Cetamol Suppositories 80 mg, 150 mg, 325 mg

Pharmaceutical form: Rectal suppositories

Composition: Each Cetamol Suppositories contains 80 mg, 150 mg, and 325 mg paracetamol as active ingredient and Hard fat.

Pharmacological group: Anilides

Pharmacodynamics:

Paracetamol is a para-aminophenol derivative with analgesic and antipyretic properties and weak anti-inflammatory activity.

The mechanism of analgesic action remains to be fully elucidated, but may be due to inhibition of prostaglandins synthesis mainly in CNS, and this shows its analgesic and antipyretic action.

Paracetamol is the preferred choice of analgesics or antipyretics especially for children in whom salicylates (because of the risk of Reye's syndrom e) or other NSAIDs are contra-indicated.

Paracetamol is less irritant to the stomach than aspirin. Paracetamol does not affect thrombocyte aggregation or bleeding time as aspirin. Paracetamol is generally well tolerated by patients hypersensitive to acetylsalicylic acid.

Pharmacokinetics:

Paracetamol is well absorbed by both oral and rectal routes. Peak plasma concentrations occur about 2 to 3 hours after rectal administration. The elimination half-life of paracetamol varies from about 1 to 3 hours. Paracetamol is metabolized predominantly in the liver and excreted in the urine mainly as the glucuronide and sulphate conjugates. Less than 5% is excreted as unchanged paracetamol.

Indications:

- as antipyretic in case of acute respiratory disease, flu, pediatric infections and other inflammatory diseases, which are followed by fever, after vaccination

- as analgetic in case of mild to moderate pain (headache, toothache, myalgia, neuralgia, traumatic pain)

Cetamol suppositories may be especially useful in patients unable to take oral forms of paracetamol, e.g. post-operatively or with nausea and vomiting.

Posology and method of administration

3-5 month – 80 mg suppositories

6 month - 3 year – 150 mg suppositories

4-10 year – 325 mg suppositories

It is preferable to use Cetamol suppositories after giving a cleansing enema or after defecation.

The average single dose depends on child's weight and it equal to 10-15mg/kg body weight and can be repeated 3-4 times a day. The maximum daily dose shouldn't exceed 60mg/kg body weight.

Repeat this dose every 4-6 hours, but more then 4 times a day.

Use paracetamol for fever not more then 3 days and for pain releif not more then 5 days.

Do not exceed recommended doses.

Use in babies aged less than 3 months on a doctor's advice.

Contraindications:

- known hypersensitivity to paracetamol or any of the excipients,
- bronchial asthma, allergy in anamnesis
- deficiency of glucose-6-phosphatedehydrogenase
- severe hepatic and renal insufficiency
- peptic ulcer, gastrointestinal bleeding

Warnings and precautions:

Cetamol Suppositories should not be combined with other analgesic medications that contain paracetamol. Paracetamol should be administered with caution to patients with hepatic or renal impairment, because of increased risk of hepatotoxicity and nephrotoxicity. If

symptoms persist for more than 3-5 days, consult a doctor. Use in babies aged less than 3 months on a doctor's advice.

Do not use suppositories in case of diarrhea.

Caution is advised if paracetamol is administered concomitantly with flucloxacillin due to increased risk of high anion gap metabolic acidosis (HAGMA), particularly in patients with severe renal impairment, sepsis, malnutrition and other sources of glutathione deficiency (e.g. chronic alcoholism), as well as those using maximum daily doses of paracetamol. Close monitoring, including measurement of urinary 5-oxoproline, is recommended.

Paracetamol may cause serious skin reactions such as acute generalized exanthematous pustulosis, Stevens-Johnson syndrome, toxic epidermal necrolysis, which may be lethal. At the first sign of these serious skin reactions, and also with the appearance of a rash or other reactions of increased sensitivity, use of the drug should be discontinued.

Administration during pregnancy and breastfeeding

Pregnancy

A large amount of data on pregnant women indicates neither malformative, nor feto/neonatal toxicity. Epidemiological studies on neurodevelopment in children exposed to paracetamol in utero show inconclusive results. 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.

Breast-feeding

Paracetamol is excreted in breast milk but not in a clinically significant amount. Available published data do not contraindicate breastfeeding.

Side effects

Reports of adverse reactions at therapeutic doses are rare and usually mild. Nausea, vomiting, stomach pain, hematological reactions including thrombocytopenia, neutropenia, leucopenia, and agranulocytosis have been reported. Skin rashes, urticaria, and other hypersensitivity reactions occur occasionally, redness or soreness of the rectal mucous membrane and liver damage.

Packaging:

5 rectal suppositories in a strip, 2 strips and leaflet insert in a paperboard box.

Storage conditions:

Do not store above 25°C. Do not freeze.

3 years.

Regulatory status:

OTC drug