Patient Information Leaflet for

MYPRODOL CAPSULES

SCHEDULING STATUS

S3

MYPRODOL CAPSULES, **10 mg/200 mg/250 mg, capsules**

Codeine phosphate, ibuprofen, paracetamol

Sugar free

Read all of this leaflet carefully because it contains important information for you.

MYPRODOL CAPSULES is available without a doctor's prescription, for you to treat a mild illness. Nevertheless, you still need to use MYPRODOL CAPSULES carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share MYPRODOL CAPSULES with any other person.
- Ask your healthcare provider or pharmacist if you need more information or advice.
- 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

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, do not use NSAIDs, including MYPRODOL CAPSULES at 20 weeks or later in your pregnancy unless specifically advised to do so by your health care professional because these medicines may cause problems in your unborn baby.

Warnings and precautions

Note that the safety of continuous use of MYPRODOL CAPSULES for more than four weeks has not been proven, and is therefore unsafe seen as unsafe to use it for longer than 4 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 a 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 for more than 2 days 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.

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.

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.
- Anti-coagulants (medicines that help to prevent blood clots, e.g. apixaban, dabigatran, edoxaban, rivaroxaban, warfarin. MYPRODOL CAPSULES may make the effects of these medicines stronger.
- Anti-platelet 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.
- Medicines for anxiety and sleeping pills, e.g. temazepam, pentobarbital and phenothiazines and alcohol as MYPRODOL CAPSULES may make the effect of these medicines stronger.

MYPRODOL CAPSULES with alcohol

Do not drink alcohol (wine, beer, spirits) whilst taking this medicine.

Pregnancy and breastfeeding

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.

Regular use of NSAIDs (as in MYPRODOL CAPSULES) during the third trimester of pregnancy may result in breathing problems of your new-born child.

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.

3. How to take MYPRODOL CAPSULES

Do not share medicines prescribed for you with any other person.

Always take MYPRODOL CAPSULES exactly as described in this leaflet or as your doctor, pharmacist or nurse have told you. Check with your doctor, pharmacist or nurse 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 to six hourly and not more than six 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.

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).

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,
- 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.

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 well-closed containers.
- 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, 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 high density polypropylene (HDPP) securitainer with a low density polyethylene (LDPE) snap on 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.

Holder of Certificate of Registration

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