucous members in the nose, which may cause a stuffy or runny nose (rhinitis),
- confusional state, nervousness, sleeplessness, excess sleepiness, depression, restlessness, anxiety, changes in mood, drowsiness, spinning (vertigo),
- tingling of the hands and feet,
- blurred vision, decreased pupil size (miosis), inflammation of the optic nerve, and other ocular (eye) reactions,
- ringing in the ears,
- bloating, dry mouth, decreased appetite,
- mouth ulcers and inflammation,
- abnormalities of liver function tests, inflammation of the liver,
- impairment of kidney function, fluid retention, kidney pain,
- sweating, facial flushing, difficulties in passing urine, ureteric or biliary spasm,
- drop in body temperature (hypothermia),
- blood disorders such as decrease in white blood cells, decrease in red blood cells. The first symptoms may include fever, sore throat, surface mouth ulcers, flu-like symptoms, severe tiredness, nasal and skin bleeding or unexplained bruising.

Side effects of unknown frequency

- MYPRODOL® SUSPENSION, especially when taken at higher than recommended doses or for a prolonged period of time, can cause damage to your kidneys and affect them removing acids properly from your blood into the urine (renal tubular acidosis). It can also cause very low levels of potassium in your blood (see section 2). This is a very serious condition and will require immediate treatment. Signs and symptoms include muscle weakness and light-headedness,
- increased sensitivity to sunlight (photosensitivity).
- Skin lumps or hives (raised, red or white, itchy patches of skin), burning and pain (FDE)

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 Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of MYPRODOL® SUSPENSION.

5. How to store MYPRODOL® SUSPENSION

- Store all medicines out of reach of children.
- Store at or below 30 °C in a well-closed container.
- Protect from light.
- 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 MYPRODOL® SUSPENSION contains
The active substance are codeine phosphate, ibuprofen and paracetamol. Each 10 ml contains codeine phosphate 10 mg, ibuprofen 200 mg, paracetamol 250 mg.
The other ingredients are blackcurrant NE 53984, citric acid anhydrous, disodium edetate, glycerine, kaolin light, polyethylene glycol 4000, polyvinylpyrrolidone (PVP) K25, purified water, raspberry red H 1277, sodium benzoate (preservative), sodium citrate, sodium cyclamate (sweetener), sodium metabisulphite (antioxidant), sodium saccharin 500 (sweetener), sodium dihydrogen phosphate dehydrate, xanthan gum TF.

What MYPRODOL® SUSPENSION looks like and contents of the pack
A homogenous, opaque pink suspension with a blackcurrant taste and odour, free from excess visible particles.
100 ml amber round glass bottle, with a polypropylene lined (with an expanded polyethylene liner) white screw cap.
200 ml amber round glass bottle, with a polypropylene lined (with an expanded polyethylene liner) white screw cap.
200 ml amber round PVC bottle with a low-density polyethylene white snap-on cap.

Holder of Certificate of Registration

Adcock Ingram Limited
1 New Road,
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1685
Midrand
Customer Care: 0860 ADCOCK/232625

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SKEDULERINGSTATUS: S3

MYPRODOL® SUSPENSION, 10 mg/200 mg/250 mg, suspensie
Kodeïenfosfaat, ibuprofeen, parasetamol
Suikervry
Bevat versoeter: natriumsiklamaat 90 mg/10 ml, natriumsakkarien 12,4 mg/10 ml

Lees hierdie hele biljet noukeurig deur voordat u begin om MYPRODOL® SUSPENSION te neem

- Hou hierdie biljet. U sal dit dalk weer moet lees.
- Indien u verdere vrae het, raadpleeg asseblief u dokter, apteker, verpleegkundige of gesondheidsorgverskaffer.
- MYPRODOL® SUSPENSION is aan u persoonlik voorgeskryf en u moenie u medisyne met ander mense deel nie. Dit kan hulle benadeel, selfs al ervaar hul dieselfde simptome as u.

Wat is in hierdie biljet

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

1. Wat MYPRODOL® SUSPENSION is en waarvoor dit gebruik word

MYPRODOL® SUSPENSION bevat parasetamol, ibuprofeen en kodeïenfosfaat en behoort tot 'n groep medisyne wat pynstillers of analgetika genoem word.
Dit word gebruik vir ligte tot matige pyn, veroorsaak deur inflammasie, met of sonder koors.

2. Wat u moet weet voordat u MYPRODOL® SUSPENSION neem

Moenie MYPRODOL® SUSPENSION neem nie:

- indien u hipersensitief (allergies) is vir parasetamol, ibuprofeen of kodeïenfosfaat, of enige van die ander bestanddele van MYPRODOL® SUSPENSION (gelys in afdeling 6),
- indien u lewer- of nierprobleme het,
- indien u hartprobleme of hartversaking het,
- indien u 'n maagseer het, of 'n geskiedenis van bloeding binne-in, of perforasie van die ingewande het of gehad het, veral na vorige behandeling met NSAIMs (nie-steroïed anti-inflammatoriese middels, soos ibuprofeen) of MYPRODOL® SUSPENSION.
- indien u asemhalings- of longprobleme het (veral indien u blou word as gevolg van lae suurstofvlakke) en 'n verhoogde hoeveelheid slym van u longe het,
- indien u 'n operasie gehad het waarby die galblaas betrokke was,

- indien u alkohol in groot hoeveelhede drink,
- indien u 'n kopbesering het, of 'n toestand waar die druk in u skedel toegeneem het,
- indien u tans 'n asma-aanval het,
- indien u hartversaking het as gevolg van voortdurende longsiekte,
- indien u monoamienoksidase-remmers neem (vir die behandeling van depressie of angs) of indien u die behandeling binne die afgelope 14 dae gestaak het,
- indien u medisyne gebruik wat bekend staan as bloedverdunners (kumarien-antikoagulante),
- indien u sensitief (of allergies) is vir aspirien,
- indien u vergroeisels in u neus het (neuspoliepe) wat verband hou met aspirien-geïnduseerde asemhalingsprobleme (bronchospasma),
- indien u in die derde trimester van swangerskap (28 tot 40 weke) is,
- Indien u u baba borsvoed
- indien u kind jonger as 12 jaar is,
- Vir pynverligting by kinders en adolessente (0-18 jaar oud) na verwydering van mangels of adenoïede as gevolg van obstruktiewe slaapapnee-sindroom.
- indien u allergiese reaksies gehad het soos loopneus, jeukerige vel, veluitslag of swelling van die lippe, gesig, tong of keel nadat u medisyne geneem het wat asetielsalisielsuur bevat (soos aspirien) of ander medisyne vir pyn en inflammasie (NSAIMs) (of indien u sensitief is vir aspirien of NSAIMs).
- indien u ernstige diarree het wat verband hou met pseudomembraanagtige kolitis.
- indien u enige bloedingsversteurings het.

Waarskuwings en voorsorgmaatreëls

MYPRODOL® SUSPENSION bevat parasetamol wat dodelik kan wees in oordosis. In die geval van oordosering of vermoedelike oordosis, en nieteenstaande die feit dat die persoon asimptomaties kan wees, moet die naaste dokter, hospitaal of gifhulpsentrum onmiddellik gekontak word.

Wees veral versigtig met MYPRODOL® SUSPENSION:

- indien u swanger is of u baba borsvoed,
- lig u dokter of gesondheidsorgverskaffer in indien u swanger is of van plan is om swanger te raak. Indien u NSAIMs neem teen ongeveer 20 weke van swangerskap of later, kan dit u ongebore baba benadeel. Indien u NSAIMs vir meer as 2 dae moet neem wanneer u 20 weke of langer swanger is, moet u gesondheidsorgverskaffer dalk die hoeveelheid vloeistof in u baarmoeder rondom u baba monitor.
- indien u MYPRODOL® SUSPENSION vir langer as vier weke gebruik, aangesien dit onveilig kan wees,
- gaan na die naaste hospitaal indien 'n oordosis plaasgevind het of vermoed word (selfs al lyk die persoon goed),
- indien u hoër as normale dosisse gebruik, aangesien dit ernstige lewerskade kan veroorsaak,
- indien u laer as normale nierfunksie het,

- indien u 'n geskiedenis van hoë bloeddruk en/of hartversaking het, aangesien u liggaam oortollige water kan terughou (vloeistofretensie) en swelling (edeem) kan veroorsaak. Die vloeistofretensie kan selfs hartversaking veroorsaak, selfs al het u nie hartprobleme nie,
- indien u 'n bejaarde persoon is, aangesien u 'n groter moontlikheid kan hê om ongewenste effekte te ervaar (soos gastroïntestinale probleme en bloeding, wat lewensgevaarlik kan wees) terwyl u MYPRODOL® SUSPENSION gebruik,
- indien u MYPRODOL® SUSPENSION meer gereeld, of in hoër as normale hoeveelhede gebruik, aangesien u 'n groter risiko het om gastroïntestinale probleme te ervaar. Indien u gastroïntestinale probleme ervaar, staak MYPRODOL® SUSPENSION,
- indien u vorige gastroïntestinale siektes gehad het, soos ulseratiewe kolitis ('n inflammatoriese dermsiekte wat inflammasie en sere veroorsaak) in u spysverteringskanaal, Crohn se siekte (ontsteking van u spysverteringskanaal), hiatusbreuk (wanneer u maag deur 'n opening in u diafragma in u bors indruk), gastro-esofageale refluksiekte ('n soort sooibrand) of angiodisplasie (abnormaliteit van die bloedvate in die spysverteringskanaal),
- indien u 'n veluitslag het, aangesien behandeling met MYPRODOL® SUSPENSION onmiddellik gestaak moet word. U kan 'n ernstige allergiese reaksie hê (wat lewensgevaarlik kan wees),
- 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).
- indien u ibuprofeen (soos in MYPRODOL® SUSPENSION) gedurende die derde trimester van swangerskap gebruik, aangesien dit asemhalingsprobleme by u pasgeborene kan veroorsaak. Dit kan ook die duur van kraam (geboorte skenk) vertraag en verleng,
- indien u MYPRODOL® SUSPENSION vir 'n lang tyd gebruik, aangesien dit kodeïen bevat, wat afhanklikheid en verslawing kan veroorsaak,
- indien u 'n onderaktiewe skildklier het, probleme met u byniere (kliere bo-op die niere), lewerprobleme, prostaatprobleme of indien u in skok is,
- indien u probleme in u ingewande het (soos inflammasie of 'n obstruksie),
- indien u 'n bejaarde of verswakte persoon is, aangesien u laer dosisse moet gebruik,
- indien u alkohol, pynstillers, slaapmiddels of medisyne wat gebruik word om psigose ('n geestesversteuring wat gekenmerk word deur 'n ontkoppeling van die werklikheid) te handel, saam met MYPRODOL® SUSPENSION neem, aangesien die kalmerende effek (die effek om u slaperig te maak) van kodeïen (soos in MYPRODOL® SUSPENSION) groter kan wees.
- indien u ly aan allergieë, hooikoors, chroniese swelling van neusslymvlies, ingeperkte asemhaling of chroniese obstruktiewe afwykings van die asemhalingskanaal. Die risiko vir die ontwikkeling van vernouing van die lugweë met probleme om asem te haal (bronchospasma) is groter, aangesien MYPRODOL® SUSPENSION asemhalingsdryfkrag kan verminder en weerstand kan verhoog.

- indien u of u kind gedehidreer is (indien u liggaam nie genoeg water en ander vloeistowwe het om sy normale funksies uit te voer nie).
- indien u 'n infeksie het, kan MYPRODOL® SUSPENSION tekens van infeksies soos koors en pyn verdoesel. Dit is dus moontlik dat MYPRODOL® SUSPENSION toepaslike behandeling van infeksie kan vertraag, wat kan lei tot 'n verhoogde risiko van komplikasies. Indien u hierdie medisyne neem terwyl u 'n infeksie het en u simptome van die infeksie duur voort of vererger, raadpleeg 'n dokter sonder versuim.
- Indien u 'n versteuring van bloedstolling of bloeding het, 'n verminderde aantal rooibloedselle (bloedarmoede).
- Indien u 'n stywe nek, hoofpyn, naarheid, braking, koors of disoriëntasie het, aangesien dit simptome van breinvliesontsteking kan wees.
- indien u aan lupus, gemengde bindweefselsiektes of 'n soortgelyke toestand ly.
- indien u akute abdominale (maag) toestande het.
- indien u stuipaanvalle (stuiptrekkings) of geskiedenis daarvan het, aangesien dit veroorsaak of vererger kan word.
- indien u galblaassiekte of galstene het, aangesien dit galwegspasma kan veroorsaak.
- indien u 'n onlangse spysverteringskanaaloperasie of enige groot operasie gehad het.
- indien u hipotireose het ('n toestand waar die tiroïedklier nie voldoende skildklierhormoon produseer nie).
- indien u 'n vergrote prostraat het of onlangs 'n urienwegoperasie ondergaan het.
- indien u inflammatoriese of obstruktiewe dermafwykings het.
- ernstige velreaksies soos toksiese epidermale nekrolise (TEN), Stevens-Johnson se sindroom (SJS), akute algemene eksantematiese pustulose (AAEP), Geneesmiddelreaksie met eosinofilie en sistemiese simptome (GRESS)/Geneesmiddel-geïnduseerde hipersensitiwiteitsindroom (GIHS) en area-spesifieke geneesmiddel-uitslag (FDE) is aangemeld by pasiënte wat parasetamol ontvang. Indien u kind enige tekens van ernstige velreaksies ervaar, soos swelling, jeukerigheid, rooi ernstige uitslag, moet u onmiddellik MYPRODOL® SUSPENSION staak en u dokter kontak (sien afdeling 4),
- moenie vir langer as 10 dae aaneenlopend gebruik sonder om 'n dokter te raadpleeg nie.

Verdraagsaamheid, afhanklikheid en verslawing:
Verhoogde risiko vir verslawing by pasiënte met persoonlike of familiegeskiedenis van dwelmmisbruik of geestesgesondheidsversteurings.

MYPRODOL® SUSPENSION bevat kodeïen, wat 'n opioïedmedisyne is.
Herhaalde gebruik van MYPRODOL® SUSPENSION kan daartoe lei dat u daaraan gewoond raak (moet hoër dosisse neem). Herhaalde gebruik van MYPRODOL® SUSPENSION kan ook lei tot afhanklikheid, misbruik en verslawing, wat kan lei tot lewensgevaarlike oordosis.
Indien u MYPRODOL® SUSPENSION vir langer as die aanbevole tyd of teen hoër as aanbevole dosisse neem, loop u die risiko van ernstige skade. Dit sluit in ernstige skade

aan die maag/ingewande en niere, sowel as baie lae vlakke van kalium in u bloed. Dit kan dodelik wees (sien afdeling 4).
Indien u enige van die volgende tekens ervaar terwyl u MYPRODOL® SUSPENSION neem, raadpleeg u dokter of apteker omdat dit 'n aanduiding kan wees dat u afhanklik of verslaaf is.
- U moet hierdie medisyne langer neem as wat aanbeveel word
- U moet meer as die aanbevole dosis neem
- U gebruik hierdie medisyne om ander redes as mediese redes, byvoorbeeld 'om kalm te bly' of om 'u te help slaap'
- U het herhaalde, onsuksesvolle pogings aangewend om op te hou of die gebruik van hierdie medisyne te beheer
- Wanneer u ophou om hierdie medisyne te neem, voel u sleg, en u voel beter sodra u hierdie medisyne weer neem ('onttrekkingseffekte').

Opioïed-geïnduseerde Hiperalgesie
Om opioïedmedikasie te lank te neem, kan pasiënte paradoksaal sensitief maak vir akute pyn, of akute pyn veroorsaak; hierdie toestand word opioïed-geïnduseerde hiperalgesie genoem. Die tipe pyn wat ervaar word, kan dieselfde wees as, of verskil van die oorspronklike onderliggende pyn, en in sommige gevalle kan pasiënte pyn ervaar as gevolg van stimuli wat gewoonlik nie-pynlik is (allodinie).

Kinders
Moenie MYPRODOL® SUSPENSION aan kinders jonger as 12 jaar gee nie.

Kodeïen word nie aanbeveel by kinders met asemhalingsprobleme nie, aangesien die simptome van morfientoksisiteit by hierdie kinders erger kan wees.

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

Lig u dokter in indien u enige van die volgende neem:
- Antikoagulante (bloedverdunnende tablette) soos aspirien, warfarien of heparien, aangesien die effek van die antikoagulant versterk kan word.
- Anti-bloedplaatjies, bloedplaatjie-aggregasie-inhibeerders (medisyne wat teen stolling gebruik word) soos tiklopidien of klopidogrel, aangesien daar 'n verhoogde risiko van gastroïntestinale bloeding kan wees.
- Antidiabetiese medisyne, soos sulfonylureums (medisyne om diabetes te behandel) aangesien u bloedsuikervlakke beïnvloed kan word.
- Anti-hipertensiewe middels, (gebruik om bloeddruk te verlaag) (bv. AOE-remmers soos kaptopriel; betablokkers soos atenolol-medisyne; angiotensien-II-reseptor antagoniste soos losartaan).
- Diuretika (watertablette) aangesien die risiko van niertoksisiteit verhoog kan word.
- Aminoglikosied-antibiotika wat in sekere infeksies gebruik word, bv. amikasien,

gentamisien, neomisien, tobramisien, aangesien MYPRODOL® SUSPENSION die uitskeiding van aminoglikosiede kan verlaag.
- Litium (gebruik om depressie en manie te behandel) aangesien die effek van litium verbeter kan word.
- Metotreksaat (gebruik vir sommige inflammatoriese siektes en sommige kankers).
- Siklosporien of takrolimus (word gebruik om sommige inflammatoriese siektes te behandel, en gebruik na oorplantings) aangesien nierskade kan voorkom.
- Kinoloon-antibiotika (gebruik vir infeksies) aangesien die risiko van stuiptrekkings (stuipaanvalle) verhoog kan word.
- Digoksien (wat gebruik word om hartprobleme te behandel) aangesien die effek van digoksien versterk kan word.
- Orale kortikosteroïede ('n anti-inflammatoriese medisyne) aangesien dit die risiko van gastroïntestinale sere of bloeding kan verhoog.
- Nie-steroïed anti-inflammatoriese middels (NSAIMs), insluitend aspirien en COX-2-inhibeerders, aangesien die gebruik van twee of meer NSAIMs gelyktydig 'n toename in newe-effekte tot gevolg kan hê.
- Mifepristoon ('n medisyne wat gebruik word om swangerskap te beëindig) aangesien MYPRODOL® SUSPENSION die effek van mifepristoon kan verminder.
- Sidovudien ('n medisyne wat in MIV-infeksie gebruik word).
- Bisfosfonate (medisyne wat gebruik word in osteoporose en om hoë kalsiumvlakke in die bloed te verminder) aangesien die risiko van gastroïntestinale perforasie, ulserasie en bloeding verhoog word.
- Okspentifillien (medisyne wat gebruik word in die behandeling van bloedsomloop) aangesien die risiko van gastroïntestinale perforasie, ulserasie en bloeding verhoog word.
- Beenmurgdepressante, byvoorbeeld azatioprien wat gebruik word in die behandeling van sekere outo-immuun siektes en in die onderhoud van orgaanoorplantings.
- Ensiem-induserende en hepatotoksiese medisyne (medisyne wat chemies-gedrewe lewerskade veroorsaak).
- Metoklopramied (gebruik as 'n anti-emetikum).
- Cholestiramien (gebruik om cholesterolvlakke in u bloed te verlaag).
- Selektiewe serotonien heropname inhibeerders (SSHIs) (medisyne wat gebruik word om depressie te behandel) soos paroksetien, sertralien, sitalopraam, aangesien dit die risiko van gastroïntestinale bloeding kan verhoog.
- Monoamienoksidase-remmers (MAO-remmers), medisyne wat gebruik word om depressie te behandel: Soms kan dodelike reaksies voorkom by pasiënte wat MAO-remmers neem, en ook binne 14 dae nadat sodanige behandeling gestaak is.
- Sentrale senuweestelsel-depressante soos narkose-middels, hipnotika en kalmeermiddels.
- Medisyne wat gebruik word om diarree te behandel, aangesien daar 'n verhoogde risiko van ernstige hardlywigheid is.
- Anticholinergiese middels, soos atropien, aangesien daar 'n verhoogde risiko vir ernstige hardlywigheid is.
- Vorikonasool en flukonasool (CYP2C9-remmers) (gebruik vir swaminfeksies),

aangesien die effek van MYPRODOL® SUSPENSION kan toeneem.
- “Ginkgo biloba” ('n kruie medisyne) aangesien daar 'n kans is dat u makliker kan bloei indien u dit saam met MYPRODOL® SUSPENSION neem.

MYPRODOL® SUSPENSION saam met alkohol
MYPRODOL® SUSPENSION moet nie saam met die gebruik van alkohol geneem word nie, aangesien dit ongewenste effekte kan veroorsaak.

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® SUSPENSION neem.

Swangerskap
U moet nie MYPRODOL® SUSPENSION tydens swangerskap gebruik nie, aangesien dit skadelik vir u ongebore kind kan wees. Raadpleeg asseblief u dokter of apteker vir advies.

Borsvoeding
U moet nie MYPRODOL® SUSPENSION gebruik terwyl u u baba borsvoed nie.

Vrugbaarheid
MYPRODOL® SUSPENSION behoort aan 'n groep medisyne (NSAIMs) wat dit moeiliker kan maak om swanger te raak.

Bestuur en gebruik van masjinerie
MYPRODOL® SUSPENSION het 'n matige invloed op u vermoë om te bestuur en masjinerie te gebruik, aangesien dit duiseligheid, lomerigheid (slaperig voel) en versteurde visie (probleme in u sig) kan veroorsaak.
Dit is nie altyd moontlik om te voorspel in watter mate MYPRODOL® SUSPENSION met u daaglikse aktiwiteite kan inmeng nie. U moet seker maak dat u nie betrokke raak by aktiwiteite wat verstandelike waaksaamheid, oordeel en/of goeie koördinasie en visie vereis nie, soos bestuur, ry, vlieg, seil of die hantering van masjiene/toerusting totdat u bewus is van die mate waartoe MYPRODOL® SUSPENSION u beïnvloed.

MYPRODOL® SUSPENSION bevat natrium
Hierdie medisyne bevat 28,77 mg (hoofkomponent van kook/tafelsout) in elke 10 ml. Dit is gelykstaande aan 1,438 % van die aanbevole maksimum daaglikse dieet-inname van natrium vir 'n volwassene.

MYPRODOL® SUSPENSION bevat natriumbensoaat
Hierdie medisyne bevat 10 mg natriumbensoaat in elke 10 ml, wat gelykstaande is aan 0,1 *% m/v*.
Natriumbensoaat kan geelsug (vergeling van die vel en oë) by pasgebore babas (tot 4

weke oud) verhoog.

MYPRODOL® SUSPENSION bevat natriummetabisulfiet
MYPRODOL® SUSPENSION bevat natriummetabisulfiet wat baie selde ernstige hipersensitiwiteitsreaksies en bronchospasma kan veroorsaak.

3. Hoe om MYPRODOL® SUSPENSION te neem
Moenie medisyne wat vir u voorgeskryf is, met enige ander persoon deel nie.
Gebruik altyd MYPRODOL® SUSPENSION presies soos u dokter of apteker u ingelig het.
Raadpleeg u dokter of apteker indien u nie seker is nie.
Moenie meer as die aanbevole dosis hieronder genoem, gebruik nie.

Die algemene dosis is:
Volwassenes
Twee tot vier medisynemates (10 tot 20 ml) vier-uurliks en nie meer as vier-en-twintig medisynemates in vier-en-twintig uur nie.
U moet die laagste effektiewe dosis gebruik vir die kortste moontlike duur van behandeling.
U moet u dokter kontak indien geen verligting verkry word met die aanbevole dosisse nie.
Skud die bottel voor gebruik.

Indien u meer MYPRODOL® SUSPENSION neem as wat u moes
In die geval van oordosering, raadpleeg u dokter of apteker. Indien nie een van hulle beskikbaar is nie, kontak die naaste hospitaal of gifhulpsentrum.
Vinnige mediese hulp is van kritieke belang. Selfs as u nie simptome van 'n oordosis toon nie, gaan dadelik na u naaste hospitaal of gifhulpsentrum.
MYPRODOL® SUSPENSION bevat parasetamol en 'n oordosis kan dodelik wees.

Die simptome kan naarheid, maagpyn, braking (kan bloed-bevlek wees) of erge diarree insluit. Benewens hierdie simptome, kan hoofpyn, bloeding in die spysverteringskanaal, versteurde visie, gelui in die ore, verwarring, rukkerige oogbeweging en verergering van asma by asmalyers voorkom. By hoë dosisse is slaperigheid, opgewerktheid, disoriëntasie, borspyn, hartkloppings, verlies van bewussyn, stuiptrekkings (hoofsaaklik by kinders), vertigo, swakheid en duiseligheid, bloed in urien, lae bloeddruk, veranderinge in die bloedstollingstyd, akute nierversaking, lewerskade, respiratoriese depressie, gevoel van ‘n koue liggaam en asemhalingsprobleme aangemeld.

Indien u vergeet om MYPRODOL® SUSPENSION te neem
Neem u oorgeslaande dosis sodra u onthou, indien binne 'n paar uur nadat u 'n dosis gemis het. Moenie 'n dubbele dosis neem om op te maak vir vergete individuele dosisse nie.

4. Moontlike newe-effekte
MYPRODOL® SUSPENSION kan newe-effekte hê.
Nie alle newe-effekte wat vir MYPRODOL® SUSPENSION aangemeld is, word in hierdie

biljet ingesluit nie. Indien u algemene gesondheid verswak of indien u enige ongewenste gevolge ervaar terwyl u MYPRODOL® SUSPENSION neem, raadpleeg asseblief u gesondheidsorgverskaffer vir advies.

Indien enige van die volgende gebeur, staak MYPRODOL® SUSPENSION en lig u dokter dadelik in, of gaan na die ongevalle-afdeling by u naaste hospitaal:

- Mondsere, koorsblare, sere op die tong of pynlike tong,
- velknoppe of galbulte (verhoogde, rooi of wit, jeukerige kolle van die vel),
- swelling van die hande, voete, enkels, gesig, lippe en mond of keel, wat probleme kan veroorsaak om te sluk of asem te haal,
- allergiese reaksies wat griepagtige simptome saam met 'n veluitslag of sonbrand kan insluit wanneer u buite was (selfs op 'n bewolkte dag), jeukerigheid, pynlike rooi areas, afskilfering of blase op u vel of binne-in u mond, neus, vagina of boude, geswelde mond, gesig, lippe, tong of keel (ook bekend as Stevens-Johnson se sindroom),
- koors, veluitslag, swelling van die limfknope en/of swelling van die gesig (ook bekend as GRESS),
- lfoute.

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

Lig u dokter dadelik in, of gaan na die ongevalle-afdeling by u naaste hospitaal indien u enige van die volgende opmerk:

- Kortasem, moegheid, swakheid, swelling in u bene, enkels en voete,
- veranderinge in die manier waarop u hart klop, byvoorbeeld indien u agterkom dat dit vinniger klop of nie ritmies nie, hartversaking, pyn op die bors, veranderinge in bloeddruk; simptome sluit in hartkloppings, duiseligheid, floute, kortasem en ongemak op die bors,
- hoë bloeddruk wat 'n ernstige hoofpyn kan veroorsaak,
- maagsere, breuke of skeure in u spysverteringskanaal (wat erge pyn kan veroorsaak) of bloed in u stoelgang,
- braking van bloed,
- maagpyn, slegte spysvertering, sooibrand, winderigheid, naarheid (naar voel) of braking (opgooi) aangesien u inflammasie in u derm, kolon (kolitis) of spysverteringskanaal (Crohn se siekte) of komplikasies van die dikderm (perforasie) kan ervaar,
- vergeling van u vel of die wit van u oë (geelsug),
- nierversaking of lewerversaking,
- ernstige daling in bloeddruk,
- asemhalingsversteurings soos stadige, ondoeltreffende of moeilike asemhaling wat hygende asemhaling of hoes, asma-aanvalle kan veroorsaak,
- toenemende druk in u skedel,
- aseptiese meningitis met simptome van stywe nek, hoofpyn, naarheid, braking, koors of disoriëntasie.

Hierdie is alles ernstige newe-effekte. U sal dalk dringend mediese hulp nodig hê.

Lig u dokter in indien u enige van die volgende opmerk:
Gereelde newe-effekte:
- naarheid (naar voel),
- braking
- diarree
- winde laat,
- hardlywigheid
- slegte spysvertering
- buikpyn
- duiseligheid
- hoofpyn.

Minder gereelde newe-effekte
- buikpyn, insluitend die risiko van inflammasie van die pankreas, wat erge pyn in die buik en rug veroorsaak,
- inflammasie van die slymvliese in die neus, wat 'n geblokte of loopneus (rinitis) kan veroorsaak,
- verwarde toestand, senuweeagtigheid, slapeloosheid, oormatige slaperigheid, depressie, rusteloosheid, angs, veranderinge in bui, lomerigheid, draaiende gevoel (vertigo),
- tinteling van die hande en voete,
- versteurde visie, verminderde pupilgrootte (miose), inflammasie van die optiese senuwee en ander oogreaksies,
- gelui in die ore,
- opgeblasenheid, droë mond, verminderde eetlus,
- mondsere en inflammasie,
- abnormaliteite van lewerfunksietoetse, inflammasie van die lewer,
- inperking van nierfunksie, vloeistofretensie, nierpyn,
- sweet, blosing van gesig, probleme met urinering, ureter- of galweg-spasma,
- daling in liggaamstemperatuur (hipotermie),
- bloedafwykings soos afname in witbloedselle, afname in rooibloedselle. Die eerste simptome kan koors, seer keel, mondsere, griepagtige simptome, erge moegheid, neus- en velbloeding of onverklaarbare kneusplekke insluit.

Newe-effekte van onbekende frekwensie
- MYPRODOL® SUSPENSION, veral wanneer dit teen hoër as aanbevole dosisse, of vir 'n lang tydperk geneem word, kan skade aan u niere veroorsaak en hulle verhoed om sure behoorlik uit u bloed in die urien te verwyder (niertubulêre asidose). Dit kan ook baie lae vlakke van kalium in u bloed veroorsaak (sien afdeling 2). Dit is 'n baie ernstige toestand en sal onmiddellike behandeling vereis. Tekens en simptome sluit in spierswakheid en lighoofdigheid,

- verhoogde sensitiwiteit vir sonlig (fotosensitiwiteit).
- Velknoppe of galbulte (verhoogde, rooi of wit, jeukerige kolle van die vel), brand en pyn (FDE)

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, apteker of verpleegkundige. Dit sluit in enige moontlike newe-effekte wat nie in hierdie biljet gelys word nie. U kan ook newe-effekte by SAHPRA aanmeld via die Med Safety Toep (Medsafety X SAHPRA) en eAanmeldingsplatform (who-umc.org) wat op SAHPRA se webwerf gevind kan word. Deur newe-effekte aan te meld, kan u help om meer inligting oor die veiligheid van MYPRODOL® SUSPENSION te verskaf.

5. Hoe om MYPRODOL® SUSPENSION te bêre

- Bêre alle medisyne buite bereik van kinders.
- Bêre teen of benede 30 °C in ‘n diggeslote houer.
- Beskerm teen lig.
- Moenie gebruik ná die vervaldatum wat op die etiket/ kartonboksie/bottel vermeld 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® SUSPENSION bevat
Die aktiewe bestanddele is kodeïenfosfaat, ibuprofeen en parasetamol. Elke 10 ml bevat kodeïenfosfaat 10 mg, ibuprofeen 200 mg, parasetamol 250 mg.
Die ander bestanddele is swartbessie NE 53984, watervrye sitroensuur, dinatriumedetaat, gliserien, ligte kaolien, poliëtileenglikol 4000, polivinielpirrolidoon (PVP) K25, gesuiwerde water, framboosrooi H 1277, natriumbensoaat (preserveermiddel), natriumsitraat, natriumsiklamaat (versoeter), natriummetabisulfiet (anti-oksidant), natriumsakkarien 500 (versoeter), natriumdiwaterstoffosfaat dehidreerder, xantaangom TF.

Hoe MYPRODOL® SUSPENSION lyk en die inhoud van die verpakking
'n Homogene, ondeursigtige pienk suspensie met 'n swartbessiesmaak en reuk, vry van oortollige sigbare deeltjies.
100 ml amber ronde glasbottel, met 'n polipropileen-gevoerde (met 'n verlengde poliëtileenvoering) wit skroefprop.
200 ml amber ronde glasbottel, met 'n polipropileen-gevoerde (met 'n verlengde poliëtileenvoering) wit skroefprop.
200 ml amber ronde PVC-bottel met 'n lae-digtheid poliëtileen wit opdruk-prop.

Houer van Sertifikaat van Registrasie
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Hierdie biljet is mees onlangs hersien op
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