

# **SUMMARY OF PRODUCT CHARACTERISTICS**

## **1 NAME OF THE MEDICINAL PRODUCT**

Erdotin 300 mg capsules

## **2 QUALITATIVE AND QUANTITATIVE COMPOSITION**

Each capsule contains 300 mg of erdosteine

For full list of excipients, see section 6.1.

## **3 PHARMACEUTICAL FORM**

Capsules, hard

The product appears as a capsule with a green cap and a yellow body

## **4 CLINICAL PARTICULARS**

### **4.1 Therapeutic indications**

As an expectorant.

For the symptomatic treatment of acute exacerbations of chronic bronchitis in adults.

### **4.2 Posology and method of administration**

Elderly and adults above 18 years:

300 mg twice daily for maximum 10 days.

The capsules must be swallowed whole with a glass of water.

### **4.3 Contraindications**

Hypersensitivity to the active substance or to any of the other excipients.

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

Patients with active peptic ulcer.

### **4.4 Special warnings and precautions for use**

No increase in adverse events has been observed with erdosteine in patients with mild liver failure; however these patients should not exceed a dose of 300 mg per day.

### **4.5 Interaction with other medicinal products and other forms of interaction**

No adverse interactions have been reported.

### **4.6 Fertility, Pregnancy and lactation**

#### Pregnancy:

There is no experience for the use of erdosteine in pregnant women.

#### Lactation:

Experience is missing.

Therefore, the use of erdosteine in pregnant or breast-feeding women is not recommended.

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

Erdotin has minor or negligible influence on the ability to drive and use machines.

## 4.8 Undesirable effects

Nervous system disorders Uncommon ( $\square$ 1/1,000 to	Headache
Respiratory, thoracic and mediastinal disorders Uncommon ( $\square$ 1/1,000 to <1/100)	Cold, dyspnoea
Gastrointestinal disorders Uncommon ( $\square$ 1/1,000 to <1/100) Common ( $\square$ 1/100)	Taste alterations, nausea, vomiting, diarrhoea
Skin and subcutaneous tissue disorders Uncommon ( $\square$ 1/1,000 to <1/100)	Angioedema and cutaneous hypersensitivity reactions, such as urticaria, erythema, oedema and eczema

### Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via Yellow Card Scheme

Website: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard).

## 4.9 Overdose

No experience of acute overdosage is available.

Symptomatic treatment and general supportive measures should be followed in all cases of overdosage.

Gastric lavage may be beneficial, followed by observation.

# 5 PHARMACOLOGICAL PROPERTIES

## 5.1 Pharmacodynamic properties

ATC Code: R 05 CB 15

Pharmacotherapeutic group: Mucolytic agent.

Mucolytic agent reducing the viscosity of mucus and purulent sputum.

Erdosteine is a prodrug, becoming active after metabolism whereby free thiol groups are formed.

This effect is due to the opening of the disulfide bonds of the bronchial mucoproteins.

It has also been demonstrated that erdosteine inhibits bacterial adhesion to epithelial cells.

Due to the presence of a free thiol group in its active metabolite, erdosteine has a significant antioxidant action, demonstrated by both 'in vitro' and 'in vivo' studies.

## 5.2 Pharmacokinetic properties

### Absorption

Erdosteine is quickly absorbed after oral administration and rapidly transformed through a first-pass metabolism to its biologically active metabolite – N-thiodiglycolyl-homocysteine (M1).

After administration of 300 mg, the peak plasma concentration of erdosteine (C<sub>max</sub>) -  $1.26 \pm 0.23 \mu\text{g/ml}$  - was reached  $1.18 \pm 0.26$  hour after administration (T<sub>max</sub>), while M1 showed a C<sub>max</sub> of  $3.46 \mu\text{g/ml}$  and a T<sub>max</sub> of 1.48 h.

The plasma concentrations of erdosteine increase in a dose-dependent manner. Plasma concentrations of M1 increased also with the dose, but not as proportionally as in the case of unchanged erdosteine.

The absorption is independent from food intake.

### Distribution

In animal models, erdosteine was distributed mainly to kidneys, bone, spinal cord and liver.

Pharmacologically active concentrations of both erdosteine and M1 were found in Broncho Alveolar Lavage.

### Elimination

The elimination T<sub>1/2</sub> is  $1.46 \pm 0.60$  h and  $1.62 \pm 0.59$  h, respectively, for erdosteine and M1. In urine, only M1 and sulphates were found, faecal elimination is negligible.

No accumulation or change in the metabolism of erdosteine and M1 has been observed after oral administration of 600 to 900 mg daily for 8 days.

### Influence of age

Age does not change the pharmacokinetics of erdosteine.

### Binding to plasma proteins

The drug binding of erdosteine to plasma proteins is 64.5% (range: 50-86%).

## 5.3 Preclinical safety data

Preclinical safety data reveal no special hazard for humans based on conventional studies of safety pharmacology, repeated dose toxicity, genotoxicity and toxicity to reproduction.

## **6 PHARMACEUTICAL PARTICULARS**

### **6.1 List of excipients**

Capsule content:

Microcrystalline cellulose

Povidone

Magnesium stearate

Capsule shell:

Gelatin

Titanium dioxide (E171)

Iron oxide, yellow (E172)

Indigotine (E132)

### **6.2 Incompatibilities**

Not applicable.

### **6.3 Shelf life**

3 years

### **6.4 Special precautions for storage**

Do not store above 25 °C.

### **6.5 Nature and contents of container**

Each PVC/PVdC/Aluminium blister pack contains 10 capsules.

Pack-sizes of 20 or 60 capsules per carton.

Not all pack sizes may be marketed.

**6.6 Special precautions for disposal**

No special requirements

**7 MARKETING AUTHORISATION HOLDER**

Galen Limited  
Seago Industrial Estate  
Craigavon  
BT63 5UA  
UK

**8 MARKETING AUTHORISATION NUMBER(S)**

PL 27827/0039

**9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

27/09/2011

**10 DATE OF REVISION OF THE TEXT**

23/05/2019