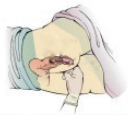
LSP

Junior Protemp Suppositories 325mg

Each suppository contains : Paracetamol 325 mg
Product description : White, bullet shape suppositories.
Pharmacodynamic : The mechanism of analgesic action has not fully determined. Paracetamol may acts by inhibiting prostaglandin synthesis in the central nervous system (CNS) and through a peripheral action by blocking pain-impulse generation. Antipyretic effect by acting centrally on the hypothalamic heat regulating center to produce peripheral vasodilation resulting in increased blood flow through the skin sweating and heat loss.
Pharmacokinetics : The rate and extent of absorption from the suppository dosage form may vary, depending on the composition of the base. Duration of action 3-4 hours. About 25% of paracetamol in blood bound to plasma proteins and has plasma half-life 1-4 hours. Approximately 90-95% of a dose is metabolized in the liver and excreted in urine. The intermediate metabolite may accumulate in overdosage after the primary metabolic pathways become saturated, is hepatotoxic and possibly nephrotoxic.
Indication : For the temporary relief of fever, minor aches, pains and headaches.
Dosage : Adult : 2 suppositories every 4-6 hours. (Not more than a total of 12 suppositories in any 24 hours period).
Children: 6-12 years: 1 suppository every 4-6 hours. (Not more than a total of 5 suppositories in any 24 hours period).
How to use :

1. Wash your hand and remove suppository from wrapper by firmly grasp each tab and slowly peel apart the suppository in a downward motion.



2. Lie down on your left side with the right knee bent (if left-handed, lie on the right side with the left knee bent). Push the suppository into the rectum with your finger. Suppository should remain in the rectum for 15 to 30 minutes.

3. If the suppository is too soft, run cold water over it before removing the foil wrapper for about 1-2 minutes.

Contraindication : Patients who known hypersensitivity to Paracetamol, severe hepatic disease.

Warning and precaution :
1. If use more than the usually recommended dosage, on the label or the leaflet, hepatotoxic may occur.
2. Patients with renal or hepatic disease should consult a physician or a pharmacist before use this drug.
3. This preparation contains PARACETAMOL. Do not take any other paracetamol containing medicines at the same time.

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.

Interaction :
- Patient who has taken barbiturates, tricyclic antidepressant and alcohol may risk of hepatotoxicity with prolonged use of high dose of paracetamol because of increased metabolism resulting from induction of hepatic microsomal enzyme activity.
- Alcohol and hepatotoxic medication can increase the hepatotoxicity of paracetamol overdose.
- Concurrent use anticoagulant, coumarin or indandione- derivative with chronic, high dose of paracetamol may increase the anticoagulant effect.
- Prolonged concurrent use of paracetamol with NSAIDs and salicylates may increase the renal adverse effect.

Pregnancy and lactation : FDA Pregnancy Category B. Paracetamol crosses the placenta and distributes into breast milk.

Undesirable effects : Side effects are significatly mild, though hematological reactions have been reports.
Cutaneous hypersensitivity reactions including skin rashes, angioedema, Stevens Johnson Syndrome/Toxic Epidermal Necrolysis have been reported.

Overdose : Overdose symptoms include: hepatic necrosis, transient azotemia, renal tubular necrosis with acute toxicity, anemia and GI disturbances with chronic toxicity.
Treatment : Acetylcysteine 140 mg/kg orally (loading) followed by 70 mg/kg every 4 hours for 17 doses or by IV N-acetyl cysteine 150 mg/kg infused over 60 minutes followed by an IV maintenance dose of 50 mg/kg infused over 4 hours. and then 100 mg/kg infused over 16 hours. Supportive care includes maintaining fluid and electrolyte balance.
Storage : Store below 30° C(86° F)
Packaging available : Plastic (PVC) sheet 100 µ thickness laminated with plastic (PE) 40 µ thickness. Each sheet contains 6 suppositories and packed in paper box, each box contains 2 sheets.

FOR RECTAL USE ONLY

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