pharmaniaga®

ActiMol Syrup 120mg/5ml

PRODUCT DESCRIPTION
An orange syrup with an orange smell.

COMPOSITION
Each 5ml contains:
• Active Ingredient: Paracetamol 120 mg
• Preservatives: Methylparaben 6 mg and Propylparaben 1 mg

PHARMACODYNAMICS
ATC Code: N02 BE01.

Pharmacotherapeutic group: Other Analgesics and Antipyretics (Anilides).

Mechanism of Action
Paracetamol is an analgesic and antipyretic. Its mechanism of action is believed to include inhibition of prostaglandin synthesis, primarily within the central nervous system.

Pharmacodynamic effects
The lack of peripheral prostaglandin inhibition confers important pharmacological properties such as the maintenance of the protective prostaglandins within the gastrointestinal tract.
Paracetamol is, therefore, particularly suitable for: patients with a history of disease or patients taking concomitant medication, where peripheral prostaglandin inhibition would be undesirable (such as, for example, those with a history of gastrointestinal bleeding or the elderly).

PHARMACOKINETICS
Absorption
Paracetamol is rapidly and almost completely absorbed from the gastrointestinal tract.

Distribution
Binding to plasma proteins is minimal at therapeutic concentrations.

Metabolism
Paracetamol is metabolized in the liver and excreted in the urine mainly as glucuronide and sulfate conjugates

Elimination
Less than 5% is excreted as unchanged paracetamol.

INDICATIONS
ActiMol Syrup 120mg/5ml is used for the relief of:
• Fever
• Headache and symptoms of cold and flu
• Toothache and discomfort of teething
• Fever after vaccination

SHAKE WELL BEFORE USE

RECOMMENDED DOSAGE
Using the body weight of your child, you can calculate the dose of Actimol your child needs. The calculation is based on recommended dosage of 15 mg paracetamol.

For Actimol Syrup 120mg/5ml, Dose = $\frac{\text{BW(kg)} \times 15\text{mg} \times 5\text{ml}}{120\text{mg}}$

Example of dose by weight:

WEIGHT (kg)	DOSE (ml)
4- 5 kg	2.5 ml
6 - 7 kg	3.5 ml
8 - 9 kg	5 ml
10 - 11 kg	6 ml

Do not take more than 4 times within 24 hours and never exceed the recommended dose unless prescribed by a doctor or pharmacist.

Not recommended in children under 1 month.

For children under 3 months: If fever persists for more than 24 hours (4 doses) seek medical advice. This is to ensure that fever that may be due to a serious infection is quickly diagnosed.

ROUTE OF ADMINISTRATION
Oral

CONTRAINDICATIONS
Hypersensitivity to paracetamol or any of the other ingredients or components of the product and contraindicated for people with severe and active hepatic impairment.

ADVERSE EFFECTS/UNDESIRABLE EFFECTS
Adverse effects of paracetamol are rare and usually mild, although hematological reactions have been reported. Skin rashes and other hypersensitivity reactions occur occasionally. Cutaneous hypersensitivity reactions including skin rashes, angioedema, Stevens Johnson syndrome, or Toxic Epidermal Necrolysis have been reported.

Significant	:	thrombocytopenia, leucopenia, neutropenia, pancytopenia, methemoglobinaemia, agranulocytosis, and angioedema
Rarely	:	hypotension and tachycardia
Potentially Fatal	:	hepatotoxicity, acute renal tubular necrosis
Skin and subcutaneous tissue disorders	:	erythema, flushing, pruritus
Gastrointestinal disorders	:	nausea, vomiting, constipation
Psychiatric disorders	:	insomnia
Nervous system disorders	:	headache

WARNINGS AND PRECAUTIONS

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 serious conditions. If these reactions occur, stop using and seek medical assistance right away.

- Keep out of reach of children.
- Do not take if allergic to paracetamol.
- Patients should contact their healthcare provider if symptoms persist (if the pain lasts for more than 10 days if there is redness or fever that last more than 3 days).
- Paracetamol should be given with care to patients with impaired kidney or liver function.
- Large doses should be avoided in patients with hepatic impairment. • Paracetamol overdose may harm the liver.
- Do not exceed recommended dose. Leave at least 4 hours between doses.
- Immediate medical advice should be sought in the event of an overdose, even if the child seems well, because of the risk of delayed serious liver damage.
- Paracetamol provides symptomatic relief only, additional therapy to treat the cause of the pain or fever should be instituted when necessary.

EFFECTS ON THE ABILITY TO DRIVE AND USE MACHINES
It is unlikely to impair a patient's ability to drive or use machinery.

INTERACTION WITH OTHER MEDICAMENTS
The anticoagulant effect of warfarin and other coumarins may be enhanced by prolonged regular daily use of paracetamol with an increased risk of bleeding; occasional doses have no significant effect.

The hepatotoxicity of paracetamol, particularly after overdosage, may be increased by drugs that induce liver microsomal enzymes such as barbiturates, tricyclic antidepressants and alcohol.

Chronic alcohol intake can increase the hepatotoxicity of paracetamol overdose and may have contributed to acute pancreatitis reported in one patient who had taken an overdose of paracetamol. Acute alcohol intake may diminish an individual's ability to metabolize large doses of paracetamol, the plasma half-life of which can be prolonged.

The speed of absorption of paracetamol may be increased by metoclopramide or domperidone and absorption reduced by cholestyramine.

Antivirals: Regular use of paracetamol possibly reduces the metabolism of zidovudine (increased risk of neutropenia).

The use of drugs that induce hepatic microsomal enzymes such as anticonvulsants and oral contraceptives may increase the extent of metabolism of paracetamol resulting in reduced plasma concentrations of the drug and a faster elimination rate.

PREGNANCY AND LACTATION
Use in pregnancy:
- Considered to be the analgesic of choice in pregnant patients.
- Although it crosses the 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 do not appear to present a risk to the nursing infant.

OVERDOSE AND TREATMENT
Symptoms:
Toxic symptoms include vomiting, abdominal pain, hypotension and sweating. The most serious adverse effect of an 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 the ingested drugs 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:

i. Acetylcysteine 20% I.V.:
Administer intravenously, 20% acetylcysteine immediately without waiting for a 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 1L 5% glucose/dextrose over 16 hours;

OR

ii. Oral Methionine:
2.5 g immediately followed by three further doses of 2.5 g at four hourly intervals. For a 3-year-old child, 1 g methionine every four hours for four doses has been used;

OR

iii. 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 ineffective.

STORAGE CONDITION
Keep the container tightly closed in a dry place, below 30°C; protect from light.

SHELF LIFE
The product should not be used beyond the expiry date imprinted on the product packaging.

PACK SIZE
Available in a bottle of 60ml syrup.

REGISTRATION NUMBER
MAL21116031XZ

KEEP MEDICINE OUT OF REACH OF CHILDREN
JAUHI UBAT-UBATAN DARI KANAK-KANAK

For further information, please consult with a doctor or pharmacist.

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Lt-230.01 Product Registration Holder And Manufacturer:
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