PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

S2

MYPAID, capsule

Ibuprofen 200 mg and 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 take 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 you pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve after 10 days.

What is in this leaflet

1. What MYPAID is and what it is used for

2. What you need to know before you take MYPAID

3. How to take MYPAID

4. Possible side effects

5. How to store MYPAID

6. Contents of the pack and other information.

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 headache, fever, muscular pain, menstrual and 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 uncontrolled asthma or bronchospasm (difficulty breathing)
- If you have bleeding disorder.
- If you have a disease affecting the heart and blood circulation
- If you have heart failure
- If you have a history of having a gastrointestinal hole, tear, sore or bleeding related to the use of anti-inflammatory medication. The risk increases with dose and in the elderly. If gastrointestinal bleeding or sores occur, MYPAID should be stopped.
- If you have renal failure
- If you have severe liver function impairment
- If you are receiving coumarin anticoagulants (medicine used to thin blood)
- If you are pregnant or breastfeeding: Do not use MYPAID at 30 weeks or later in 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 previously had hypersensitivity reactions (e.g. asthma, running nose, swelling or a rash) after having taken aspirin or other anti-inflammatory medication
- If you have abnormal lumps in the nose that can sometimes be cancerous associated with difficulty breathing because the airways have narrowed due to taking aspirin

Warnings and precautions

Special care should be taken with MYPAID:

- MYPAID contains paracetamol. Do not take more than the recommended dosage, this may cause severe damage to the liver. Consult your doctor if no relief is obtained with the recommended dosage.

- If you suffer from liver disease, do not give paracetamol-containing preparations without consulting a doctor
- Do not use continuously for longer than 10 days without consulting your doctor
- MYPAID should be given with care to the elderly.
- Patients with congestive heart failure (failure of the heart resulting in fluid build-up in the lungs, other body tissues, or both), cirrhosis (serious liver disorder in which connective tissue replaces normal liver tissue, and liver failure often occurs), water pill volume loss, or kidney insufficiency are at greater risk of developing renal dysfunction.
- Ibuprofen should be discontinued in patients who experience blurred or weaker vision or changes in colour vision.
- Patients with collagen disease (systemic autoimmune diseases) may be at increased risk of developing aseptic meningitis (inflammation of the membrane covering the brain and spinal cord)
- Patients with a history of high blood pressure should be careful. MYPAID can cause fluid retention and swelling in these patients. Heart failure may unexpectedly occur in some compromised patients.
- Caution should be advised in patients receiving associated medications which could increase the risk of holes, tears or bleeding, such as oral corticosteroids (steroid medicines that help reduce inflammation and suppress the immune system in various conditions), selective serotonin-reuptake inhibitors (antidepressant medicines or anti-platelet medicines (blood thinning medicines) such as aspirin.
- MYPAID should be given with care to patients with a history of gastrointestinal disease (e.g. ulcerative colitis [inflammation of the large intestine causing tears and bleeding], Crohn’s disease [an inflammatory disease affecting the gut], hernia [bulging of an organ through an abnormal opening in a muscle wall], heartburn, angiodysplasia (an abnormality with the blood vessels in the gastrointestinal tract); as these conditions may worsen.
- Serious skin reactions, some of them fatal, including severe inflammation of the skin, Stevens-Johnson syndrome (life-threatening reaction with flu-like symptoms and painful rash affecting the skin, mouth, eyes and genitals), and toxic epidermal necrolysis (life-threatening reaction with flu-

like effects and blistering in the skin, mouth eyes and genitals) have been reported. MYPAID should be discontinued at the first appearance of skin rash, site of the injury or disease in the moist lining of digestive, respiratory, reproductive, and urinary tracts) or any other sign of allergy.

- 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.
- If you have an infection or think that you have an infection, as MYPAID may hide signs of infections such as fever and pain. If you take this medicine while you have an infection and your symptoms of the infection persist or worsen, consult a doctor without delay. Drug Reaction with Eosinophillia and Systemic Symptoms [DRESS] (a severe reaction affecting the skin, blood and internal organs) has been reported in patients taking NSAIDs (medicines that relieve or reduce pain & inflammation) such as MYPAID. Some of these events have been life-threatening or could lead to death. DRESS typically, presents with fever, rash, enlarged lymph nodes, and/or facial swelling. Sometimes symptoms of DRESS may resemble an acute viral infection. Eosinophillia (higher number of a specific type of white blood cell) is often present Because this disorder is variable in its presentation, other organ systems not noted here may be involved. It is important to note that early manifestations of hypersensitivity, such as fever or enlarged lymph nodes, may be present even though rash is not evident. If such signs or symptoms are present, discontinue MYPAID and see the doctor immediately.
- Serious skin reactions such as toxic epidermal necrolysis (TEN) [life-threatening reaction with flu-like effects and blistering in the skin, mouth eyes and genitals], Steven-Johnson syndrome (SJS) [life-threatening reaction with flu-like symptoms and painful rash affecting the skin, mouth, eyes and genitals], acute generalized exanthematous pustulosis (AGEP) [a rare skin reaction that is usually caused by a drug allergy], eosinophilia [an excess of eosinophils, a type of white blood cell] and systemic (DRESS) [a severe reaction affecting the skin, blood and internal organs] /Drug-induced hypersensitivity syndrome (DIHS) [a severe reaction to medication that can cause serious problems in many different body systems] and fixed drug eruptions (FDE) [a distinctive cutaneous allergic reaction that characteristically recurs at the same site(s) on re-exposure to the medication or other

chemical agent] have been reported in patients receiving paracetamol. If you experience any signs of serious skin reactions such as swelling, itching, red severe rash, stop using MYPAID immediately and contact your doctor (see Section 4).

Other medicines and MYPAID

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

- *NSAIDs*: use of two or more NSAIDs taken together could result in an increase in side effects
- *Anti-coagulants:* MYPAID may increase the effects of anti-coagulants (Blood thinning medicine) such as warfarin
- *Anti-platelet medicines* (medicines used to prevent clots) and *selective serotonin reuptake inhibitors (SSRIs)* (antidepressant medicines): increased risk of gastrointestinal bleeding
- *Aspirin*: simultaneous use of MYPAID and aspirin is not generally recommended due to the increased side effects
- *Antihypertensives* (medicines that lower blood pressure) or *diuretics* (a medicine that increases urine production): MYPAID may reduce the effect of these medicines
- *Alcohol, corticosteroids* (steroid medicines that help reduce inflammation and suppress the immune system in various conditions), *clopidogrel* (medicine used to prevent clots), *ticlopidine* (medicine used to lessen the chance of having a stroke), *bisphosphonates* (medicines that slow down or prevent bone loss, strengthening bones), *oxpentifylline* (medicine used to treat muscle pain in people with peripheral artery disease) may increase the risk of gastrointestinal perforation (holes/tears), bleeding and ulceration (sores) (PUBs)
- *Cardiac glycosides* (medicines that increase the output force of the heart and decrease its rate of contractions): MYPAID may worsen heart failure, reduce kidney function and increase blood sugar levels.
- *Lithium*: MYPAID may increase the concentration of lithium in the body for longer.
- *Methotrexate*: MYPAID may increase and prolong the methotrexate blood concentration and increase risk of methotrexate toxicity.

- *Nephrotoxic* (damaging or destructive to the kidney) *medicines* e.g. *ciclosporin* (immunosuppressant medicine), *tacrolimus* (immunosuppressant medicine) may increase the risk of kidney damage further
- *Quinolones antibiotics*: Patients taking MYPAID and quinolones may have an increased risk of developing seizures.
- *Mifepristone* (medicine used for abortion or miscarriage): MYPAID should not be used for 8 to 12 days after mifepristone use as MYPAID can reduce the effect of it.
- *Phenytoin*: MYPAID may enhance the effects of phenytoin
- *Sulphonylurea antidiabetics* (medicines used to manage Type 2 diabetes): MYPAID may enhance the effects of these medicines.
- *Bone marrow depressants*: The leucopenic (low white blood cell count) and/or thrombocytopenic (low platelet level count) effects of these medicines may be increased.
- *Hepatotoxic* (liver damaging) *medicines* (*zidovudine* [medicine used to prevent and treat HIV/AIDS], *co-trimoxazole* [antibiotic], *isoniazid* [antibiotic used to treat & prevent TB], *tuberculosis* [bacterial infection that usually results in a serious lung disorder] medicines): Hepatotoxic substances may increase the possibility of paracetamol accumulation and overdose. The risk of liver damage by paracetamol may be increased by medicines which induce liver microsomal enzymes such as anticonvulsants (medicines used to treat and prevent seizures) and alcohol.
- *Metoclopramide* and *domperidone* (medicine used to treat and prevent nausea and vomiting): Absorption of MYPAID may be accelerated.
- *Cholestyramine* (medicine used to lower cholesterol): Absorption of MYPAID is reduced if given within one hour of cholestyramine.
- *Probenecid* (medicine used to prevent and treat gout): MYPAID excretion may be affected, and blood concentrations increased
- *Medicines which decrease gastric emptying*: MYPAID absorption is decreased by substances that decrease gastric emptying, e.g. *propantheline*, *antidepressants with anticholinergic properties, and narcotic analgesics*
- *Chloramphenicol* (antibiotic): MYPAID may increase chloramphenicol blood concentrations.
- *Moclobemide* (antidepressant medicine): The effects of MYPAID might be greater with use of moclobemide.

MYPAID with laboratory tests

- Diabetic patients may experience false results with blood glucose tests.

MYPAID with food, drink and alcohol

MYPAID may be taken with food or after meals with sufficient water

Pregnancy, breastfeeding and fertility

MYPAID is not recommended for use by pregnant or breastfeeding women. 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.

The use of MYPAID may impair female fertility and is not recommended in women attempting to conceive. In women who have difficulties conceiving or who are undergoing investigation of infertility, withdrawal of MYPAID should be considered.

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 effects on ability to drive and use machines has not been established. MYPAID may impair the ability to drive and use machinery. No studies on the effect of ability to drive or use machines have been performed. Undesirable effects such as dizziness, fatigue and visual disturbances are possible after taking NSAIDs. If affected, patients should not drive or operate machinery.

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

3. How to take MYPAID

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

Always take MYPAID capsules exactly according to instructions. You should check with a doctor or pharmacist if you are unsure.

Always take MYPAID exactly as described in this leaflet or as your health care professional has told you. Check with your health care professional if you are not sure.

The usual dose is:

Adults and children over 12 years two capsules every four hours, but not more than six capsules in twenty-four hours.

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

Consult your doctor if no relief is obtained with the recommended dosage.

Use the lowest effective dose for the shortest possible duration of treatment.

DO NOT EXCEED THE RECOMMENDED DOSE

Not recommended for use in children under twelve years of age.

If you take more MYPAID than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, seek help at the nearest hospital or poison control center immediately. Take this leaflet and the rest of the remaining capsules with you so the doctor will know what you have taken. Should your child or somebody else have taken an overdose of MYPAID, the following symptoms may be experienced (due to paracetamol overdose): loss of appetite, nausea, vomiting, pale skin and stomach pain. These symptoms may be mild and do not reflect the potential seriousness of the overdosage which can result in liver damage or death. Treatment must be started within 24 hours in order to prevent this.

If you forget to use MYPAID

Use your next dose at your regular time.

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

If any of the following happens, stop giving MYPAID 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)
- Blisters on your skin or inside your mouth, nose, vagina or bottom
- The appearance of a rash or sunburn when you have been outside (even on a cloudy day)
- swelling of the eyelids, face, tongue or lips
- severe dizziness
- difficulty in breathing
- Serious skin reactions such as swelling, itching, red severe rash especially those covering your whole body (appearing as allergic wheals), stop giving MYPAID immediately and contact your doctor (see Section 2).

Tell your doctor if you notice any of the following:

Frequent	**Less frequent**	**Unknown**
Nervousness, dizziness, headache, indigestion, upset stomach, nausea, vomiting, diarrhoea, abdominal cramps and pain, bloating, constipation, mouth	Aseptic meningitis (inflammation of the membrane covering the brain and spinal cord) with symptoms of stiff neck, headache, nausea, vomiting, fever or disorientation; blood disorders, haematopoietic (blood cell production) disorders, bleeding episodes; hypersensitivity reactions including skin	Drug-induced hypersensitivity syndrome (DIHS) [Hypersensitivity reactions characterised by urticaria, dyspnoea, and hypotension], high-anion gap metabolic acidosis, Drug Reaction with Eosinophilia and Systemic

sores, inflammatory bowel disease, Crohn's disease (serious inflammation of any part of the gastrointestinal tract), inflammation of the stomach, sore in the stomach or in the lining of the stomach, gastrointestinal bleeding and ulcers with symptoms of melaena (bloody stool) haematemesis (vomiting blood).	rashes, hives, itchiness, asthmatic attacks; severe hypersensitivity reactions where symptoms can include facial, tongue and larynx swelling, trouble breathing, fast heart rate, low blood pressure up to life-threatening shock; serum sickness (a reaction of the immune system to proteins or antiserum that contains antibodies used to treat or protect against infections or toxins), lupus erythematosus syndrome (chronic disorder of connective tissue in which there can be skin rash, arthritis, kidney problems, and anemia, among other problems), Henoch-Schönlein vasculitis (is a disease that causes the antibody immunoglobulin A to collect in small blood vessels, which then become inflamed and leak blood), angioedema (is a disease that causes the antibody immunoglobulin A to collect in small blood vessels, which then become inflamed and leak blood), abnormal breast enlargement, low blood sugar, depression, confusion, emotional lability (the tendency to fluctuate quickly and abruptly between distinct emotional states), hallucinations, dream abnormalities, paraesthesia (sensations like numbness, tingling, pins and needles), drowsiness, difficulty sleeping, sleepiness, paradoxical stimulation (unintended effect of a drug), inflammation of the optic nerve, psychomotor impairment (a condition that affects the way you move, talk, react and think), extrapyramidal effects (involuntary movements that you cannot control), shakiness, seizures, visual impairment, blurred eyesight, and other eyesight problems, ringing sound in the ears), light-headedness, swelling of legs and hands, heart failure, angina pectoris (chest pain	Symptoms (DRESS syndrome) [a severe reaction affecting the skin, blood and internal organs], Acute Generalised Exanthematous Pustulosis (AGEP) [a rare skin reaction that is usually caused by a drug allergy], Fixed drug eruptions (FDE) [a distinctive cutaneous allergic reaction that characteristically recurs at the same site(s) on re-exposure to the medication or other chemical agent]

	due to decreased oxygen being supplied to the heart), abnormal heart rhythm, palpitations (irregular heartbeats that you can feel), high blood pressure, wheezing, thickened respiratory tract secretions, inflammation of the pancreas, gas passed through the anus/ rectum, decreased appetite, abnormalities of liver function tests, liver damage, acute inflammation of the liver, jaundice (too much bile in the blood causing a yellow colour to the skin, gums, eye, and other tissues), skin rash, itchiness, reversible skin rash (usually erythematous (superficial reddening of the skin) or urticarial (itchy), but sometimes more serious and may be accompanied by fever and injury/ disease in the moist lining of digestive, respiratory, reproductive, and urinary tracts), exfoliative dermatoses (rare, inflammatory skin reaction that leads to widespread skin discoloration, peeling, and swelling) and bullous (fluid filled blister) reaction including Stevens-Johnson syndrome (life-threatening reaction with flu-like symptoms and painful rash affecting the skin, mouth, eyes and genitals), toxic epidermal necrolysis (life-threatening reaction with flu-like effects and blistering in the skin, mouth eyes and genitals), kidney disorder, nephrotic syndrome (collection of symptoms due to kidney damage), inflammation of the kidneys, urinary retention, acute reversible renal failure, renal colic (Pain felt when kidney stones block the urinary tract)	

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

Reporting of side effects

If you have any side effects, talk to your health care professional. You can report side effects to the **Adcock Ingram Pharmacovigilance** department by e-mail to Adcock.Aereports@adcock.com or call 011 635 0134.

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

5. How to store MYPAID

Store all medicine out of reach of children.

Store at or below 25 ºC.

Do not use after 24 months.

Do not use after the expiry date on the label.

Do not dispose of unused medicines in drains or sewerage systems.

6. Contents of the pack and other information

What it MYPAID contains:

Each capsule contains:	
Ibuprofen	200 mg
Paracetamol	250 mg

The other ingredients are microcrystalline cellulose (Avicel pH 101) [E460], starch 1500 and sodium stearyl fumarate.

What MYPAID looks like and contents of the pack

Hard empty gelatin capsules of size 'O' having opaque white body and opaque dark green cap, printed with 'R25' in black colour. Containing white granular powder.

Plastic containers with 30 and 60 capsules.

Blister packs of 30 and 60 capsules

Not all pack sizes may be marketed at the same time.

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