

PARACETAMOL TABLETS BP

Dolo-650

Composition:

Each uncoated tablet contains:
Paracetamol BP 650 mg

Pharmacological Action:

Analgesic and Antipyretic agent.

Chemistry:

Acetaminophen; N-acetyl-p-amino phenol.

Mechanism of Action:

The analgesic and antipyretic actions of paracetamol are similar to those of the salicylates. Analgesia is mediated peripherally and also centrally by inhibition of prostaglandin synthesis, whereas antipyresis is produced by a central action on the hypothalamic regulatory center.

Pharmacokinetics:

Paracetamol is readily absorbed from the GIT with peak plasma concentration occurring about 10-60 min after oral administration. Paracetamol is distributed into most body tissues. Plasma protein binding is negligible. Paracetamol is metabolized predominantly in the liver and excreted in the urine mainly as the glucuronide and sulphate conjugate. The elimination half life varies from about 1-3 hours.

Indications:

Paracetamol is indicated for the relief of painful disorders such as headache, dysmenorrhea, conditions involving musculoskeletal pain, myalgias, and neuralgias. It is also indicated as an analgesic and antipyretic in conditions accompanied by discomfort and fever, such as the common cold and viral Infections. Paracetamol is an effective analgesic after dental work and tooth extractions, and in teething.

Contraindications:

Paracetamol is contraindicated in patients hypersensitive to this drug.

Warnings and Precautions:

Chronic use should be avoided. Should not be taken for more than 10 consecutive days, unless directed. Exercise caution in patients with impaired kidney and liver function, in patients taking other drugs that affect the liver.

Serious skin reactions

Rarely, Paracetamol may cause serious skin reactions such as acute generalized Exanthematous pustulosis (AGEP), Stevens-Johnson syndrome (SJS), and toxic epidermal necrolysis (TEN), which can be fatal. Patients should be informed about the signs of serious skin reactions, and use of the drug should be discontinued at the first appearance of skin rash or any other sign of hypersensitivity.

Usage in Pregnancy & Lactation:

The drug may cause birth defects and interfere with the development of the fetus, therefore pregnant women should consult doctor before taking it. Since paracetamol is excreted in breast milk, caution should be exercised in nursing mothers.

Adverse Reactions:

Side effects of paracetamol are rare and usually mild, though haematological reactions including Thrombocytopenia, Leucopenia, Pancytopenia, Neutropenia and agranulocytosis have been reported. Skin rashes and other hypersensitivity reactions occur occasionally.

Drug Interactions:

Paracetamol potentiates the effect of oral anticoagulants. Anticholinergics, and narcotics may decrease the rate of absorption of paracetamol. Absorption is increased by metoclopramide. Excretion may be affected and plasma concentrations altered when administered with Probenecid.

Dosage:

Adults: 0.5 to 1g every 4 to 6 hours up to a maximum of 4g daily. For long term therapy, daily dose not to exceed 2.6g unless the patient is monitored.

Children: Under 3 months: 10 mg /kg body wt (5mg / kg body wt if jaundiced)

3 months to 1 year: 60 to 120mg

1 to 5 years: 120 to 250 mg

6 to 12 years: 250 to 500 mg. These doses may be given 3 to 4 times daily.

Known Symptoms of Over dosage and Treatment:

The consequence of over dosage may be serious. Ingestion of as little as 10 to 15 g of paracetamol may cause severe hepatocellular necrosis and less often renal tubular necrosis. Symptoms include nausea, vomiting, lethargy, sweating, abdominal pain. Hepatic failure, encephalopathy, coma and death may result. Treatment: Patient must be hospitalized. Gastric lavage should be carried out. Activated charcoal may be given. Magnesium or Sodium sulphate may be instilled into stomach after lavage. Early administration of compounds supplying sulphydryl groups may prevent or minimize hepatic damage. Oral and IV administration of Acetylcysteine has been used.

Presentation:

5 x (10 x 10's)

Storage:

Store below 25°C, in a dry place. Keep away from children.

Date of Publication:

August 2005

Date of Revision:

Jun. 2016



SIN 11097 P

EXG-ML12I-1450/A

MICRO LABS LIMITED
INDIA.