SCHEDULING STATUS: S3

MYPRODOL® SUSPENSION, 10 mg/200 mg/250 mg, suspension
Codeine phosphate, ibuprofen, paracetamol
Preservative (sodium benzoate): 0,1 % *m/v*
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 to 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 medicines, 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) (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 medicines (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 26,88 mg (main component of cooking/table salt) in each 10 ml. This is equivalent to 1,344 % 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 well-closed containers.
- 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.
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.

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