PROFESSIONAL INFORMATION FOR MEDICINES FOR HUMAN USE

SCHEDULING STATUS: **S2**

1. NAME OF MEDICINE

MYPAID

Strength

Each capsule contains:

Ibuprofen 200 mg

Paracetamol 250 mg

Pharmaceutical form

Capsule

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each capsule contains:

Ibuprofen	200 mg
Paracetamol	250 mg

Sugar free

3. PHARMACEUTICAL FORM

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

4. CLINICAL PARTICULARS

4.1. Therapeutic indications:

MYPAID capsule 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.

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 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.

4.3. Contraindications:

MYPAID not recommended for use by pregnant or breast-feeding 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.

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 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. 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.

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 ofgastrointestinal 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

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**
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.
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 and nausea. 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.

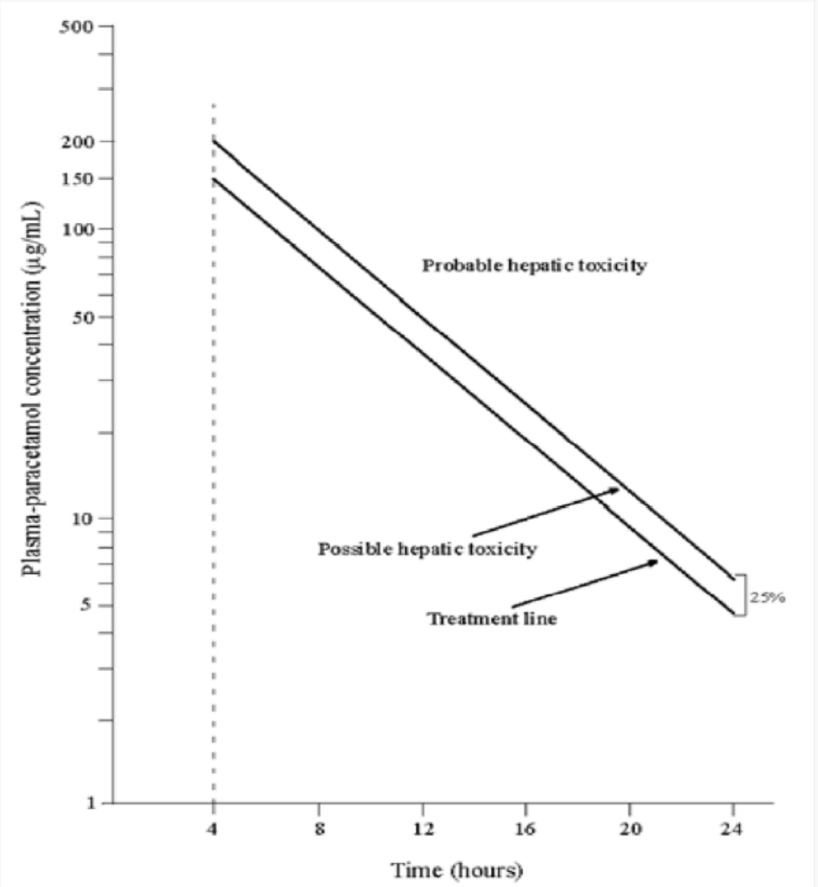

Figure 1. A semi-logarithmic plot of plasma-paracetamol concentration against hours after ingestion.

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), Starch 1500, Sodium stearyl fumarate.

6.2. Incompatibilities

Not applicable.

6.3. Shelf life

24 months

6.4. Special precautions for storage

Store at or below 25 ºC.

KEEP OUT OF REACH OF CHILDREN

6.5. Nature and contents of container

Plastic containers with 30 and 60 capsules.

Blister packs of 30 and 60 capsules.

7. HOLDER OF THE CERTIFICATE OF REGISTRATION

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8. REGISTRATION NUMBER

27/2.8/0289

9. DATE FIRST AUTHORISATION/RENEWAL OF AUTHORISATION

07 MAY 1993

10. DATE OF REVISION OF THE TEXT

03 JANUARY 2022