

Cetamol 100 mg/ml

Pharmaceutical Form: Pediatric oral drops with cherry flavor.

Composition: Active ingredient: Paracetamol 100 mg/ml Inactive ingredients Propylene glycol, saccharine sodium, citric acid, methylparaben, propylparaben, cherry flavor, ponceau (E124). Alcohol free.

Pharmacological group: Non-steroidal anti-inflammatory drugs.

Pharmacodynamics:

Paracetamol is clinically proven analgetic and antipyretic. Paracetamol produces analgesia by elevation of the pain threshold and antipyresis through action on the hypothalamic heat-regulating center. Paracetamol is equal to aspirin in analgesic and antipyretic effectiveness and it is unlikely to produce many of the side effects associated with aspirin and aspirin-containing products. It doesn't irritate gastrointestinal tract and doesn't effect on water-salt metabolism, as it doesn't effect on prostaglandines synthesis in periferic tissues.

Pharmacokinetics:

Paracetamol is readily absorbed from the gastrointestinal tract. Peak plasma concentration is occuring about 10 to 60 minutes after ingestion. Paracetamol is distributed into most body tissues.

Plasma-proteine binding is negligible at usual therapeutic concentrations but increases with increasing concentrations. The elimination half-life varies from 1 to 3 hours. Paracetamol is metabolised predominantly in liver and excreted in the urine mainly as the glucuronide and sulphate conjugates. Less then 5% is excreted unchanged. It is usually detoxified by conjugation with liver glutathione, but may accumulate following paracetamol overdose and cause tissue damage.

Indications:

As antipyretic: acute respiratory diseases, flu, pediatric infections, post-vaccination period, and diseases which proceed with high temperature. As analgesic: mild to moderate pain such as: headache, toothache, myalgia, neuralgia traumatic pains.

Posology and Method of Administration:

Dosage of Cetamol drops depends on child's age and weight. Single dose of Cetamol drops varies between 10-15mg/kg per body weight, maximum daily dose of Cetamol drops is 60mg/kg per body weight. Dose may be repeated every 4 hours, but not more then 5 times a day. Dosage is calculated as follows 2 drops of Cetamol drops for 1kg of body weight.

10mg = 2 drops

1kg =2 drops

Age	Body weight	Single dose
1-3 month	by medical advise	
3-5 month	6-8 kg	12-16 drops
5 month 1 year	8-10 kg	16-20 drops
1-2 year	10-12 kg	20 - 24 drops

2-3 year	12-16 kg	24 - 32 drops
4-5 year	16-21 kg	32 – 42 drops

If child is significantly under or over weight, dosage may need to be adjusted accordingly.

Cetamol Oral Drops may be given directly into the mouth or may be mixed with baby's meal, fruit juice or water.

Do not take more than 3 days as antipyretic.

Do not take more than 5 days as analgetic.

Contraindications:

- Hypersensitivity to Paracetamol and/or other constituents.
- Impaired kidney and liver function
- Kidney and liver severe dysfunction

Precautions and Warnings:

Do not give with other product containing Paracetamol concurrently. If your baby was born prematurely and is less than 3 months old consult your doctor before use. In cases of accidental overdose seek medical attention immediately. Care is advised in the administration of Paracetamol to patients with severe renal or severe hepatic impairment, in case of glucose-6-phosphate dehydrogenase deficiency and severe blood diseases (severe anaemia, leucopenia, thrombocytopenia). Methyl and propyl hydroxybenzoates are contained in this product which may cause allergic reactions (possibly delayed). Ponceau (E124) is contained in this product which may cause allergic reactions. Do not exceed the stated dose.

Undesirable Effects:

Adverse effects of Paracetamol are rare in therapeutic doses and less serious. There have been reports of nausea, vomiting, stomachache, blood reactionc (thrombocytopenia, neutropenia, leucopenia, agranulocytosis). Skin rash, urticaria and other hypersensitivity reactions may occur.

Shelf-Life:

2 years.

Storage:

Preserve in tight containers, and store below 25 °C.

This medicine should be kept out of reach of children.

Package:

30 ml plastic bottle with dropper.

Legal status:

OTC drug.