

ERDOSTEINE

ECTRIN

**300 mg Capsule
175 mg/5 mL Powder for Suspension**

MUCOLYTIC

FORMULATION

Each capsule contains :

Erdosteine 300 mg

Each 5 mL (1 tsp) suspension contains :

Erdosteine 175 mg

PHARMACOKINETIC PROPERTIES

Peak plasma levels is after 30-60 minutes. Subsequent complete metabolization in similar metabolites.

INDICATIONS

Erdosteine is indicated for the treatment of acute bronchitis, chronic bronchitis and its exacerbations. Respiratory disorders characterized by abnormal bronchial secretions and impaired mucus transport.

DOSAGE AND ADMINISTRATION

Capsule : Take one capsule (300 mg) two to three times daily

Suspension : Pediatric Daily Dose : 15 – 19 kg : 5 mL (1 tsp) twice a day

20 – 30 kg : 5 mL (1 tsp) three times a day

More than 30 kg (and adults) : 10 mL (2 tsp) twice a day

Or as prescribed by the physician.

CONTRAINDICATIONS

Known hypersensitivity towards the product. Because of a possible interference of the product metabolites with the methionine metabolism, Erdosteine is contraindicated in patients suffering from hepatic cirrhosis and deficiency of the cystathionine-synthetase enzyme.

Phenylketonuria, due to the presence of aspartame, only for the powder for suspension.

SPECIAL WARNINGS AND SPECIAL PRECAUTIONS FOR USE

The product contains sucrose. Keep this into consideration in case of diabetes or low-calorie diets

INTERACTION WITH OTHER MEDICINAL PRODUCTS AND OTHER FORMS

OF INTERACTION

No harmful interactions have been observed with other medicaments and the drug can therefore be administered together with antibiotics, bronchodilators (theophylline or beta-2-mimetics and cough sedatives)

USE DURING PREGNANCY AND LACTATION

The safety of Erdosteine during human pregnancy has not been established and therefore, as with all other new drugs, its use is not recommended. It is also not recommended during lactation.

EFFECTS ON ABILITY TO DRIVE AND USE OF MACHINES

No effects have been reported.

UNDESIRABLE EFFECTS

No gastro-intestinal nor systemic side effects due to the drug have been observed.

OVERDOSAGE

With dosages exceeding the recommended dose (1200 mg/day), sweating, vertigo and flushing have been observed.

Store at a temperature not exceeding 30° C. Protect from light.

DIRECTION FOR RECONSTITUTION

To reconstitute to make 60 mL suspension : add 42 mL of water and shake well until all the powder are evenly suspended. The reconstituted suspension is stable for one week (7 days) at temperature not exceeding 30°C (room temperature) and 2 weeks (14 days) at 2-8°C temperature (refrigerated).

To reconstitute to make 100 mL suspension : add 70 mL of water and shake well until all the powder are evenly suspended. The reconstituted suspension is stable for one week (7 days) at temperature not exceeding 30°C (room temperature) and 2 weeks (14 days) at 2-8°C temperature (refrigerated).

CAUTION

Foods, Drugs, Devices and Cosmetics Act prohibits dispensing without prescription.

Store at a temperature not exceeding 30° C. Protect from light.

AVAILABILITY

ERDOSTEINE (ECTRIN) 300 mg Capsule X20's and 100's / box / blister pack

ERDOSTEINE (ECTRIN) 175 mg/5 mL Powder for Suspension X 60 mL in 100 mL bottle and 100 mL in 120 mL bottle



Manufactured by : Hizon Laboratories, Inc.
Assumption Road, Sumulong Highway, Antipolo City
Under license from : Edmond Pharma S.r.l
Via Dei Giovi, 131 Paderno Dugnano, Milano, Italy
For : OEP PHILIPPINES, INC.
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