

Information For the User  
Drotaverine (80mg) + Aceclofenac (100mg)

## Dotahub Spas tablet

### Drotaverine (80 mg) + Aceclofenac (100 mg) Tablet

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#### Description:

This combination tablet contains Drotaverine and Aceclofenac, formulated to provide effective relief from pain and spasms associated with various musculoskeletal and gastrointestinal conditions. Drotaverine helps alleviate smooth muscle spasms, while Aceclofenac reduces inflammation, pain, and swelling, making this combination effective for conditions involving both spasm and inflammation.

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#### Composition and Mechanism of Action:

1. **Drotaverine (80 mg):** A spasmolytic (muscle relaxant) agent that works by inhibiting phosphodiesterase IV, which relaxes smooth muscles and helps in relieving spasms. Drotaverine is commonly used to treat conditions involving smooth muscle spasms such as abdominal cramps, dysmenorrhea (painful menstruation), and colicky pain.
  2. **Aceclofenac (100 mg):** A nonsteroidal anti-inflammatory drug (NSAID) that works by inhibiting the cyclooxygenase (COX) enzymes, reducing the production of prostaglandins responsible for pain, inflammation, and swelling. Aceclofenac is effective in managing pain and inflammation in conditions like osteoarthritis, rheumatoid arthritis, muscle pain, and other inflammatory disorders.
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#### Indications:

This combination tablet is indicated for:

- Pain and spasms associated with musculoskeletal disorders like osteoarthritis, rheumatoid arthritis, and soft tissue injuries
  - Abdominal pain and cramping due to gastrointestinal conditions like irritable bowel syndrome (IBS), dyspepsia, and colitis
  - Menstrual pain (dysmenorrhea) involving both cramping and inflammation
  - Acute pain management with muscle spasms (e.g., back pain, muscle strains)
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#### Dosage and Administration:

- **Adults:** One tablet every 8–12 hours as required, or as directed by a healthcare provider. Do not exceed three tablets in a 24-hour period.
- **Route of Administration:** Oral, to be taken with water.
- **Timing:** Preferably after meals to reduce the risk of stomach irritation caused by Aceclofenac.

**Note:** Dosage may vary depending on the severity of symptoms and patient's medical history. Always follow the instructions provided by your healthcare provider.

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#### Precautions and Warnings:

1. **Alcohol:** Avoid alcohol consumption while taking this medication, as it may increase the risk of gastrointestinal irritation (due to Aceclofenac) and other side effects.
2. **Pregnancy and Breastfeeding:** Consult your doctor before using this medication during pregnancy or breastfeeding, especially in the later stages of pregnancy.
3. **Pre-existing Conditions:** Use with caution in individuals with a history of gastrointestinal ulcers, kidney or liver disease, heart disease, or hypertension.

4. **Gastrointestinal Effects:** Prolonged use of Aceclofenac may increase the risk of gastrointestinal ulcers or bleeding. If you experience symptoms like black stools or vomit resembling coffee grounds, discontinue use and consult your doctor.

- **CNS Depressants:** Caution should be exercised when combining with sedatives or central nervous system depressants.

**Note:** Always inform your healthcare provider about any other medications or supplements you are taking.

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## Contraindications:

- Known hypersensitivity to Drotaverine, Aceclofenac, or any other ingredients in the formulation
- Active gastrointestinal bleeding, peptic ulcer disease, or severe liver or kidney impairment
- Severe heart failure or uncontrolled hypertension
- Pregnancy (especially in the third trimester) or breastfeeding without medical advice

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## Side Effects:

- **Common Side Effects:** Nausea, abdominal discomfort, indigestion, dizziness, headache, and mild gastrointestinal disturbances.
- **Serious Side Effects (rare):** Signs of gastrointestinal bleeding (e.g., black stools, vomiting blood), liver dysfunction (e.g., jaundice, dark urine), allergic reactions (e.g., skin rash, difficulty breathing), and kidney dysfunction (e.g., decreased urine output).

If any serious side effects occur, discontinue use immediately and seek medical attention.

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## Storage:

- Store in a cool, dry place at room temperature, away from light and moisture.
- Keep out of reach of children.

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## Disclaimer:

This medication should be used under the supervision of a healthcare provider. It provides symptomatic relief from pain and spasms, but does not address the underlying cause of the condition. Always follow the prescribed dosage and instructions for safe and effective use.

Manufactured in India for:

**Cafoli**<sup>TM</sup>  
L I F E C A R E

**Cafoli Lifecare Pvt. Ltd.**

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Panchkula-134113

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## Drug Interactions:

- **Anticoagulants:** Use with blood thinners (e.g., warfarin) may increase the risk of bleeding.
- **Other NSAIDs or Steroids:** Avoid combining with other NSAIDs or corticosteroids due to an increased risk of gastrointestinal irritation or ulcers.
- **Antihypertensive Medications:** Concomitant use with blood pressure-lowering medications may reduce their effectiveness.