Paracetamol Injection 150mg/ml

Ifimol® Inj

Composition:
Each ml contains
Paracetamol IP..... 150 mg
Benzyl Alcohol IP..... 2% v/v
(As preservative)
Water for Injection IP..... q.s.

DOSAGE FORM:
IM / IV use
Solution for Injection

INDICATIONS:
Ifimol injection is indicated for the treatment of mild to moderate pain and pyrexia.

DOSE AND METHOD OF ADMINISTRATION:
Paracetamol 150 mg/ml solution for injection based in 10 mg/kg body weight, to be given via slow IV push or via deep IM injection, every 4-6 hours a day, or approximately as follows:

Age Group	***IV/IM dose every 4 to 6 hours***
Children	
<6 months	0.25 – 0.5 mL
6-12 months	0.5 – 0.75 mL
1-2 years	0.75 – 1 mL
3-6 years	1 – 1.25 mL
7-12 years	1.25 – 2 mL
Adults	2 – 4 mL

Method of administration
Paracetamol 150 mg/ml solution for injection may be given 4-6 hours via slow IV push or via deep IM injection while symptoms persist, but not to exceed 5 doses in each 24-hr period for not >5 days unless otherwise directed by a physician.

USE IN SPECIAL POPULATIONS:
Pregnancy: There are no studies of intravenous paracetamol in pregnant women; however, epidemiological data on oral Paracetamol use in pregnant women show no increased risk of major congenital malformations. Paracetamol injection should be given to a pregnant woman only if clearly needed.
Lactation: Paracetamol is excreted in breast milk in small quantities. No undesirable effects on nursing infants have been reported. Paracetamol injection may be used in breast-feeding women.

CONTRA-INDICATIONS:
It is contraindicated in patients with known hypersensitivity to Paracetamol to any of the excipients of the formulation. In cases of severe hepatocellular insufficiency.

WARNINGS & PRECAUTIONS:
Hepatic injury: Administration of Paracetamol in doses higher than recommended may result in hepatic injury, including the risk of severe hepatotoxicity and death. Do not exceed the maximum recommended daily dose of paracetamol.
Use caution when administering paracetamol in patients with hepatic impairment or active hepatic disease, alcoholism, chronic malnutrition, severe hypovolemia (e.g., due to dehydration or blood loss), or severe renal impairment (creatinine clearance ≤ 30 mL/min).
Serious skin reactions: Rarely, paracetamol may cause serious skin reactions such as acute generalized exanthematous pustulosis (AGEP), Stevens - Johnson syndrome (SJS), and toxic epidermal necrolysis (TEN), which can be fatal. Patients should be informed about the signs of serious skin reactions, and use of the drug should be discontinued at the first appearance of skin rash or any other sign of hypersensitivity.
Patients should take precaution if your baby is less than 4 weeks old, consult and take advice to your physician or pharmacist before giving them paracetamol 150 mg/ml solution for injection in particular if the baby is given other medicines that contain propylene glycol or alcohol.
The solution is to be inspected visually for particulate matter and discolouration prior to administration and should only be used if it is clear and free from particles.

DRUG INTERACTIONS:
Anticoagulants: Prolonged regular use of paracetamol possibly enhances anticoagulant effect of coumarins.
Antidiabetics: Absorption of paracetamol possibly reduced when giver 1 to 4 hours after lixisenatide.
Antiepileptics: Metabolism of paracetamol possibly accelerated by carbamazepine, phenobarbital and phenytoin (also isolated reports of hepatotoxicity).
Cytotoxics: Paracetamol possibly inhibits metabolism of intravenous busulfan (manufacturer of intravenous busulfan advises caution within 72 hours of paracetamol); caution with paracetamol advised by manufacturer of imatinib.
Lipid-regulating Drugs: Absorption of Paracetamol reduced by colestyramine.
Metoclopramide: Rate of absorption of Paracetamol increased by metoclopramide.

UNDESIRABLE EFFECTS:
Side-effects rare, malaise, skin reactions including Stevens-Johnson syndrome, toxic epidermal necrolysis, acute generalised exanthematous pustulosis; blood disorders including thrombocytopenia, leucopenia, neutropenia reported; hypotension, flushing, and tachycardia reported on infusion.
Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorization of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Kindly report any suspected adverse reactions to pharmavigil@jbpharma.com

OVERDOSE:
Symptoms: 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. Abnormalities of glucose metabolism and metabolic acidosis may occur. In severe poisoning, hepatic failure may progress to encephalopathy, haemorrhage, hypoglycaemia, cerebral oedema and death. Acute renal failure with acute tubular necrosis, haematuria and proteinuria, may develop even in the absence of severe liver damage. Cardiac arrhythmias and pancreatitis may occur.
Treatment: Treatment of paracetamol overdose may include the antidote N-acetyl cysteine (NAC) by the IV or oral route. In overdoses of oral paracetamol NAC is administered, if possible, before 10 hours but may give some degree of protection from liver toxicity even after this time. Other symptomatic and supportive treatment.

PHARMACODYNAMIC AND PHARMACOKINETIC PROPERTIES:
Pharmacodynamics:
Paracetamol may act predominantly by inhibiting prostaglandin synthesis in the central nervous system (CNS) and, to a lesser extent, through a peripheral action by blocking pain impulse generation. The peripheral action may also be due to inhibition of prostaglandin synthesis or to inhibition of the synthesis or actions of other substances that sensitize pain receptors to mechanical or chemical stimulation. Paracetamol probably produces antipyresis by acting centrally on the hypothalamic heat regulating centre to produce peripheral vasodilation resulting in increased blood flow through the skin, sweating and heat loss. The central action probably involves inhibition of prostaglandin synthesis in the hypothalamus.

Pharmacokinetics:
Absorption: Paracetamol pharmacokinetics is linear up to 2 g after single administration and after repeated administration during 24 hours.
Distribution: The volume of distribution of Paracetamol is approximately 1 L/kg. Paracetamol is not extensively bound to plasma proteins.
Metabolism: Paracetamol Injection is metabolized mainly in the liver following two major hepatic pathways: glucuronic acid conjugation and sulphuric acid conjugation. The later route is rapidly saturable at doses that exceed the therapeutic doses. A small fraction (less than 4%) is metabolised by cytochrome P450 to a reactive intermediate (N-acetyl benzoquinone imine) which, under normal conditions of use, is rapidly detoxified by reduced glutathione and eliminated in the urine after conjugation with cysteine and mercapturic acid.
Half-life: Plasma elimination half-life is approximately 2.7 hours.
Excretion: The metabolites of paracetamol are mainly excreted in the urine. 90% of the dose administered is excreted within 24 hours, mainly as glucuronide (60-80%) and sulphate (20-30%) conjugates. Less than 5% is eliminated unchanged.

NONCLINICAL PROPERTIES:
Animal Toxicology and/or Pharmacology Preclinical data reveal no special hazard for humans beyond the information included in other sections of the pack insert. Studies on local tolerance of paracetamol IV in rats and rabbits showed good tolerability. Absence of delayed contact hypersensitivity has been tested in guinea pigs.

INCOMPATABILITIES:
Paracetamol Inj should not be mixed with other medicinal products.

PACKAGING INFORMATION:
Ampoule of 2ml

Storage: Store in cool place. Protect from light.

Marketed by & ® Regd. Trade Mark of :
J. B. CHEMICALS & PHARMACEUTICALS LTD.
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