

Spusoft™

Erdosteine Capsule and Suspension

Presentation

Spusoft™ Capsule: Each capsule contains Erdosteine INN 300 mg.

Spusoft™ Powder for Suspension: After reconstitution each 5 ml suspension contains Erdosteine INN 175 mg.

Description

Erdosteine is a mucolytic drug. It is a prodrug and it becomes active after metabolism. It acts by reducing the viscosity of mucus. In addition, it has a significant antioxidant action and it inhibits bacterial adhesion to epithelial cells.

Indications

Erdosteine is a mucolytic drug used in the treatment of acute and chronic respiratory diseases. It also improves the symptoms associated with short episodes of chronic bronchitis.

Dosage and Administration

Elderly patients and adults above 18 years: 1 capsule 2 times daily. Suspension: 10 ml 2 times daily.

Children (from 2 years of age):

| Body weight (kg) | Dose |
|------------------|---------------------|
| 15 - <20 kg | 5 ml 2 times daily |
| 20 - 30 kg | 5 ml 3 times daily |
| >30 kg | 10 ml 2 times daily |

The maximum duration of therapy is 10 days.

Directions for Reconstitution

To make 60 ml reconstituted suspension, loosen the powder by shaking and slowly add 42 ml of water, then replace cap and shake well.

Use in Pregnancy and Lactation

The use of Erdosteine in pregnant or breast-feeding women is not recommended.

Side Effects

Common side effect is epigastric pain. Other side effects include headache, cold, difficulty in breathing, taste alterations, nausea, vomiting, diarrhea, angioedema and other skin allergic reactions.

Precautions

It should be used with caution in mild liver failure. In that case, should not exceed a dose of 300 mg per day.

Contraindications

It is contraindicated to patients who have hypersensitivity to Erdosteine. It should not be used in patients with creatinine clearance <25ml/min, or with severe liver failure.

Storage

Do not store above 30°C. Keep away from light and out of the reach of children.

Commercial Pack

Spusoft™ Capsule: Each box contains 2 blister strips of 10 capsules.

Spusoft™ Powder for Suspension: Each box contains one bottle containing dry powder for reconstituting 60 ml suspension and a measuring cup.