



PRITAMOL SUPPOSITORIES 125MG

Description: White suppositories.

Content: Each suppository contains paracetamol 125mg

Indications

For symptomatic relief of fever associated with common childhood infections. For the relief of minor pains like headache, toothache and earache.

Pharmacology

Paracetamol is rapidly absorbed after rectal administration. It is mainly conjugated to form glucuronide and ethereal sulphate. Oxidation occurs to a small extent after the therapeutic doses and becomes more significant after large doses. Neonates produce more of the sulphate conjugate than the glucuronide whilst the adult, the proportions of the two conjugates are either approximately equal or the glucuronide fraction is larger. About 85% of a therapeutic dose is excreted in the urine in 24 hours. Larger amounts of the mercaptopuric acid and cysteine conjugates are excreted in overdose.

Adverse effects/ Undesirable Effects:

Side effects of paracetamol are usually mild, though, haematological reactions have been reported. Skin rashes and other allergic reactions occur occasionally.

Cutaneous hypersensitivity reactions including skin rashes, angioedema, Stevens Johnson Syndrome/ Toxic Epidermal Necrolysis have been reported.

Warning

Allergy alert: Paracetamol may cause severe skin reactions. Symptoms may include skin reddening, blisters or rash. These could be signs of a serious condition. If these reactions occur, stop use and seek medical assistance right away.

Precaution

Paracetamol should be given with care to patients with impaired kidney or liver function. Paracetamol should also be given with care to patients taking other drugs that affect the liver.

Contraindications

It is contraindicated in patients hypersensitive to paracetamol.

Overdosage and treatment

Signs of overdose are diarrhea, increased sweating, loss of appetite, nausea, vomiting and stomach cramps. Less frequent complications of paracetamol overdose include cardiac damage, generalised bleeding, renal damage and hypoglycemia. Treatment with cysteine or methionine should be initiated as soon as possible within the first 10 hours to minimise damage to the liver by toxic metabolites. They should not be given at later stages since they are not effective and may also precipitate hepatic coma.

Instituting haemodialysis or hemoperfusion to remove paracetamol from the circulation may be beneficial if acetylcysteine administration cannot be instituted within 24 hours following ingestion of a massive paracetamol overdose. Monitoring renal and cardiac function and administering appropriate therapy as required.

Instituting supportive treatment including monitoring fluid and electrolyte balance, correcting hypoglycemia and administering vitamin K1 (if prothrombin time ratio exceeds 1.5) and fresh frozen plasma or clotting factor concentrate (if prothrombin time ratio exceeds 3.0)

Dosage and Administration

To be inserted well up into the rectum 3 - 4 times a day

1-6 years : 1-2 supp.

FOR RECTAL USE ONLY

Storage : Keep container tightly closed. Store in a cool, dry place, below 30C. Protect from light.

Presentation / : 5 X 20 strips / box

Shelf life : 3 years

Product : PRIME PHARMACEUTICAL SDN. BHD.

Registration : 1505, Lorong Perusahaan Utama 1, Taman Perindustrian Bukit Tengah,

Holder : 14000 Bukit Mertajam, Penang, Malaysia.