Summary of Product Characteristics

1. TRADE NAME OF THE MEDICINAL PRODUCT

Erdotin

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each capsule contains:
Erdosteine 300 mg
For complete list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Capsules

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

Mucolytic agent in acute and chronic respiratory diseases.

4.2. Posology and method of administration

Oral formulations*:*
300 mg capsule, 1 capsule 2-3 times a day, per os

4.3. Contra-indications

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.
Patients with active peptic ulcer.
Because of a possible interference of the product metabolites with the methionine metabolism, ERDOTIN is contraindicated in patients suffering from hepatic cirrhosis and deficiency of the cystathionine-synthetase enzyme.

Since there are no data in patients with renal failure with creatinine clearance < 25 ml/min or with severe liver failure, the use of erdosteine is not recommended in these patients.

4.4. Special warnings and special precautions for use

The possible presence of sulphureous odour is not a sign of product alteration, but it is a characteristic of the active ingredient.

4.5. Interactions with other medicinal products and other forms of interaction

No harmful interactions with other drugs have been reported and the product can therefore be administered together with antibiotics and bronchodilators (theophylline or beta-2-mimetics, cough sedatives, etc…).

4.6. Fertility, Pregnancy and lactation

Pregnancy
The safety of erdosteine in pregnancy has not been established, therefore, its use is not recommended.
Breast-feeding
All the same, its use is not recommended during breast-feeding.

4.7. Effects on ability to drive and use machines

Erdotin has no influence on ability to drive and use machines.

4.8. Undesirable effects

Less than 1 patient in 1,000 is expect to have gastrointestinal undesirable effects.

The below reported frequency is defined as follows: very common (≥1/10), common (≥1/100, <1/10), uncommon (≥1/1,000, <1/100), rare (≥1/10,000, <1/1,000), very rare (<1/10,000), unknown (frequency cannot be estimated from available data)

Nervous system disorders Very rare (<1/10,000)	 Headache
Respiratory, thoracic and mediastinal disorders Very rare (<1/10,000) Frequency unknown	 Dyspnoea Bronchial obstruction
Gastrointestinal disorders Very rare (<1/10,000)	 Taste alterations, nausea, vomiting, diarrhoea, epigastric pain
Skin and subcutaneous tissue disorders Very rare (<1/10,000)	 Urticaria, erythema, eczema

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorization of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Any suspected adverse events should be reported to the Ministry of Health according to the National Regulation by using an online form https://sideeffects.health.gov.il

4.9 Overdose

With dosages exceeding those recommended (1200 mg/die) sweating, vertigo and flushing have been observed.

5. PHARMACOLOGICAL PROPERTIES

ERDOTIN (erdosteine) acts pharmacologically as a fluidifying agent of bronchial mucus.

5.1. Pharmacodynamic properties

Pharmaco-therapeutic group
Erdosteine is classified under the mucolytic drugs. ATC code: R05CB15
Mechanism of action/pharmacodynamic effects
Erdosteine, the active ingredient of ERDOTIN, in addition to its mucolytic properties on bronchial mucus thus facilitating expectoration, shows effects in both antagonizing the local formation of free radicals and inhibiting the activity of the elastase enzyme. Pharmacological studies have demonstrated that Erdosteine does not possess these properties as such, but it is active only after metabolism. In fact, the SH groups, to which the activity is ascribed, are chemically blocked and become free only after metabolism or in alkaline environment. This property guarantees a good palatability with no bad taste and mercaptanic regurgitations, and a good gastric tolerability.

5.2. Pharmacokinetic properties

Peak plasma concentrations of the product after 30-60 minutes.
Subsequent complete metabolism to similar metabolites.
Very good bioavailability by oral route.

5.3. Pre-clinical safety data

Acute toxicity:
LD (mouse, rat per os) > 5,000 mg/kg
LD (rat i.p.) > 5,000 mg/kg
LD (mouse i.v.) > 3,500 mg/kg

Toxicity after long-term administration:
Rat (per os, 26 weeks) absence of toxicity up to 1,000 mg/kg
Dog (per os, 26 weeks) absence of toxicity up to 200mg/kg

Fetal toxicity:
Rat per os absence of toxicity up to 1,000 mg/kg
Rabbit per os absence of toxicity up to 250 mg/kg

6. PHARMACEUTICAL PARTICULARES

6.1. List of excipients

Microcrystalline cellulose ,Povidone K30, , Magnesium stearate, Gelatin, Titanium dioxide (E 171), Yellow ferric oxide (E 172), Indigotine (E 132)

6.2. Incompatibilities

None known.

6.3. Shelf-life

The expiry date of the product is indicated on the packaging materials

6.4. Special precautions for storage

Store below 25ºC

6.5. Nature and contents of container

300 mg capsule: box of 20 capsules in PVC / PVdc -aluminium blisters

6.6. Instructions for use/handling

No special requirements.

7. MANUFACTURER

Edmond Pharma S.R.L
VIA DEI GIOVI 131-20037 PADERNO DUGNANO (MI), ITALY

8. ISRAEL MARKETING AUTHORISATION HOLDER

Megapharm Ltd, POB 519, Hod-HaSharon 4510501

9. MARKETING AUTHORISATION NUMBER

135-02-31112

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