1.3.1.1 PACKAGE INSERT

SCHEDULING STATUS: **S2**

PROPRIETARY NAME **MYPAID**

(AND DOSAGE FORM): **(CAPSULE)**

COMPOSITION:

Each **MYPAID** capsule contains:

lbuprofen 200 mg

Paracetamol 250 mg

Sugar free

List of excipients:

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

PHARMACOLOGICAL CLASSIFICATION:

A: 2.8 Analgesic combinations

PHARMACOLOGICAL ACTION:

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

INDICATIONS:

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

CONTRAINDICATIONS:

MYPAID is 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 and in those who are receiving coumarin anticoagulants.

Severe liver function impairment.

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

WARNINGS:

Patients suffering from liver or kidney disease should only take paracetamol under medical supervision. Dosages in excess of those recommended may cause severe liver damage. Do not use continuously for more than ten days without consulting your doctor.

Consult a doctor if no relief is obtained from the recommended dosage.

DOSAGE AND DIRECTIONS FOR USE:

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.

SIDE EFFECTS AND SPECIAL PRECAUTIONS:

Ibuprofen - The most frequent adverse effects are gastrointestinal disturbances. Peptic ulceration and gastrointestinal bleeding have been reported. Other side effects include headache, dizziness, nervousness, skin rash, pruritis, tinnitus, oedema, depression, drowsiness, insomnia, blurred vision and other ocular reactions. Sensitivity reactions, abnormalities of liver function tests, impairment of renal function, agranulocytosis and thrombocytopenia have been observed. Acute, reversible renal failure has been reported. In view of the product's inherent potential to cause oedema, heart failure may be precipitated in some compromised patients.

Paracetamol - Patients suffering from liver or kidney disease should take paracetamol under medical supervision. Sensitivity reactions resulting in reversible skin rash or blood disorders e.g. neutropenia, leucopenia and pancytopenia may occur. The skin rash is usually erythematous or urticarial, but sometimes more serious and may be accompanied by fever and mucosal lesions.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:

Ibuprofen - The most likely symptoms of overdosage are epigastric pains and nausea. Treatment is symptomatic and supportive.

Paracetamol - Symptoms of paracetamol overdosage in the first 24 hours are pallor, nausea, vomiting, anorexia, and abdominal pain. Liver damage may become apparent 12 to 48 hours after ingestion.

Abnormalities of glucose metabolism and metabolic acidosis may occur.

Acute renal failure with acute tubular necrosis may develop even in the absence of severe liver damage. Cardiac arrhythmias have been reported.

Symptoms during the first 2 days of acute poisoning do not reflect the potential seriousness of the overdosage. Nausea, vomiting, anorexia and abdominal pain may persist for a week or more. Liver injury may become manifest on the second day, (or later) initially by elevation of serum transaminase and lactic dehydrogenase activity, increased serum bilirubin concentration and prolongation of prothrombin time. The liver damage may progress to encephalopathy, coma and death. Cerebral oedema and nonspecific myocardial depression have also occurred.

In the event of overdosage consult a doctor or take the patient to the nearest hospital immediately. Specialized treatment is essential as soon as possible.

Prompt treatment is essential. Any patient who has ingested about 7,5 g of paracetamol in the preceding 4 hours should undergo gastric lavage. Specific therapy with an antidote such as acetylcysteine or methionine may be necessary. If decided upon, acetylcysteine should be administered IV as soon as possible.

Acetylcysteine: Acetylcysteine should be administered as soon as possible, preferably within 8 hours of overdosage.

IV: An initial dose of 150 mg/kg in 200 ml dextrose injection, given intravenously over 15 minutes, followed by an intravenous infusion of 50 mg/kg in 500 ml of dextrose injection over the next 4 hours, and then 100 mg/kg in 1 000 ml over the next 16 hours. The volume of intravenous fluids should be modified for children.

Orally: 140 mg/kg as a 5 % solution initially, followed by a 70 mg/kg solution every 4 hours for 17 doses. Acetylcysteine is effective if administered within 8 hours of overdosage.

IDENTIFICATION:

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

PRESENTATION:

Plastic containers with 30 and 60 capsules.

Blister packs of 30 and 60 capsules.

STORAGE INSTRUCTIONS:

Store in a dry place at or below 25 °C. Protect from light.

KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER:

27/2.8/0289

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION:

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