Information For the Use Paracetamol (1000mg)

Paraplom IV Infusion

Paracetamol (1000mg) Infusion

Description

Paracetamol (1000mg) Infusion is a sterile, aqueous solution of paracetamol used for the intravenous treatment of pain and fever in patients who cannot take oral medication. Paracetamol is a widely used analgesic and antipyretic drug that works by inhibiting the production of prostaglandins in the body, which helps in reducing pain and lowering body temperature. This intravenous formulation offers a convenient and effective option for patients in a hospital setting who require rapid pain relief or fever reduction.

Composition

Each 100ml of the infusion contains:

- Paracetamol (as Paracetamol Monohydrate) 1000mg
- Excipients: Water for injection, sodium hydroxide, hydrochloric acid (to adjust pH), and other stabilizers.

Indications

Paracetamol (1000mg) Infusion is indicated for the following conditions:

- Acute Pain Management: For patients experiencing moderate pain, such as postoperative pain, injury-related pain, or pain from medical procedures.
- Fever Management: To reduce fever in patients where oral medication is not suitable or possible (e.g., due to vomiting, difficulty swallowing, or non-compliance).

 Post-operative Care: As part of postoperative analgesia, where oral administration may not be effective or available.

Mechanism of Action

Paracetamol exerts its analgesic and antipyretic effects by inhibiting cyclooxygenase (COX) enzymes, particularly COX-2, in the brain. This reduces the production of prostaglandins, which are chemicals responsible for causing inflammation, pain, and fever. Paracetamol is effective for mild to moderate pain relief and lowering fever, but it does not have significant anti-inflammatory effects compared to other pain-relieving drugs such as nonsteroidal antiinflammatory drugs (NSAIDs).

Dosage and Administration

Adult Dosage:

- The usual dose for adults is 1000mg (1 vial) administered intravenously over 15 minutes.
- If additional doses are required, a gap of at least 4–6 hours should be maintained between doses, with a maximum dose of 4000mg per 24-hour period.

For patients with hepatic or renal impairment:

• Dosage adjustment may be necessary based on individual clinical assessment, especially for patients with liver or kidney dysfunction.

Administration:

Paracetamol (1000mg) Infusion should be administered intravenously.

- The infusion should be administered slowly over a period of 15 minutes.
- The infusion should not be injected rapidly or bolus administered due to the risk of adverse reactions.

For Pediatric Patients:

• This formulation is generally not recommended for pediatric patients under the age of 12 years. Alternative formulations (e.g., oral) should be considered for pediatric pain management.

Contraindications

Paracetamol (1000mg) Infusion should not be used in the following situations:

- Hypersensitivity: Known allergy to paracetamol or any of the excipients in the formulation.
- Severe Hepatic Impairment: Patients with severe liver dysfunction should not be given paracetamol due to the risk of liver toxicity.
- Acute Hepatic Encephalopathy: Not suitable for patients with acute liver failure or conditions where hepatic detoxification is impaired.
- Severe Renal Impairment: Caution is needed in patients with renal impairment.

Precautions

- Hepatic Impairment: Use with caution in patients with mild to moderate liver impairment. Paracetamol is metabolized in the liver, and excessive doses may lead to liver damage.
- Renal Impairment: Dose adjustments may be necessary in patients with renal dysfunction. Prolonged use should be avoided unless strictly necessary.

- Chronic Alcohol Use: Chronic alcohol users may have an increased risk of liver damage with high doses of paracetamol.
- Overdose: Overdose may lead to severe liver damage and requires urgent medical attention. Symptoms of overdose include nausea, vomiting, loss of appetite, confusion, and jaundice.

Side Effects

Common side effects are rare, but may include:

- Injection site reactions: Pain, redness, or irritation at the injection site.
- Hypotension: Drop in blood pressure may occur with rapid infusion.
- Allergic Reactions: Rash, itching, swelling, or more serious reactions such as anaphylaxis in rare cases.
- Gastrointestinal: Nausea, vomiting, or stomach discomfort.
- Liver Function: Prolonged or high-dose usage may lead to liver damage, evidenced by elevated liver enzymes, jaundice, or abnormal liver function tests.

Serious side effects:

- Liver damage: Symptoms of liver toxicity such as yellowing of the skin/eyes, dark urine, or abdominal pain.
- Severe allergic reactions: Difficulty breathing, swelling of the face/tongue, severe rash, or anaphylactic shock.

If any of these serious side effects occur, discontinue the infusion and seek medical help immediately.

Drug Interactions

- Alcohol: Alcohol consumption can increase the risk of liver damage, and should be avoided during treatment.
- Warfarin: Chronic use of paracetamol may increase the anticoagulant effect of

warfarin, potentially leading to bleeding complications.

Anticonvulsants: Drugs like phenytoin and carbamazepine may induce liver enzymes and lower paracetamol efficacy.

 Other Hepatotoxic Drugs: Avoid concurrent use with other drugs that have a known hepatotoxic effect.

Storage Instructions

•

- Store the infusion in a cool, dry place at a temperature between 15–30°C.
- Protect from light.
- Do not freeze.
- Once opened, use the infusion solution immediately. Discard any unused portion.
- Keep the infusion out of reach of children.

Presentation

- Form: Infusion solution (1000mg/100ml).
- Packaging: Available in vials of 100ml for intravenous infusion.

Conclusion

Paracetamol (1000mg) Infusion is an effective option for managing moderate pain and fever in hospitalized patients. It provides rapid relief when oral administration is not possible, ensuring adequate pain management and temperature control. Always use this medication as prescribed and under the supervision of a healthcare professional, especially in patients with hepatic or renal impairment.

Manufactured in India for:



Cafoli Lifecare Pvt. Ltd. (An ISO 9001: 2015 Certified Co.) Plot no.: 367-FF, Industrial Area Phase-I, Panchkula-134113 TM: Trademark Applied for