Modules 1.3.1.1.2 – CLEAN AMENDED PACKAGE INSERT

SCHEDULING STATUS: **S3**

PROPRIETARY NAME AND DOSAGE FORM:

MYPRODOL CAPSULES (Capsules)

COMPOSITION:

Each capsule contains:

Codeine phosphate	10 mg
Ibuprofen	200 mg
Paracetamol	250 mg

Sugar free

List of excipients: Magnesium stearate, maize starch, potassium sorbate, colloidal silica and gelatine capsule.

PHARMACOLOGICAL CLASSIFICATION:

A: 2.8 Analgesic combinations

PHARMACOLOGICAL ACTION:

MYPRODOL CAPSULES have an analgesic, anti-inflammatory and antipyretic action.

INDICATIONS:

MYPRODOL CAPSULES are indicated for the relief of mild to moderate pain of inflammatory origin with or without fever.

CONTRAINDICATIONS:

Impaired hepatic and renal function, peptic ulceration or a history of such ulceration. Cardiovascular disease.

Hypersensitivity to any of the active ingredients.

Contraindicated in respiratory depression, especially in the presence of cyanosis and excessive bronchial secretion, after operations on the biliary tract, acute alcoholism, head injuries and conditions in which intracranial pressure is raised. It should not be given during an attack of bronchial asthma or in heart failure secondary to chronic lung disease.

Contraindicated in patients taking monoamine oxidase inhibitors or within fourteen days of stopping such treatment.

Caution is advised in those patients who are receiving coumarin anticoagulants.

Patients who are sensitive to aspirin should not be given **MYPRODOL CAPSULES**.

WARNINGS AND SPECIAL PRECAUTIONS:

The safety of continuous administration of **MYPRODOL CAPSULES** has not been established for a period greater than four weeks.

Codeine:

Exceeding the prescribed dose, together with prolonged and continuous use of this medication may lead to dependency and addiction.

Paracetamol:

Dosages in excess of those recommended may cause severe liver damage.

PREGNANCY AND LACTATION:

MYPRODOL CAPSULES are not recommended for use by pregnant or breast feeding women.

Regular use of NSAID's 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 newborn. The onset of labour may be delayed and its duration increased.

DOSAGE AND DIRECTIONS FOR USE:

Not recommended for children under twelve years of age.

Adults:

One to two capsules four hourly and not more than twelve capsules per twenty four hours. Consult your doctor if no relief is obtained with the recommended dosage.

SIDE EFFECTS:

In view of the product's inherent potential to cause fluid retention, heart failure may be precipitated in some compromised patients.

Ibuprofen:

Peptic ulceration and gastrointestinal bleeding have been reported. Other side effects include dizziness, dyspepsia, nausea, nervousness, skin rash, pruritus, tinnitus, oedema, depression, drowsiness, insomnia, blurred vision and other ocular reactions.

Hypersensitivity reactions, abnormalities of liver function tests, impairment of renal function, agranulocytosis and thrombocytopenia have occasionally been reported. Acute reversible renal failure has been reported. Ibuprofen should be used with care in patients with impaired renal function.

Paracetamol:

Sensitivity reactions resulting in reversible skin rash or blood disorders may occur. Haematological reactions have been reported.

Codeine phosphate:

Codeine phosphate may cause nausea, vomiting, constipation, drowsiness, confusion, dry mouth, sweating, facial flushing, vertigo, bradycardia, palpitations, orthostatic hypotension, hypothermia, restlessness, changes of mood and miosis. Micturition may be difficult and there may be ureteric or biliary spasm. Raised intracranial pressure may occur. Reactions such as urticaria and pruritus may occur. Codeine phosphate should be given with caution to patients with hypothyroidism, adrenocortical insufficiency, impaired liver function, prostatic hypertrophy or shock. It should be used with caution in

patients with inflammatory or obstructive bowel disorders. The dosage should be reduced in elderly and debilitated patients.

The depressant effects of codeine are enhanced by depressants of the central nervous system such as alcohol, anaesthetics, hypnotics and sedatives, and phenothiazines.

The prolonged use of high doses of codeine has produced dependence of the morphine type.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:

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 non-specific myocardial depression have also occurred.

In the event of overdosage consult a doctor or take the patient to the nearest hospital immediately. Specialised 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 (intravenously) 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 glucose injection, given intravenously over 15 minutes, followed

by an intravenous infusion of 50 mg/kg in 500 ml of glucose 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.

Ibuprofen:

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

Codeine phosphate:

Symptoms of overdosage include excitement and, in children, convulsions may occur. Large doses produce respiratory depression.

Treatment of overdosage is symptomatic and supportive.

IDENTIFICATION:

A hard gelatin capsule. The cap is opaque green, and the body is opaque red. "RIO" is printed in black on both the cap and body.

PRESENTATION:

30 capsules in white polypropylene securitainers with white LDPE (low-density polyethylene) closures or white HDPE (high-density polyethylene) containers with a white HDPE screw-on closures.

10, 30, 60 or 100 capsules in blister packs.

STORAGE INSTRUCTIONS:

Store at or below 25 ºC in well-closed containers.

KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER:

T/2.8/244

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

Adcock Ingram Limited

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