For the use of a Registered Medical Practitioner or a Hospital or a Laboratory only.

Paracetamol Suppositories BP 500 mg

AMERICAN PARACAN 500 Suppositories

Composition :
Each Suppository contains :
Paracetamol BP 500 mg
Suppository Base q.s.

Pharmacodynamic properties:
Paracetamol is an aniline derivative with analgesic and antipyretic actions. It does not affect thrombocyte aggregation or bleeding time. Paracetamol is generally well tolerated by patients hypersensitive to acetylsalicylic acid.

Pharmacokinetic properties:
Paracetamol is well absorbed by rectal route. Peak plasma concentrations occur about 2 to 3 hours after rectal administration. The plasma half life is about 2 hours.
Paracetamol is primarily metabolised in the liver by conjugation to glucuronide and sulphate. A small amount (about 3-10% of a therapeutic dose) is metabolised by oxidation and the reactive intermediate metabolite thus formed is bound preferentially to the liver glutathione and excreted as cysteine and mercapturic acid conjugates. Excretion occurs via the kidneys. 2-3% of a therapeutic dose is excreted unchanged; 80-90% as glucuronide and sulphate and a smaller amount as cysteine and mercapturic acid derivatives.

Indications: Symptomatic relief of pain and fever.
The dose should not be repeated more frequently than every 4 hours. The recommended dose should not be exceeded. Higher doses do not produce any increase in analgesic effect. Only whole suppositories should be administered – do not break suppository before administration.

Contraindications :
Paracetamol Suppositories are contraindicated in patients with hypersensitivity to Paracetamol.

Precautions & Warnings:
Doses higher than those recommended involve a risk of very severe liver damage. Do not exceed the recommended dose. If symptoms persist consult your doctor. Keep out of the reach and sight of children.
Paracetamol should be given with care to patients with impaired kidney or liver function.

Pregnancy and Lactation:
Use of Paracetamol during pregnancy and lactation should be only under medical practitioner if benefits outweigh the risk.

Interactions:
Caution should be taken while administering Paracetamol with drugs such as barbiturates or other anticonvulsants, anticoagulants, probenecid, chloramphenicol, phenytoin, phenobarbital, carbamazepine, primidone and alcohol.

Side effects:
Common side effects observed is possibility of redness of the rectal mucous membranes. Rarely allergic reaction, liver damage, exanthema, urticaria, angioedema, blood dyscrasias and hepatic necrosis may be observed.

Overdose:
Symptoms of Paracetamol overdosage in the first 24 hours are pallor, nausea, vomiting, anorexia and abdominal pain. Liver damage may become apparent 12 to 48 hours after administration. In severe poisoning, hepatic failure may progress to encephalopathy, haemorrhage, hypoglycaemia, cerebral oedema, and death. Cardiac arrhythmias and pancreatitis have been reported.
Immediate treatment is essential in the management of Paracetamol overdose. Treatment with N-acetylcysteine may be used for up to 24 hours after administration of paracetamol. If required, the patient should be given intravenous N-acetylcysteine, in line with the established dosage schedule. If vomiting is not a problem, then oral methionine may be a suitable alternative for remote areas, outside hospital.

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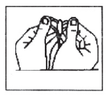
PARACETAMOL OVERDOSE MAY BE INJURIOUS TO LIVER

Storage:
Store Protected from light and moisture at a temperature not exceeding 25°C.
Keep the medicine out of the reach children.

Dosage & Administration
Not to be taken by mouth. For rectal use only.
Paracetamol 500mg Suppositories Adults and Children 12 years and over:
1 -2 500mg suppositories every 4 to 6 hours up to a maximum of 4 or 8 suppositories in 24 hours.
Children 10-12 years (30-40 kg):1 x 500mg suppository every 4 to 6 hours up to a maximum of 4 x 500mg suppositories in 24 hours. or As directed by Physician.

How to use Suppository.



1. When practical, clean the area around the rectum with mild soap and warm water and rinse thoroughly. Gently dry by patting or blotting with toilet tissue or a soft cloth.
2. Do not open suppository if seems soft, hold the foil wrapper under cold water or place it in refrigerator for few minutes to harden it before removing the wrapper.
3. Position the patient to lie on one side with knees bent up to their abdomen or lie on back with feet and legs held up.
4. Detach the suppository by holding strip upright and carefully peel the wrapper evenly down both sides. (moisten the suppository if dry)
5. Hold the suppository between index finger and thumb, locate the anus and gently insert suppository tip end first with the index finger. The suppository should be fully inserted in to rectum against the wall of rectum.
6. Hold buttocks together lying down for about 5 minutes to avoid having the suppository comes out.
7. Discard used materials and wash your hands thoroughly.

Manufactured by:

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