

Reset[®] 1g

Paracetamol solution for IV infusion



Presentation

Reset[®] 1g: Each 100ml bottle contains paracetamol BP 1 gm solution for infusion.

Description

Paracetamol solution for infusion is a clear and slightly yellowish solution. Paracetamol infusion provides onset of pain relief within 5 to 10 minutes after the start of administration. The peak analgesic effect is obtained in 1 hour and the duration of this effect is usually 4 to 6 hours. Paracetamol infusion reduces fever within 30 minutes after the start of administration with a duration of the antipyretic effect of at least 6 hours.

Indications & uses

Paracetamol 10 mg/mL solution for infusion is indicated for the relief of mild to moderate pain and the reduction of fever where an intravenous route of administration is considered necessary.

Dosage and administration

Intravenous route :

Reset solution for infusion should not be mixed with other medicinal products.

Patient	Body weight	Dosage and frequency
Adult	>50 kg	1 gm/100ml, up to 4 times a day
	33 kg to 50 kg	15 mg/kg body wt, up to 4 times a day
Neonates, infants and children	Up to 33 kg	15 mg/kg body wt, up to 4 times a day
	Less than 10 kg	7.5 mg/kg body wt, up to 4 times a day

The minimum interval between each administration must be 4 hours in patients without hepatic or renal impairment. In patients with renal and/or hepatic impairment the minimum interval between doses must not be less than 6 hours. For adults weighing from 33 to 50 kg, the maximum daily dose from all sources of paracetamol must not exceed 60mg/kg. In patients with chronic or active hepatic disease, especially those with hepatocellular insufficiency, chronic alcoholism, chronic malnutrition and dehydration the dose should not exceed 3 g/day.

Method of administration

The paracetamol solution is administered as a 15-minutes intravenous infusion. Paracetamol solution for infusion can be diluted in a 0.9% Sodium Chloride or 5% Glucose solution up to one tenth. In this case, use the diluted solution within the hour following its preparation (infusion time included).

Contraindications

Paracetamol solution for infusion is contraindicated:

- In cases of hypersensitivity to paracetamol or to any of the excipients
- In cases of severe hepatocellular insufficiency
- In patients with hepatic failure or active liver disease

Precautions

Paracetamol infusion should be used with caution in cases of:

- Hepatocellular insufficiency
- Severe renal insufficiency (creatinine clearance \leq 30 mL/min)
- Glucose-6-Phosphate Dehydrogenase (G6PD) deficiency
- Chronic alcoholism
- Anorexia, cachexia, chronic malnutrition
- Dehydration, hypovolemia

The total dose of paracetamol should not exceed 4 gm per day.

Adverse reactions

Injection site pain and burning sensation, nausea, vomiting, constipation. Very rare cases of hypersensitivity reactions ranging from simple skin rash or urticaria to anaphylactic shock have been reported and require discontinuation of treatment. Isolated reports of thrombocytopenia have been observed.

Use in pregnancy & lactation

Paracetamol is not contraindicated during pregnancy and in breast-feeding women.

Drug Interactions

Cautions should be given to the concomitant intake of paracetamol with probenecid, barbiturates, isoniazid, anticoagulants, zidovudine, amoxicillin-clavulanic acid, carbamazepine, ethanol, phenytoin, busulfan and diflunisal as these drugs interact with paracetamol.

Over dosage

There is a risk of poisoning, particularly in elderly subjects, in young children, in patients with liver disease, in cases of chronic alcoholism, in patients with chronic malnutrition and in patients receiving enzyme inducers. Poisoning may be fatal in these cases. Acute overdose with paracetamol may also lead to acute renal tubular necrosis. Symptoms generally appear within the first 24 hours and comprise of nausea, vomiting, anorexia, pallor and abdominal pain.

Storage

Do not store above 30 °C. Do not refrigerate or freeze. Keep in a cool and dry place, away from light. Keep out of the reach of children.

Cautions

Do not use if the bottle leaks. Before administration, the product should be visually inspected for any particulate matter and discoloration. For single use only. The product should be used immediately after opening and any unused solution should be discarded.

Commercial pack

Reset[®] 1g IV infusion : Each pack contains a single 100 ml bottle containing 1gm / 100 ml paracetamol solution for infusion with one infusion set, one alcohol pad, one first aid band & Hanger.