(Paracetamol 10 mg/ml)

IV Infusion

Description

Paracetamol is a non-salicylate antipyretic and non-opioid analgesic agent. Paracetamol IV injection is a sterile, clear, colorless, non pyrogenic, isotonic formulation of Paracetamol intended for intravenous infusion.

Indications

Napa® IV is indicated for the management of mild to moderate pain, the management of moderate to severe pain with adjunctive opioid analgesics, the reduction of fever.

Dosage and Administration

Adults and adolescents weighing 50 kg and over: the recommended dosage of Paracetamol IV is 1000 mg every 6 hours or 650 mg every 4 hours, with a maximum single dose of Paracetamol IV of 1000 mg, a minimum dosing interval of 4 hours, and a maximum daily dose of Paracetamol of 4000 mg per day.

Adults and adolescents weighing under 50 kg: the recommended dosage of Paracetamol IV is 15 mg/kg every 6 hours or 12.5 mg/kg every 4 hours, with a maximum single dose of Paracetamol IV of 15 mg/kg, a minimum dosing interval of 4 hours, and a maximum daily dose of Paracetamol of 75 mg/kg per day.

Children ≥ 2 to 12 years of age: the recommended dosage of Paracetamol IV is 15 mg/kg every 6 hours or 12.5 mg/kg every 4 hours, with a maximum single dose of Paracetamol IV of 15 mg/kg, a minimum dosing interval of 4 hours, and a maximum daily dose of Paracetamol of 75 mg/kg per day.

Pregnancy and Lactation

Pregnancy Category C. 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. Animal reproduction studies have not been conducted with IV Paracetamol and it is not known whether Paracetamol IV can cause fetal harm when administered to a pregnant woman. Paracetamol IV should be given to a pregnant woman only if clearly needed. There are no adequate and well-controlled studies with Paracetamol IV during labor and delivery; therefore, it should be used in such settings only after a careful benefit-risk assessment. While studies with Paracetamol IV have not been conducted, Paracetamol is secreted in human milk in small quantities after oral administration.

Pediatric Use

The safety and effectiveness of Paracetamol IV for the treatment of acute pain and fever in pediatric patients ages 2 years and older is supported by evidence from adequate and well-controlled studies of Paracetamol IV in adults.

Geriatric use

No overall differences in safety or effectiveness were observed between these subjects and younger subjects, and other reported clinical experience has not identified differences in responses between the elderly and younger patients.

Patients with Hepatic Impairment

Paracetamol is contraindicated in patients with severe hepatic impairment or severe active liver disease and should be used with caution in patients with hepatic impairment or active liver disease. A reduced total daily dose of Paracetamol may be warranted.

Patients with Renal Impairment

In cases of severe renal impairment (creatinine clearance ≤ 30 ml/min), longer dosing intervals and a reduced total daily dose of Paracetamol may be warranted.

Contraindications

Paracetamol is contraindicated:

- in patients with known hypersensitivity to Paracetamol or to any of the excipients in the intravenous formulation.
- in patients with severe hepatic impairment or severe active liver disease

Adverse Reactions

As all paracetamol products, adverse drug reactions are rare (>1/10000, <1/1000) or very rare (<1/10000). Frequent adverse reactions at injection site have been reported during clinical trials (pain and burning sensation). Very rare cases of hypersensitivity reactions ranging from simple skin rash or urticaria to anaphylactic shock have been reported and require discontinuation of treatment. Cases of erythema, flushing, pruritus and tachycardia have been reported.

Precautions

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 the following conditions: 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). There were infrequent reports of life-threatening anaphylaxis requiring emergent medical attention. Discontinue Paracetamol IV immediately if symptoms associated with allergy or hypersensitivity occurs. Do not use Paracetamol IV in patients with Paracetamol allergy.

Pharmaceutical Precautions

Store in a cool & dry place & away from children. For single use only. The product should be used within 6 hours after opening. Do not refrigerate or freeze.

Commercial Pack

Napa® IV: Supplied in a 100 ml glass bottle containing 1000 mg Paracetamol (10 mg/ml).

Manufactured by

beximco pharmaceuticals ltd.

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