

Reset[®] ER

Paracetamol 665 mg Tablet



Presentation

Reset[®] ER: Each tablet contains Paracetamol BP 665mg.

Description

Reset[®] ER is the preparation of Paracetamol 665 mg extended release formulation of bilayer tablet. Immediate release formulation for immediate response and extended release formulation for extended response of 8 hours.

Indications and usage

Reset[®] ER is effective for the relief of persistent pain associated with osteoarthritis and muscle aches and pains such as backache. It also provides effective temporary relief from the pain and discomfort associated with headache, tension headache, period pain, toothache and pain after dental procedures, cold & flu. Reset[®] ER tablet is also effective in reducing fever.

Dosage and administration

Adults and children over 12 years: 2 tablets, swallowed whole, every 6 to 8 hours (maximum of 6 tablets in any 24 hours). The tablets must not be crushed.

Contraindications

Reset[®] ER is contraindicated if any hypersensitivity to paracetamol or to any of the excipients present.

Precaution

Reset[®] ER should be administered with caution to patients with hepatic or renal dysfunction.

Drug interaction

Anticoagulant dosage may require reduction if paracetamol medication is prolonged. Paracetamol absorption from immediate release preparations is increased by drugs which increase gastric emptying e.g. metoclopramide, and decreased by drugs which decrease gastric emptying, e.g. propantheline, antidepressants with anticholinergic properties, narcotic analgesics. However, concurrent administration of metoclopramide may reduce the absorption of paracetamol from this extended release dosage form, as it accelerates gastric emptying and intestinal transit. Paracetamol may increase chloramphenicol concentrations. The likelihood of paracetamol toxicity may be increased by the concomitant use of enzyme inducing agents such as alcohol or anticonvulsant drugs.

Over dosage

Paracetamol overdose may cause hepatic failure due to prolonged exposure of paracetamol in the blood from the extended release form. Immediate medical management is required in the event of overdose even symptoms of overdose are not present.

Adverse Reactions

Reports of adverse reactions are rare. Although the following adverse reactions have been reported, a causal relationship to the administration of paracetamol has been neither confirmed nor refuted: dyspepsia, nausea, allergic and haematological reactions.

Use in pregnancy and lactation

Pregnancy: Reset ER tablet has been categorized as Category A.

Lactation: Paracetamol is excreted in breast milk. It has been reported that from a single 665 mg dose, 0.04 to 0.23% will be available for ingestion by the infant. These results are based on immediate release preparations of paracetamol. There is no data available on the excretion of extended release paracetamol preparations in breast milk.

Storage

Do not store above 30 °C. Keep away from light and out of the reach of children.

Commercial Pack

Reset[®] ER: Each box contains 10 alu-pvc blister strips of 10 tablets.

Manufactured by
 **Incepta Pharmaceuticals Ltd**
Savar, Dhaka, Bangladesh
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