Cosmol®

Paracetamol
Analgesic/Antipyretic

22400
Ref. No: B2122400/22.01

COSMOL® TABLETS 100MG
COSMOL® TABLETS 500MG
COSMOL® SUSPENSION 120MG/5ML

PRESENTATION:
Cosmol® Tablets 100mg: Pink, circular, flat, bevelled-edge tablet plain on both sides. Each tablet contains: Paracetamol 100mg.
Cosmol® Tablets 500mg: White, circular, flat, bevelled-edge tablet embossed 'COSMOL' on one side and P 500 with a breakline on the other side. Each tablet contains: Paracetamol 500mg.
Cosmol® Suspension 120mg/5mL: Clean, light pink, viscous suspension free from visible evidence of contamination with fruity odour. Each 5mL contains: Paracetamol 120mg.

CLINICAL PHARMACOLOGY:
Paracetamol, a para-aminophenol derivative, has analgesic, antipyretic and weak anti-inflammatory activity. Paracetamol selectively inhibits cyclo-oxygenase enzyme in the brain and spinal cord thus relieving pain and reducing fever without having unwanted gastro intestinal side effects. Paracetamol interferes with nerve conduction and is known to block impulse generations at bradykinin-sensitive chemoreceptors which evoke pain.

Pharmacokinetics:
Paracetamol is readily absorbed from the gastro-intestinal tract with peak plasma concentrations occurring about 10 to 60 minutes after oral doses. Paracetamol is distributed into most body tissues. It crosses the placenta and is present in breast milk. Plasma protein binding is negligible at usual therapeutic concentrations but increases with increasing concentrations. The elimination half-life of paracetamol varies from about 1 - 3 hours. Paracetamol is metabolised predominantly in the liver and excreted in the urine mainly as the glucuronide and sulfate conjugates.

USES:
Cosmol® preparations are recommended for the treatment of most painful and febrile conditions. It relieves headache, backache, toothache, rheumatic, muscle and period pains. COSMOL® helps relieve pain and fever in colds, influenza, sore throat also high body temperature and mild pain due to non-serious arthritis.
Cosmol® is recommended for the treatment of painful and febrile conditions of childhood such as teething, headache, toothache, earache, general aches and pains, colds, influenza and reactions after immunization and vaccination.

DOSAGE AND ADMINISTRATION:
Doses to be given 3-4 times a day or as directed by the physician.
Cosmol® 100 Tablets:
Dispersible tablets to be dissolved or mixed with water before taking.
Children: **1 - 5 years:** One to two tablets.
6 - 9 years: Two to three tablets a day.
Cosmol® Suspension 120mg/5mL:
Children: **6 - 12 years:** Two-four spoonfuls (10-20mL) 3 to 4 times a day.
1 - 6 years: One - two spoonfuls (5.0-10mL) a day.
3 months - 1 year: Half - one spoonful (2.5-5mL) a day.
Under 3 months: Not recommended
Cosmol Tablets 500mg:
Adults: 1 - 2 tablets 3-4 times a day
Children from 7 - 12 years: $^1/_2$ - 1 tablet 3- 4 times a day

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Do not take more than 8 tablets in 24 hours.
Children should not be given doses of Cosmol® Suspension more than every 4 hours and not more than 4 doses should be given in any 24 hours.

CONTRA-INDICATIONS AND WARNINGS:
Precautions:
Paracetamol should be given with care to patients with impaired kidney or liver function. It should also be given with care to patients with alcohol dependence, chronic malnutrition or dehydration.

Adverse Effects:
Adverse 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.

Overdosage:
Overdosage with Paracetamol can result in severe liver damage and sometimes acute renal tubular necrosis.
Gastric lavage should be carried out especially if the overdose was taken within the previous hours; full supportive measures should also be instituted. Activated charcoal is given to reduce gastro-intestinal absorption, especially in cases of multiple drug overdosage. However, if acetylcysteine or methionine is to be administered by mouth, the charcoal is best cleared from the stomach to prevent it reducing the absorption of the antidote.

Interactions:
The risk of Paracetamol toxicity may be increased in patients receiving other potentially hepatotoxic drugs or drugs that induce liver microsomal enzymes. The absorption of paracetamol may be accelerated by drugs such as metoclopramice. Excretion may be affected and plasma concentrations altered when given with probenecid.

Pregnancy and Lactation:
Pregnancy: If clinically needed, paracetamol can be used during pregnancy. However, it should be used at the lowest effective dose for the shortest possible time and at the lowest possible frequency.
Lactation: Paracetamol is excreted in breast milk but not in a clinically significant amount. Available published data does not contraindicate breast feeding.

PHARMACEUTICAL PRECAUTIONS:
Store in a dry place below 30°C. Protect from light. Keep all medicines out of the reach of children.

LEGAL CATEGORY:
Over The Counter (OTC)
General Sales List (GSL)

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COSMOS
Cosmos Limited,
Rangwe Rd; Off Lunga Lunga Rd,
Nairobi, Kenya