SCHEDULING STATUS: Not Scheduled:

PROPRIETARY NAME: (and dosage form):
PAINOGESIC SYRUP

COMPOSITION:
Each 5 ml contains:
Paracetamol 120 mg
Alcohol 11,2% v/v

Contains: Sugar

PHARMACOLOGICAL CLASSIFICATION:
A 2.7 Anti-pyretic or anti-pyretic and anti-inflammatory analgesics.

PHARMACOLOGICAL ACTION:
Paracetamol has analgesic and anti-pyretic properties.

INDICATIONS:
PAINOGESIC SYRUP is indicated for the relief of mild to moderate pain and fever.

CONTRAINDICATIONS:
Sensitivity to any of the ingredients.
Severe liver function impairment

WARNINGS:
Doses that exceed the recommended dose can cause severe liver damage.
1. Consult your doctor if no relief is obtained with the recommended dosage
2. Do no use continuously for more than 10 days without consulting your doctor.
3. Store in a safe place out of reach of children.
4. Patients suffering from liver or kidney disease should take paracetamol under medical supervision.

DOSAGE AND DIRECTIONS FOR USE:
Children:
3 months to 1 year: 60 - 120 mg. Half to one medicine measure (2,5 ml - 5 ml).
1 to 6 years: 120 - 240 mg. One to two medicine measures (5 - 10 ml).
7 to 12 years: up to 480 mg. Four medicine measures (20 ml).

Repeat dosage 4 hourly if necessary (3 - 4 times per day) but not more than 4 doses in 24 hours.

SIDE EFFECTS AND SPECIAL PRECAUTIONS:
Sensitivity reactions resulting in reversible skin rash or blood disorders including neutropenia, pancytopenia, and leucopenia may occur. The skin rash is usually erythromatous or urticarial, but sometimes more serious and may be accompanied by fever and mucosal lesions.

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 and metabolic acidosis may occur. Acute renal failure with acute tubular necrosis may develop even in the absence of 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 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 1000 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 four hours for 17 doses. Acetylcysteine is effective if administered within 8 hours of overdosage.

IDENTIFICATION:
A red raspberry flavoured syrup.

PRESENTATION:
100 ml amber or white opaque plastic bottles.
2.5 L amber bottles

STORAGE INSTRUCTIONS:
Store in a cool place at or below 25 °C. Protect from light.
KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER:
A 27/2.7/0015

NAME AND BUSINESS ADDRESS OF THE APPLICANT:
ASTRAL PHARMA (PTY) LTD
49 RIBOVILLE ROAD
RANDJIESFONTEIN
MIDRAND
1683
SOUTH AFRICA

DATE OF PUBLICATION OF THIS PACKAGE INSERT:
20 April 2005

05/03/2025
Lindi Karstens