

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS S2

MYPAID, each capsule contains:

Ibuprofen 200 mg

Paracetamol 250 mg

Sugar free

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

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

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

- Keep this leaflet. You may need to read it again.
- Do not share MYPAID 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 after 10 days.

1.WHAT MYPAID IS AND WHAT IT IS USED FOR

MYPAID contains ibuprofen and paracetamol which belongs to a group of medicine referred to as non-steroidal anti-inflammatory medicines (NSAIDs).

MYPAID is used for the relief of mild to moderate pain associated with inflammation and fever including:

- Headache
- Muscular aches and pain

- Menstrual pain
- Dental pain

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE MYPAID

Do not take MYPAID

- If you are allergic to ibuprofen or paracetamol or any of the other ingredients of MYPAID tablets (listed in section 6.1).
- If you have asthma or bronchospasm (difficulty breathing)
- If you have bleeding disorder.
- If you have renal failure
- If you have heart disease.
- If you have severe liver function impairment and in those who are receiving coumarin anticoagulants.
- If you have peptic ulceration or a history of such ulceration.
- If you are pregnant, do not use MYPAID 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 are younger than 12 years old.

Warnings and precautions

Special care should be taken with MYPAID:

- Tell your doctor or health care provider if you are pregnant or plan to become pregnant. Taking MYPAID at around 20 weeks of pregnancy or later may harm your unborn baby. If you need to take MYPAID 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 MYPAID around 30 weeks of pregnancy or later.
- Ibuprofen should be given with care to the elderly.
- Ibuprofen should be discontinued in patients who experience blurred or diminished vision or changes in colour vision.
- Patients with collagen disease may be at increased risk of developing aseptic meningitis.
- In view of the product's inherent potential to cause fluid retention, heart failure may be precipitated in some compromised patients.
- The elderly have an increased frequency of adverse reactions to NSAIDs including MYPAID, especially gastrointestinal perforation, ulceration and bleeding (PUBs) which may be fatal.
- The risk of gastrointestinal perforation, ulceration or bleeding (PUBs) is higher with increasing doses of MYPAID, in patients with a history of ulcers, and the elderly.
- When gastrointestinal bleeding or ulceration occurs in patients receiving MYPAID, treatment with MYPAID should be stopped.
- MYPAID should be given with caution to patients with a history of gastrointestinal disease (e.g. ulcerative colitis, Crohn's disease, hernia, heartburn, angiodysplasia (an

abnormality with the blood vessels in the gastrointestinal tract); as the condition may worsen.

- Serious skin reactions, some of them fatal, including severe inflammation of the skin, Stevens-Johnson syndrome, and other rare and serious skin conditions have been reported. MYPAID should be discontinued at the first appearance of skin rash, mucosal lesions, or any other sign of allergy.

Use in children and adolescents

Do not give MYPAID to children under the age of 12 years.

Other medicines and MYPAID

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

NSAIDs: use of two or more NSAIDs concomitantly could result in an increase in side effects

Corticosteroids: increased risk of gastrointestinal perforation, ulceration or bleeding (PUBs)

Anti-coagulants: MYPAID may enhance the effects of anti-coagulants such as warfarin

Anti-platelet medicines and selective serotonin reuptake inhibitors (SSRIs): increased risk of gastrointestinal bleeding

MYPAID with food and drink

No known interactions with food and drink.

Pregnancy and breast-feeding

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 MYPAID.

Driving and using machines

The effect on ability driving and using of machines has not been established.

3. HOW TO TAKE MYPAID

Always take MYPAID exactly as described in this leaflet or as your doctor or pharmacist have told you. Check with your doctor or pharmacist if you are not sure.

Adults and children 12 years of age and older

The recommended initial dose is two capsules every four hours.

Capsules to be taken with food or after meals with enough water.

Do not take more than six capsules in twenty-four hours.

If you take more MYPAID than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison Centre.

The most likely symptoms of overdosage are stomach pain and nausea and vomiting.

If you forget to take MYPAID

Do not take a double dose to make up for forgotten doses.

4. POSSIBLE SIDE EFFECTS

MYPAID can have side effects:

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

Side effects includes:

- Nervousness, depression, difficulty sleeping.
- Drowsiness, headache, dizziness.
- Blurred eyesight and other eyesight problems.
- Ringing sound in the ear.
- Indigestion, upset stomach and bleeding may occur.
- Liver and kidney disorders.
- Retention of fluid or swelling legs and hands.
- Blood disorders including anaemia.
- Skin rashes and itching of the skin.
- Allergic reactions may occur.
- Bloody stools.
- High blood pressure, heart failure.

- ulcers, diarrhoea, bloating, vomiting, constipation.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist. 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.

May also report to Adcock Ingram Limited using the following email:

Adcock.AEReports@adcock.com

5. HOW TO STORE

Store all medicine out of reach of children.

Store at or below 25 °C.

Do not use after 24 months.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What it contains:

MYPAID contains the active ingredient ibuprofen and paracetamol, each capsule contains ibuprofen 200 mg and 250 mg of paracetamol.

The other ingredients are:

Microcrystalline cellulose (Avicel pH 101), Starch 1500, Sodium stearyl fumarate.

What MYPAID looks like and contents of the pack:

Green and white, hard gelatin capsule, with R25 imprinted on cap and body; containing white, granular powder.

Holder of Certificate of Registration

Adcock Ingram Limited

1 New Road

Erand Gardens

Midrand, 1685

Private Bag X69

Bryanston, 2021

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Access to the corresponding professional information

It is contained in the packaging of the medicine