PROFESSIONAL INFORMATION

SCHEDULING STATUS: **S2**

1.NAME OF THE MEDICINE

MYPAID Capsules

Strength

Each capsule contains:

Ibuprofen 200 mg

Paracetamol 250 mg

2.QUALITATIVE AND QUANTITATIVE COMPOSITION:

Each capsule contains:

Ibuprofen	200 mg
Paracetamol	250 mg

Sugar free

For full list of excipients, see section 6.1.

3.PHARMACEUTICAL FORM

Capsules.

Hard empty gelatin capsules of size '0' having opaque white body and opaque dark green cap, printed with 'R25' in black colour. Containing white granular powder.

4.CLINICAL PARTICULARS

4.1. Therapeutic indications:

MYPAID capsules are indicated for the relief of headache from musculo-skeletal origin, feverishness, muscular, menstrual and dental pain.

4.2 Posology and method of administration

Not recommended for children under twelve years of age.

Adults and children over 12 years of age: Take two capsules orally every four hours, but not more than six capsules in twenty-four hours. Capsules are to be taken with food or after meals with sufficient 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

4.3 Contraindications:

MYPAID is not recommended for use by pregnant or breastfeeding women. It should not be given to patients with asthma or bronchospasm, bleeding disorders, cardiovascular disease, peptic ulceration or a history of such ulceration, renal failure, severe liver function impairment and in those who are receiving coumarin anticoagulants.

Where there is a history of gastrointestinal perforation, ulceration or bleeding (PUBs) related to previous NSAIDs, including MYPAID; including active or history of recurrent ulcer/haemorrhage/perforations.

Patients who are sensitive to any ingredients or aspirin should not be given MYPAID.

Avoid use of NSAIDs in women around 30 weeks gestation and later in pregnancy due to the risks of oligohydramnios/ foetal renal dysfunction and premature closure of the foetal ductus arteriosus.

4.4 Special warnings and precautions for use:

This product 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.

Paracetamol:

Dosages in excess of those recommended may cause severe liver damage. Consult a doctor if no relief is obtained from the recommended dosage. Do not use for more than ten days without consulting a doctor.

Ibuprofen:

Ibuprofen should be given with care to the elderly, to patients with asthma or bronchospasm, bleeding disorders, cardiovascular disease or in liver or renal failure. Patients with congestive heart failure, cirrhosis, diuretic-induced volume depletion, or renal insufficiency require local synthesis of vasodilating prostaglandins to maintain renal perfusion and therefore these patients are at greater risk of developing renal dysfunction due to NSAID-induced inhibition of renal prostaglandin synthesis. 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.

Caution is required in patients with a history of hypertension and/or heart failure as fluid retention and oedema have been reported in association with MYPAID therapy. In view of the MYPAID's inherent potential to cause fluid retention, heart failure may be precipitated in some compromised patients.

Caution is required in patients with significant risk factors for cardiovascular events (e.g. hypertension, hyperlipidaemia, diabetes mellitus, smoking) and should only be treated with diclofenac after careful consideration.

Elderly: 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, hiatus hernia, gastro- oesophageal reflux disease, angiodysplasia) as the condition may be exacerbated.

Serious skin reactions, some of them fatal, including exfoliative dermatitis, Stevens-Johnson syndrome, and toxic epidermal necrolyis have been reported. MYPAID should be discontinued at the first appearance of skin rash, mucosal lesions, or any other sign of hypersensitivity.

Regular use of NSAIDs such as MYPAID during the third trimester of pregnancy, may result in premature closure of the foetal ductus arteriosus in utero, and possibly, in persistent pulmonary hypertension of the new-born. The onset of labour may be delayed and its duration increased.

Foetal Toxicity: Limit use of NSAIDs, including MYPAID, between 20 to 30 weeks of pregnancy due to the risk of oligohydramnios/foetal renal dysfunction. Avoid use of MYPAID in women around 30 weeks gestation and later in pregnancy due to the risks of oligohydramnios/foetal renal dysfunction and premature closure of the foetal ductus arteriosus.

If NSAIDs treatment is necessary between 20 weeks and 30 weeks gestation, limit MYPAID use to the lowest effective dose and shortest duration possible. Consider ultrasound monitoring of amniotic fluid if MYPAID treatment extends beyond 48 hours. Discontinue MYPAID if oligohydramnios occurs and follow up according to clinical practice.

4.5 Interaction with other medicines and other forms of interaction

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.

4.6 Fertility, pregnancy and lactation

Use of NSAIDs, including MYPAID, can cause premature closure of the foetal ductus arteriosus and foetal renal dysfunction leading to oligohydramnios and, in some cases, neonatal renal impairment. Because of these risks, the use of MYPAID dose and duration between 20 and 30 weeks of gestation should be limited and avoided at around 30 weeks of gestation and later in pregnancy. Safety and efficacy in lactation and fertility has not been established.

4.7 Effects on ability to drive and use machines

The effects on ability to drive and use machines has not been established.

4.8 Undesirable effects

System organ class	**Undesirable effects**
All the below adverse effects have no known frequency	
Blood and lymphatic system disorders	Blood disorders e.g., neutropenia, leucopenia and pancytopenia may occur. Agranulocytosis, thrombocytopenia, oedema (heart failure may be precipitated in some compromised patients).
Cardiac disorders	Oedema, hypertension and cardiac failure.
Eye disorders	Blurred vision and other ocular reaction.
Ear and labyrinth disorders	Tinnitus.
Gastrointestinal system disorders	Peptic ulcers, perforation or gastrointestinal bleeding, sometimes fatal. Nausea, vomiting, diarrhoea, flatulence, constipation, dyspepsia,

	abdominal pain, melaena, haematemesis, ulcerative stomatitis, exacerbation of colitis and Crohn's disease, gastritis.
Hepato-biliary disorders	Abnormalities of liver function tests. Patients suffering from liver or kidney disease should take paracetamol under medical supervision.
Immune system disorders	Sensitivity reactions
Nervous system disorders	Drowsiness, headache, dizziness
Psychiatric disorders	Nervousness; depression, insomnia
Nervous system disorders	Drowsiness, headache, dizziness
Renal and urinary disorders	Impairment of renal function. Patients suffering from liver or kidney disease should take paracetamol under medical supervision.
Skin and subcutaneous tissue disorders	Pruritis, sensitivity reactions resulting in reversible skin rash. The skin rash is usually erythematous or urticarial, but sometimes more serious and may be accompanied by fever and mucosal lesions. Bullous reactions, including Stevens-Johnson syndrome and toxic epidermal necrolysis.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Health care providers are asked to report any suspected adverse reactions to SAHPRA via the **"6.04 Adverse Drug Reactions Reporting Form",** found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8 **.**

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

Adcock.AEReports@adcock.com

4.9 Overdose

IBUPROFEN:

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

Treatment is symptomatic and supportive.

PARACETAMOL:

Prompt treatment is essential. In the event of an overdosage, consult a doctor immediately, or take the person directly to a hospital. A delay in starting treatment may mean that antidote is given too late to be effective. Evidence of liver damage is often delayed until after the time for effective treatment has lapsed.

Susceptibility to paracetamol toxicity is increased in patients who have taken repeated high doses (greater than 5 -10 g/day) of paracetamol for several days, in chronic alcoholism, chronic liver disease, AIDS, malnutrition, and with the use of drugs that induce liver microsomal oxidation such as barbiturates, isoniazid, rifampicin, phenytoin and carbamazepine.

Symptoms of paracetamol overdosage in the first 24 hours include pallor, nausea, vomiting, anorexia and possibly abdominal pain. Mild symptoms during the first two days of acute poisoning, do not reflect the potential seriousness of the overdosage.

Liver damage may become apparent 12 to 48 hours, or later after ingestion, initially by elevation of the serum transaminase and lactic dehydrogenase activity, increased serum bilirubin concentration and prolongation of the prothrombin time. Liver damage may lead to encephalopathy, coma and death. Acute renal failure with acute tubular necrosis may develop even in the absence of severe liver damage. Abnormalities of glucose metabolism and metabolic acidosis may occur. Cardiac arrhythmias have been reported.

Treatment for paracetamol overdosage: Although evidence is limited it is recommended that any adult person who has ingested 5 - 10 grams or more of paracetamol (or a child who has had more than 140 mg/kg) within the preceding four hours, should have the stomach emptied by lavage (emesis may be adequate for children) and a single dose of 50 g activated charcoal given via the lavage tube. Ingestion of amounts of paracetamol smaller than this may require treatment in patients susceptible to paracetamol poisoning (see above). In patients who are stuperose or comatose endotracheal intubation should precede gastric lavage in order to avoid aspiration.

N-acetylcysteine should be administered 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, especially if more than 150 mg/kg of paracetamol was taken. An initial dose of 150 mg/kg N-acetylcysteine in 200 ml dextrose injection given **intravenously** over 15 minutes, followed by an infusion of 50 mg/kg in 500 ml dextrose injection over the next four hours, and then 100 mg/kg in 1 000 ml dextrose injection over the next sixteen hours. **The volume of intravenous fluid should be modified for children.**

Although the oral formulation is not the treatment of choice, 140 mg/kg dissolved in water may be administered initially, followed by 70 mg/kg every four hours for seventeen doses. A plasma paracetamol level should be determined four hours after ingestion in all cases of suspected overdosage. Levels done before four hours may be misleading. Patients at risk of liver damage, and hence requiring continued treatment with N-acetylcysteine, can be identified according to their 4-hour plasma paracetamol level. The plasma paracetamol level can be plotted against time since ingestion in the nomogram below.

The nomogram should be used only in relation to a single acute ingestion. Those whose plasma paracetamol levels are above the “normal treatment line”, should continue N-acetylcysteine treatment with 100 mg/kg IV over sixteen hours repeatedly until recovery. Patients with increased susceptibility to liver damage as identified above, should continue treatment if concentrations are above the “high risk treatment line”. Prothrombin index correlates best with survival.

Monitor all patients with significant ingestions for at least ninety-six hours.

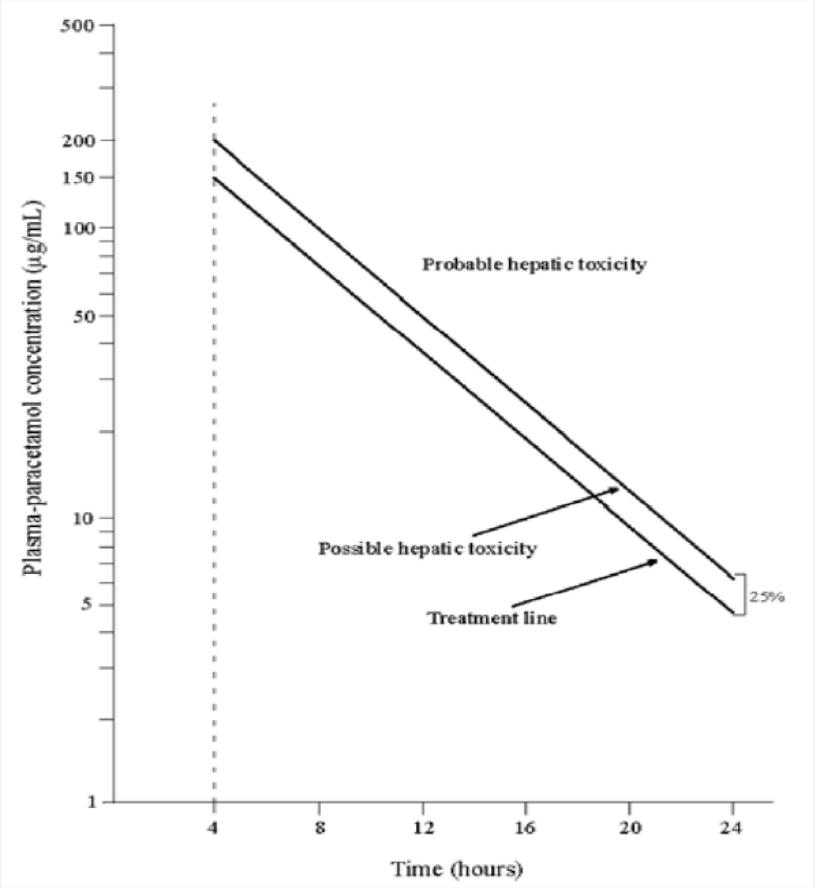

Figure 1. A semi-logarithmic plot of plasma-paracetamol concentration against hours after ingestion.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamics properties

A 2.8 Analgesic combinations

Mechanism of action

MYPAID capsules have an analgesic, anti-inflammatory and antipyretic action.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

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

Capsule Composition:

Cap (opaque dark green) - Brilliant Blue (C.I: 42090), gelatin, Quinoline Yellow (C.I: 47005), Sunset Yellow (C.I: 15985), titanium dioxide (C.I: 77891).

Body (opaque white) – gelatin, titanium dioxide (C.I: 77891).

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

24 months

6.4 Special precautions for storage

Store at or below 25 ºC.

Protect from light.

6.5 Nature and contents of container

30 capsules in white plain securitainer 0204 with closure.

60 capsules in white securitainer 0205 with closure.

Blister packs of 30 and 60 capsules in PVC rigid film and foil aluminium.

Not all pack sizes indicated are necessarily marketed.

6.6 Special precautions for disposal

None.

7. HOLDER OF CERTIFICATE OF REGISTRATION

Adcock Ingram Limited

1 New Road,

Erand Gardens,

Midrand, 1685

Customer Care: 0860 ADCOCK/232625

8. REGISTRATION NUMBER

27/2.8/0289

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

07 May 1993

10. DATE OF REVISION OF THE TEXT

03 January 2022

Namibia: NS1 04/2.8/1024

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