**PACKAGE INSERT**

## 1. TRADE NAME OF THE MEDICINAL PRODUCT

ERDOMED 300 MG HARD CAPSULES
Erdosteine 300 mg capsules are presented as size 1 hard gelatine capsules, with green cap and yellow body, containing an ivory powder.

ERDOMED 300 MG DISPERSIBLE TABLETS
Erdosteine 300 mg dispersible tablets are round, flat, light orange tablets with score on one side.

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

ERDOMED 300 mg hard capsules:
Each hard capsule contains: Erdosteine 300 mg

ERDOMED 300 mg dispersible tablets
Each dispersible tablet contains: Erdosteine 300 mg

Excipients with known effects:
Dispersible tablets:
Lactose and sun-set yellow lake

For complete list of excipients, see section. 6.1

## 3. PHARMACEUTICAL FORM

Hard capsules
Dispersible tablets

## 4. CLINICAL PARTICULARS

### 4.1. Therapeutic indications

Mucolytic agent for use in adults with acute and chronic respiratory disorders (including chronic obstructive pulmonary disease, acute exacerbations of chronic obstructive pulmonary disease, rhinosinusitis, pharingolaryngotracheitis, acute and chronic bronchitis) associated with excessive mucus production.

### 4.2. Posology and method of administration

Elderly and adults above 18 years:
Oral formulations*:*
Posology
*300 mg hard capsules:* 1 capsule 2-3 times a day, for oral use.
*300 mg dispersible tablets:* 1 tablet 2-3 times a day, for oral use.

Method of administration for *dispersible tablets*
The tablets should be dissolved in a glass of water. The dispersion should be stirred with a spoon and drunk immediately. The score-line on the tablet does not divide the tablet into equal half-doses.

## 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 methionine metabolism, ERDOMED 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.**

The drug is contraindicated in children younger than 2 years (oral forms).

## 4.4. Special warnings and special precautions for use

The dispersible tablets contain lactose and sun-set yellow lake (E110).

*Lactose*
Patients with rare hereditary problems of galactose intolerance, Lapp-lactase deficit, or glucose-galactose malabsorption should not take this medicine.

*Sun-set yellow lake (E110)*
It may cause allergic reactions.

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

Paediatric population
Mucolytics may induce bronchial obstruction in children younger than 2 years. In fact, the drainage capacity of bronchial mucus is limited in this age, due to the physiological characteristics of the respiratory tract. They are therefore not be used in children younger than 2 years (see section 4.3). No studies available for the recommended doses of erdosteine in children.

No data available in severe renal and hepatic impairment.

## 4.5. Interaction 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 beta2-mimetics, cough sedatives, etc…).

## 4.6. Fertility, pregnancy and lactation

Pregnancy
The safety of erdosteine in pregnancy has not been established, therefore, as with all new drugs, its use is not recommended.

Breast-feeding
Equally, its use is not recommended during breast-feeding.

## 4.7. Effects on ability to drive and use machines

Erdomed has no influence on the ability to drive and use machines.

## 4.8. Undesirable effects

Less than 1 in 1,000 patients may experience gastrointestinal undesirable effects.

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| The 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<br>very rare (<1/10,000) | Headache |
| Respiratory, thoracic and mediastinal disorders<br>very rare (<1/10,000) | Dyspnoea |
| Gastrointestinal disorders<br>very rare (<1/10,000) | Taste alterations, nausea, vomiting, diarrhoea, epigastric pain |
| Skin and subcutaneous tissue disorders<br>very rare (<1/10,000) | Urticaria, erythema, eczema |

## 4.9. Overdose

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

# 5. PHARMACOLOGICAL PROPERTIES

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

## 5.1. Pharmacodynamic properties

***Pharmaco-therapeutic group: medicines for cough and cold diseases.***
ATC code: R05CB15

***Mechanism of action/pharmacodynamic effects***
Erdosteine, active ingredient of ERDOMED, in addition to its mucolytic properties on bronchial mucus thus facilitating expectoration, shows effects in 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 metabolization. In fact, the SH groups, to which the activity is ascribed, are chemically used and become free only after metabolization 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 concentration of the product occurs after 30-60 minutes.
Subsequent complete metabolization to similar metabolites.
Very good bioavailability by oral route.

### 5.3. Preclinical safety data

***Acute toxicity***:

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| 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***:

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|---|---|
| Rat (per os, 26 weeks) | absence of toxicity up to 1,000 mg/kg |
| Dog (per os, 26 weeks) | absence of toxicity up to 200 mg/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 PARTICULARS

### 6.1. List of excipients

***300 mg hard capsule***
Povidone, microcrystalline cellulose, magnesium stearate, gelatin, titanium dioxide (E 171), yellow iron oxide (E 172), indigotine (E 132)

***300 mg dispersible tablets***
Lactose, microcrystalline cellulose, sucralose, croscarmellose sodium, talc, magnesium stearate, mango flavour, sun-set yellow lake (E110), povidone K30, colloidal silicon dioxide.

### 6.2. Incompatibilities

None known.

### 6.3. Shelf-life

With sealed package:
300 mg dispersible tablets: 3 years
300 mg hard capsules: 3 years.

### 6.4. Special precautions for storage

ERDOMED 300 mg dispersible tablets: Do not store above 30°C.
ERDOMED 300mg hard capsules: Do not store above 30°C.

**6.5. Nature and contents of container**

300 mg hard capsule:
Box of 20 capsules in Pa/Alu/PVC//Alu blisters.
Box of 30 capsules in Pa/Alu/PVC//Alu blisters.

300 mg dispersible tablets:
Box of 20 tablets in Pa/Alu/PVC//Alu blisters.
Box of 30 tablets in Pa/Alu/PVC//Alu blisters.

**6.6 Instructions for use/handling**

No special requirements.
Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

**7. NAME AND ADDRESS OF THE MANUFACTURER**

Edmond Pharma S.r.l. – Strada Statale dei Giovi 131, 20037 Paderno Dugnano (MI) Italy.

**8. DATE OF REVISION OF THE TEXT:** October 2019