SCHEDULING STATUS

S3

MYPAID FORTE 400 mg/325 mg film-coated tablets Ibuprofen/Paracetamol

Sugar free

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

MYPAID FORTE is available without a doctor's prescription, for you to treat a mild illness.

Nevertheless, you still need to use MYPAID FORTE carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share MYPAID FORTE with any other person.
- Ask your health care provider or pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve.

What is in this leaflet

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

1. What MYPAID FORTE is and what it is used for

MYPAID FORTE contains two active ingredients. These are ibuprofen and paracetamol.

Ibuprofen belongs to a group of medicines known as non-steroidal anti-inflammatory drugs (NSAIDs). NSAIDs work by reducing pain, reducing swelling, and lowering high temperatures.

Paracetamol is an analgesic which works in a different way from ibuprofen to relieve pain and fever.

MYPAID FORTE is used to relieve mild and moderate pain and reduce swelling, with or without fever.

2. What you need to know before you take MYPAID FORTE

Do not take MYPAID FORTE

- if you are hypersensitive (allergic) to ibuprofen or paracetamol or any of the other ingredients of MYPAID FORTE.
- If you are pregnant, do not use NSAIDs 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.
- if you have heart failure (a chronic condition in which the heart does not pump blood as well as it should).
- If you have or have had a stomach ulcer or have a history of inflammation and bleeding in the bowels.
- if you are sensitive to aspirin or another non-steroidal anti-inflammatory medicine.
- if you suffer from asthma or have ever had an allergic reaction or suffered from wheezing after taking ibuprofen, aspirin or any other anti-inflammatory pain killers.
- if you suffer from swelling and irritation inside the nose.
- if you have a condition which increases your tendency to bleed.
- if you have severe liver or kidney function impairment.
- if you are pregnant or breastfeeding.
- if you are taking blood thinners.

Warnings and precautions

Special care should be taken with MYPAID FORTE:

- Higher than recommended doses of paracetamol may cause severe liver damage. Therefore, use MYPAID FORTE exactly as indicated (see section 3, How to take MYPAID FORTE).
- If you have an infection as MYPAID FORTE may mask the symptoms and the infection may get worse.
- if you have kidney or liver problems, including those due to drinking too much alcohol as you may be more at risk of the side effects of paracetamol (see Do not take [PRODUCT NAME]).
- If you have heart problems (see Do not take MYPAID FORTE) or high blood pressure.
- If you suffer from water retention (oedema).
- If you suffer from inflammatory or ulcerative disease of the upper or lower gastrointestinal tract.
- If you have renal function impairment- Renal failure may be provoked, especially in patients with pre-existing renal impairment.
- If you have asthma, a history of asthma or any other allergic disease (see Do not take MYPAID FORTE).
- If you are anaemic (feeling very weak, tired and looking pale).
- If you bleed easily (see Do not take MYPAID FORTE).
- If you have gastrointestinal problems (nausea, vomiting, stomach pain, heartburn, indigestion) and or stomach ulcer(s) (see Do not take MYPAID FORTE).
- If you are diabetic. MYPAID FORTE may influence your blood glucose results.
- If you are an elderly person. The elderly and patients with a history of stomach ulcers are more susceptible to develop side-effects affecting the bowels when using NSAIDs. Therefore, they should be carefully monitored for stomach ulcers and bleeding as it may be fatal.

- If you are going to have an operation. MYPAID FORTE may increase your risk of bleeding during surgery.
- If you have or have had any allergies or allergic reactions (including hives, swelling of the face, lips, tongue, and/or throat which may cause difficulty in breathing or swallowing) which required hospital treatment.

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 after around 30 weeks or later of pregnancy.

Children

MYPAID FORTE is not recommended for children under 12 years of age.

Other medicines and MYPAID FORTE

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

Tell your doctor or pharmacist if you are currently using:

- Hepatotoxic medicines (medicines that can cause damage to your liver) may increase risk of toxic liver disease.
- Enzyme inducing medicines may increase the risk of toxic liver disease and possibly decrease therapeutic effects of paracetamol.
- Metoclopramide (used to relieve feelings of sickness (nausea) or being sick (vomiting) may increase the absorption of paracetamol.
- Cholestyramine (used to treat high cholesterol) may reduce the absorption of paracetamol when taken within an hour of taking MYPAID FORTE.
- Anticoagulant medicines which thin the blood (e.g., warfarin): if taken with [PRODUCT

NAME], you may be at an increased risk of bleeding, therefore your doctor is likely to monitor you more closely.

- Corticosteroids (used to treat inflammation in your body) may increase the risk of ulcers and/or bleeding.
- Ticlopidine (used to thin your blood) may increase the risk of ulcers and/or bleeding.
- Clopidogrel (used to prevent your blood from clotting) may increase the risk of ulcers and/or bleeding.
- Bisphosphonates (used to treat osteoporosis, a condition in which your bones become brittle and fragile) may increase the risk of ulcers and/or bleeding.
- Pentoxifylline (used to treat muscle pain) may increase the risk of ulcers and/or bleeding.
- Antidiabetic medicines (used to treat high sugar levels) may increase effects of low blood sugar.
- Digoxin (used to treat heart failure and a fast heartbeat) concentration in the blood may increase.
- Lithium concentrations in the blood may increase to toxic levels.
- Methotrexate (used to treat rheumatoid arthritis, certain types of cancer and severe psoriasis) may be increased and prolonged, therefore increasing the risk of toxicity.
- Ciclosporin (used to prevent organ rejection after a transplant) may increase the risk of toxic kidney disease.
- Antihypertensives (used to treat high blood pressure) or diuretics (water pills) effects may be reduced when taken with MYPAID FORTE.
- Bone marrow depressants effects may be reduced when taken with MYPAID FORTE.
- Anti-platelet medicines and selective serotonin reuptake inhibitors (SSRIs) used for depression: if taken with MYPAID FORTE, you may be at an increased risk of bleeding if you suffer from stomach ulcers.
- Anti-inflammatory medicines such as NSAIDs (e.g., aspirin, diclofenac, etc.): if taken with MYPAID FORTE it may increase your side-effects.

MYPAID FORTE with food, drink and alcohol

MYPAID FORTE should be taken with food or after meals with sufficient water. The use of alcohol with MYPAID FORTE should be avoided as it increases the risk of stomach ulcers or gastrointestinal bleeding.

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 this medicine.

Do not take MYPAID FORTE if you are pregnant as it may be harmful for your unborn baby and may delay the onset of labour and increase the duration.

Do not take MYPAID FORTE if you are breastfeeding your baby, as the safety and efficacy during breastfeeding has not been established.

Driving and using machines

It is not always possible to predict to what extent MYPAID FORTE may interfere with your daily activities. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which MYPAID FORTE affects them.

3. How to take MYPAID FORTE

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

Always take MYPAID FORTE 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.

Use the lowest effective dose for the shortest possible duration of treatment. MYPAID FORTE is not recommended for children under 12 years of age.

The usual dose is for adults and children over 12 years of age is: two (2) tablets every four (4) hours when necessary. Do not exceed six (6) tablets in 24 hours. Tablets are to be taken with food or after meals with sufficient water.

You should talk to you doctor if your symptoms worsen, if your pain does not go away within 7 days, or if your fever persists for longer than 3 days.

Your doctor will tell you how long your treatment will last. Your doctor will prescribe MYPAID FORTE for the shortest possible duration.

If you have the impression that the effect of MYPAID FORTE is too strong or too weak, tell your doctor or pharmacist.

If you take more MYPAID FORTE than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre even if you feel well. This is because too much paracetamol can cause delayed, serious liver damage. Specialised treatment is essential as soon as possible.

Symptoms

The most common symptoms of paracetamol overdosage is nausea, vomiting, loss of appetite and possible stomach pain. Additional symptoms resulting from ibuprofen may include tiredness, drowsiness, bleeding in the stomach or bowels, kidney failure, fits and coma.

Mild symptoms of paracetamol overdose during the first two days of acute poisoning do not reflect the potential seriousness of the overdosage. Liver damage may lead to brain damage, coma and death. Kidney failure may develop even in the absence of sever liver damage and heart rhythm problems (arrhythmias) have also been reported.

Treatment
It is recommended that any adult person who has taken 5 to 10 g or more of paracetamol (or a child who has had more than 140 mg/kg) within a four-hour period, should have the stomach emptied by lavage (stomach pumping) and a single dose of 50 g activated charcoal given (by lavage tube).

N-acetylcysteine should be administered (preferably intravenously or less preferably, orally) to all cases of suspected overdose as soon as possible, preferably within eight hours of overdosage, although treatment up to 36 hours after ingestion may still be of benefit.
All patients treated for overdose should be monitored for at least ninety-six hours.

If you forget to take a dose of MYPAID FORTE

If you miss a dose, take it as soon as possible. However, if it is almost time for the next dose, skip the missed dose and go back to your regular dosing schedule. Do not take a double dose to make up for forgotten individual doses.

4. Possible side effects

MYPAID FORTE can have side effects.

Not all side effects reported for MYPAID FORTE are included in this leaflet. Should you not experience pain relief, or your general health worsens, or if you experience any untoward effects while taking MYPAID FORTE, please consult your doctor, pharmacist or other healthcare professional for advice.

If any of the following happens, stop taking MYPAID FORTE and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing.
- Rash or itching.

- Fainting.

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

Tell your doctor if you notice any of the following:

Frequent side effects:

- Dizziness.
- Nausea, stomach pain, vomiting, diarrhoea, flatulence, constipation, indigestion, stomach ulceration, perforation, or bleeding, bloody stool, haematemesis (if you vomit blood), and gastritis (inflammation of the lining of the stomach).

Less frequent side effects:

- Changes in your blood cell counts (agranulocytosis, thrombocytopaenia, anaemia, neutropenia, eosinophilia)
- Nervousness, headache, ringing/buzzing noise in ear(s), depression, drowsiness, sleeplessness.
- Blurred vision, changes in visual colour perception and other toxic amblyopia (damage to optic nerve).
- Changes in the way your heart beats (beating faster), flushing, high blood pressure, and heart failure.
- Yellowing of your skin and eyes, also called jaundice or hepatitis.
- Kidney problems, which may lead to kidney failure (you may pass more or less urine, have blood in the urine or cloudy urine, feel breathless, very tired or weak, have no appetite, or have swollen ankles).
- Aseptic meningitis (infection around the brain or spinal cord with fever, nausea, vomiting, headache, stiff neck and extreme sensitivity to bright light).

Side effects with an unknown frequency:

- Crohn's disease (an inflammatory disease that can affect any part of the gastrointestinal track causing symptoms such as pain, fever, diarrhoea and loss of body mass).
- Painful, blistering or peeling skin rash, such as Stevens-Johnson syndrome, toxic epidermal necrolysis or erythema multiforme.
- Interstitial nephritis (passing more or less urine than is normal for you, dark urine, nausea, vomiting).

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. 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 MYPAID FORTE.

5. How to store MYPAID FORTE

- Store all medicines out of reach of children.
- Store at or below 30 °C. Protect from light and moisture.
- Do not use after the expiry date stated on the container or 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 MYPAID FORTE contains

The active substances are ibuprofen and paracetamol.
Each film-coated tablet contains 400 mg of ibuprofen and 325 mg of paracetamol.

The other ingredients are calcium hydrogen phosphate (Dihydrate), Opadry 06G53189 orange (containing hypromellose, macrogol/PEG 6000, polyethylene glycol, sodium laurilsulfate, Sunset Yellow and titanium dioxide), povidone (PVPK K 30), pregelatinised starch (starch 1500), and purified talc.

What MYPAID FORTE looks like and contents of the pack

MYPAID FORTE are orange coloured, oval, film-coated tablets.

The film-coated tablets are available in a carton containing 30, 60 or 100 tablets in blister strips of 10 tablets each, or a HDPE bottle containing 500 tablets.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

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