SCHEDULING STATUS: **S0** **Pack sizes equal to or smaller than 25 tablets**

S1 **Pack sizes larger than 25 tablets**

PROPRIETARY NAME AND DOSAGE FORM:

ADCO-NAPAMOL TABLETS

COMPOSITION:

Each tablet contains:

Paracetamol	500 mg
Preservative:	
Potassium sorbate	0,12 % m/m

Sugar free

List of excipients: colloidal silica, maize starch, magnesium stearate

PHARMACOLOGICAL CLASSIFICATION:

A 2.7 Anti-pyretic or anti-pyretic and anti-inflammatory analgesics

PHARMACOLOGICAL ACTION:

Paracetamol has analgesic and antipyretic properties.

INDICATIONS:

For the symptomatic treatment of mild to moderate pain and fever.

CONTRAINDICATIONS:

Hypersensitivity to any of the ingredients. Patients with severe liver function impairment.

WARNINGS AND SPECIAL PRECAUTIONS:

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

Patients suffering from liver or kidney disease should take paracetamol under medical supervision. Consult a doctor if no relief is obtained from the recommended dosage. Do not use continuously for more than 10 days without consulting a doctor.

PREGNANCY AND LACTATION:

Safety and/or efficacy has not been established.

DOSAGE AND DIRECTIONS FOR USE:

Do not exceed the stated dose.

Adults: 1 or 2 tablets every 4 to 6 hours as required but not more than 8 tablets to be taken daily.

Children: Not more than 4 doses daily.

6 to 12 years: ½ to 1 tablet given 3 to 4 times daily as required.

SIDE EFFECTS:

Pancreatitis, skin rashes and other allergic reactions may occur. The rash is usually erythematous or urticarial but sometimes more serious and may be accompanied by drug fever and haematological reactions including pancytopenia, neutropenia, leucopenia, thrombocytopenia and agranulocytosis.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:

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 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 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 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.

IDENTIFICATION:

White, round, flat tablet with bevelled edges and bisected on one side.

PRESENTATION:

48 x 2, 10 and 20 tablets in aluminium foil/clear PVC blister packs.

50 and 100 tablets in white securitainers.

5 000 and 20 000 tablets in amber HDPE buckets.

5 000 tablets in square white HDPE buckets.

STORAGE INSTRUCTIONS:

Store at or below 25 °C. Protect from light and moisture.

KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER:

B/2.7/1404

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

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