Information For the Use Thiocolchicoside (4mg) Thiotale 4 Capsule

Product Information: Thiocolchicoside (4mg) Capsule

Composition:

Each capsule contains:

Thiocolchicoside: 4 mg

Pharmacological Class:

 Thiocolchicoside: Muscle relaxant, classified as a GABA receptor agonist with anti-inflammatory and analgesic properties.

Indications:

Thiocolchicoside (4mg) Capsule is indicated for the following conditions:

- 1. Muscle Spasms: Thiocolchicoside is used to relieve muscle spasms associated with various musculoskeletal disorders, such as:
 - Cervical spondylosis.
 - Lumbar spondylosis.
 - Osteoarthritis.
 - Muscle sprains and strains.
- 2. Pain Relief: It is also indicated as an adjunct treatment for pain and inflammation resulting from musculoskeletal injuries or conditions.

3. Neuromuscular Disorders: It can be used in conditions involving muscle spasticity, such as cerebral palsy and multiple sclerosis (MS), where it helps reduce muscle stiffness and spasms.

Mechanism of Action:

Thiocolchicoside is a synthetic derivative of colchicine, a compound known for its antiinflammatory and muscle-relaxant properties. It acts primarily by:

- Binding to GABA receptors (Gamma-Aminobutyric Acid receptors) in the central nervous system. This action results in muscle relaxation through inhibitory pathways, leading to reduced muscle tone and spasm.
- Anti-inflammatory effect: Thiocolchicoside may also reduce inflammation in the muscles and joints, further helping in conditions like arthritis and sprains.
- Centrally Acting Muscle Relaxant: It inhibits the firing of motor neurons in the spinal cord, leading to reduced muscle contractions and spasms.

Dosage and Administration:

• Usual Adult Dose: Take one capsule (4 mg) of Thiocolchicoside twice daily, or as prescribed by the healthcare provider.

- For severe muscle spasms, the dose may be adjusted by the physician.
- Administration: Swallow the capsule whole with a glass of water. It can be taken with or without food.
- Duration of Treatment: The treatment duration typically lasts for 5 to 7 days, depending on the severity of the condition. Prolonged use is not recommended unless advised by a healthcare professional.

Contraindications:

- Hypersensitivity to Thiocolchicoside, colchicine, or any of the capsule's excipients.
- Pregnancy: Thiocolchicoside is contraindicated during pregnancy, particularly in the first trimester, due to potential risks to fetal development.
- Breastfeeding: Use during breastfeeding is contraindicated as it may pass into breast milk and harm the infant.
- Severe Hepatic Impairment: Contraindicated in patients with severe liver dysfunction.
- Children: Not recommended for use in children under the age of 18.

Warnings and Precautions:

 Pregnancy and Lactation: Thiocolchicoside is contraindicated during pregnancy and breastfeeding. It should not be used in women who are pregnant or planning to become pregnant.

- Hepatic Dysfunction: Caution should be exercised when prescribing to patients with mild to moderate liver disease. Regular liver function tests may be recommended during treatment.
- Allergic Reactions: In rare cases, Thiocolchicoside may cause allergic reactions such as skin rashes, itching, or swelling. Discontinue use and seek medical attention if any allergic symptoms occur.
- Caution in Geriatric Patients: Older adults may be more sensitive to the effects of Thiocolchicoside, especially the risk of dizziness or sedation.
 Close monitoring is recommended.
- Driving and Operating Machinery: Thiocolchicoside may cause dizziness or drowsiness, especially when standing up quickly. Patients should be cautioned about engaging in activities that require alertness, such as driving or operating machinery, until they understand how the medication affects them.

Adverse Effects:

- Common Side Effects:
 - \circ $\,$ Drowsiness or sedation.
 - Dizziness, especially when standing up.
 - Nausea, vomiting, or gastrointestinal discomfort.
 - Dry mouth or throat.
- Serious Side Effects:
 - Severe allergic reactions (e.g., swelling of the face, lips, tongue, or throat, which may cause difficulty breathing).
 - Liver toxicity: Symptoms may include jaundice (yellowing of

the skin or eyes), dark urine, or severe abdominal pain.

• Cardiovascular effects: Rare cases of low blood pressure or irregular heartbeat.

If any serious side effects occur, contact a healthcare provider immediately.

Drug Interactions:

- CNS Depressants: Concomitant use with other central nervous system depressants (e.g., benzodiazepines, alcohol, opioids) may enhance sedative effects, leading to excessive drowsiness or respiratory depression.
- Anticoagulants (Warfarin): Thiocolchicoside may alter the effect of blood thinners, potentially increasing the risk of bleeding. Regular monitoring of INR (International Normalized Ratio) is recommended when used with anticoagulants.
- Antiepileptic Drugs: As Thiocolchicoside has muscle-relaxant properties, caution is advised when combining with antiepileptic medications, as it may alter seizure control.

Use in Special Populations:

 Pregnancy: Contraindicated.
Thiocolchicoside has been classified as a pregnancy category C drug, indicating potential harm to the fetus. It should not be used during pregnancy unless deemed absolutely necessary by a healthcare provider.

- Lactation: Contraindicated. It is not recommended for use during breastfeeding due to the potential risk of adverse effects in the infant.
- Elderly: Older adults may be more prone to side effects such as dizziness or sedation. Lower starting doses and careful monitoring may be required.
- Renal and Hepatic Impairment: Use with caution in patients with liver or kidney disorders. Dosage adjustments may be necessary.

Storage:

- Store at room temperature (15-30°C).
- Protect from moisture and light.
- Keep out of reach of children.

Packaging:

• Available in blister packs or bottles containing 10, 20, or 30 capsules.

Patient Instructions:

- 1. Dosage: Take one capsule twice a day or as prescribed by your healthcare provider. Swallow the capsule whole with a glass of water.
- 2. Missed Dose: If a dose is missed, take it as soon as you remember unless it is almost time for your next dose. Do not double the dose to make up for a missed one.
- 3. Side Effects: If you experience dizziness, drowsiness, or any allergic reactions such as rash, difficulty

breathing, or swelling, contact your doctor immediately.

- 4. Driving: Use caution when driving or operating machinery until you know how Thiocolchicoside affects you.
- 5. Disposal: Safely dispose of unused or expired medication. Do not flush it down the toilet or throw it into the trash.

Thiocolchicoside (4mg) Capsule is an effective treatment for musculoskeletal pain and muscle spasms, providing relief in a variety of conditions. It helps to relax muscles, reduce inflammation, and improve the overall quality of life for patients with musculoskeletal disorders. Always use under the supervision of a healthcare provider to ensure its safe and effective use.

Manufactured in India for:

