Information For the User Drotaverine (40mg) Dotahub Injection

Drotaverine (40 mg) Injection

Generic Name:

Drotaverine Hydrochloride

Strength:

40 mg/ml

Dosage Form:

Injectable solution

Route of Administration:

Intramuscular (IM) or Intravenous (IV)

Indications:

Drotaverine is indicated for the treatment of smooth muscle spasms associated with:

- Renal colic
- Biliary colic
- Gastrointestinal spasms (e.g., irritable bowel syndrome, enteritis)
- Dysmenorrhea
- Postoperative smooth muscle spasms

Pharmacological Information

Mechanism of Action:

Drotaverine is a selective inhibitor of phosphodiesterase-IV (PDE-IV), an enzyme that degrades cyclic adenosine monophosphate (cAMP). By increasing cAMP levels, it relaxes smooth muscles, reduces spasm, and relieves pain.

Dosage and Administration

Adults:

- Intramuscular (IM): 40–80 mg (1–2 ml) administered 1–3 times per day based on clinical condition.
- Intravenous (IV): 40–80 mg slowly, preferably diluted, to be given in acute conditions such as renal or biliary colic.

Pediatric Use:

• Not routinely recommended due to limited safety and efficacy data.

Preparation:

For IV administration, ensure a slow injection over 30–60 seconds to minimize the risk of side effects.

Contraindications

- Hypersensitivity to Drotaverine or any excipients in the formulation
- Severe hepatic, renal, or cardiac impairment
- Hypotension or shock

Warnings and Precautions

- **Cardiovascular Monitoring**: Use cautiously in patients with low blood pressure as Drotaverine can cause hypotension.
- Pregnancy and Lactation: Avoid use unless deemed absolutely necessary by a healthcare provider.
- Allergic Reactions: Discontinue immediately if signs of hypersensitivity occur.

Adverse Effects

- Common:
 - o Dizziness

- o Nausea
- o Headache
- Injection site pain or redness
- Rare but Serious:
 - Severe hypotension
 - o Tachycardia
 - Allergic reactions (e.g., rash, swelling, difficulty breathing)

Storage and Handling

- Store at room temperature (below 25°C or 77°F).
- Protect from light and moisture.
- Keep out of reach of children.

Note: This injection should only be administered under medical supervision. Follow the prescribed dosage and instructions strictly. Always consult a healthcare professional before use.

Manufactured in India for:

