Front - 52mm

Back-52mm

126mm

MILI SYRUP 120MG/5ML

Name and Strength of Active Ingredient(s)
Each 5 ml contains :
Paracetamol BP ..... 120 mg
Preservative :
Sodium Benzoate ..... 0.1% w/v

Product Description
Red colour syrup with raspberry and strawberry flavour.

Pharmacodynamics
Paracetamol is metabolised predominantly in the liver and excreted in the urine mainly as the glucuronide and sulphate conjugates. Less than 5% is excreted as unchanged paracetamol. The elimination half-life of paracetamol varies from about 1 to 3 hours. Plasma-protein binding is negligible at usual therapeutic concentrations but increases with increasing concentrations. A minor hydroxylated metabolite (N-acetyl-p-benzoquinoneimine) which is usually produced in very small amounts by mixed-function oxidases in the liver and kidney and which is usually detoxified by conjugation with glutathione may accumulate following paracetamol overdosage and cause tissue damage.

Pharmacokinetics
Paracetamol is readily absorbed from the gastro-intestinal tract with peak plasma concentrations occurring about 10 to 60 minutes after oral administration.

Indications
For fever & relief of mild to moderate pain.

Recommended Dose
10 to 15mg/kg/dose orally every 4 to 6 hours.
3 months to 1 year: 2.5 to 5ml/dose.
1 to 5 years: 5 to 10ml/dose.
These doses may be given every 4 to 6 hours if necessary up to a maximum of 4 doses in 24 hours.

Route of Administration
Oral

Contraindications
Mili Syrup 120mg/5ml is contraindicated in patients with known hypersensitivity to paracetamol or any of the other ingredients/ components.

Warnings and Precautions

WARNING
This preparation contains Paracetamol. Do not take any other paracetamol containing medicines at the same time.
Allergy alert: Paracetamol may cause severe skin reactions. Symptoms may include skin reddening, blisters or rash. These could be signs of a serious condition. If these reactions occur, stop use and seek medical assistance right away.

Paracetamol should be given with care to patients with impaired kidney or liver function. If there is no relief of symptoms after 3 days, please consult your physician.

Interactions With Other Medicaments
The anticoagulant effect of warfarin and other coumarine may be enhanced by prolonged regular daily use of paracetamol with increased risk of bleeding; occasional doses have no significant effect.

Pregnancy and Lactation
Use in pregnancy:
- Considered to be the analgesic of choice in pregnant patients.
- Although it crosses placenta, paracetamol is considered to be safe in normal therapeutic doses for short-term use as a minor analgesic/ antipyretic in pregnancy.

Use in lactation:
- Excreted in breast milk.
- Maternal ingestion of paracetamol in normal therapeutic doses does not appear to present a risk to the nursing infant.

Side Effects
Side effects of paracetamol are rare and usually mild, although haematological reactions including thrombocytopenia, leucopenia, pancytopenia, neutropenia, and agranulocytosis have been reported. Skin rashes, and other hypersensitivity reactions occur occasionally. Cutaneous hypersensitivity reactions including skin rashes, angioedema, Stevens Johnson Syndrome/Toxic Epidermal Necrolysis have been reported.

Symptoms and Treatment of Overdose
Symptoms:
Toxic symptoms include vomiting, abdominal pain, hypotension and sweating. The most serious adverse effect of acute overdose of paracetamol is a dose-dependent, potentially fatal hepatic necrosis. Clinical and laboratory evidence of hepatoxicity may be delayed for up to one week. Major manifestations of liver failure such as jaundice, hypoglycemia and metabolic acidosis may take at least 3 days to develop.
Treatment:
In cases of overdose, methods of reducing the absorption of ingested drug are important. Gastric lavage is essential even if several hours have elapsed. Prompt administration of 50 g activated charcoal and 500 ml iced mannitol 20% by mouth, may reduce absorption. If the history suggests that 15 g Paracetamol or more has been ingested, administer one of the following antidotes:
Acetylcysteine 20%i.v.: Administer intravenously, 20% acetylcysteine (Parvolex, Glaxo) immediately without waiting for positive urine test or plasma level results: initial dose of 150 mg/kg over 15 minutes, followed by continuous infusion of 50 mg/kg in 500 ml 5% glucose/dextrose over 4 hours and 100 mg/kg in 1 L 5% glucose/dextrose over 16 hours;
OR
Oral Methionine: 2.5 g immediately followed by three further doses of 2.5 g at four hourly intervals. For a 3 years old child, 1 g methionine every four hours for four doses has been used;
OR
Oral Acetylcysteine 5%: 140 mg/kg as a loading dose, then 70 mg/kg every 4 hours for a total of 17 maintenance doses. If more than ten hours have elapsed since the overdosage was taken, the antidote may be in ineffective.

Storage Conditions
Keep container tightly closed. Store below 30°C. Protect from light.
Keep out of reach of children. Jauhi daripada kanak-kanak.

Dosage Forms
Oral liquid

Presentation
60ml, 90ml, 100ml and 120ml bottle.

Registration Number
MAL19962480XZ

Manufactured by & Product Registration Holder :
KCK Pharmaceutical Industries Sdn. Bhd.
Plot 61, Bayan Lepas Industrial Park Phase 4, Lintang Bayan Lepas 1,
11900 Bayan Lepas, Pulau Pinang, Malaysia.

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