

Cetamol syrup 120 mg/5ml

Pharmaceutical Form: Pediatric oral syrup with cherry flavor.

Composition: Active ingredient: Paracetamol 120 mg/5ml.

Inactive ingredients: propylene glycol, saccharine sodium, glycerin, citric acid, saccharose, methylparaben, propylparaben, cherry flavour, ponceau (E124). Alcohol free.

Pharmacological group: Non-steroidal anti-inflammatory drugs.

Pharmacodynamic:

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 prostaglangines synthesis in periferic tissues.

Pharmacokinetic:

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 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.

Contraindications:

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

Posology and method of administration:

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

Age	Body weight	Single dose
1-3 month	by medical advise	
3-5 month	6-8 kg	2,5-4 ml
5 month 1 year	8-10 kg	4-5 ml
1-2 year	10-12 kg	5-7.5 ml
2-3 year	12-16 kg	8 ml
4-5 year	16-21 kg	10 ml
6-8 year	22-26 kg	10-13 ml
9-10 year	28-30 kg	14 -17 ml
10-12 year	30-34 kg	17-20 ml

If child is significantly under or over weight, dosage may need to be adjusted accordingly. Do not take more than 3 days as antipyretic. Do not take more than 5 days as analgetic

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.

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 deseases (severe anaemia, leucopenia, thrombocytopenia) Each 5ml contains 1.500 g sucrose/saccharose. Patients with hereditary fructose intolerance, glucosegalactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine. The sucrose content should be taken into account in patients with diabetes mellitus. It may also be harmful to teeth. 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.

Package:

Glass bottle 100 ml with dosing cup

Shelf-Life:

3 years

Storage:

Preserve in tight containers, and store below 25 °C. This medicine should be kept out of reach of children.

Legal status:

OTC drug