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 <25ml/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 interactions

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 (≥1/1,000 to ,1/100)	Headache
Respiratory, thoracic and mediastinal disorders Uncommon (≥1/1,000 to <1/100)	Cold, dyspnoea
Gastrointestinal disorders Uncommon: (≥1/1,000 to <1/100) Common (≥1/100 to <1/10)	Taste alterations, nausea, vomiting, diarrhoea, Epigastric pain
Skin and subcutaneous tissue disorders Uncommon (≥1/1,000 to <1/100)	Angiodema 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
HPRA Pharmacovigilance
Earlsfort Terrace
IRL - Dublin 2
Tel: +353 1 6764971
Fax: +353 1 6762517
Website: http://www.hpra.ie/
e-mail: medsafety@hpra.ie.

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

R 05 CB 15 Mucolytic Agent

5.1 Pharmacodynamic properties

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 (Cmax) - 1.26 ± 0.23 mcg/ml - was reached 1.18 ± 0.26 hour after administration (Tmax), while M1 showed a Cmax of 3.46 mcg/ml and a Tmax 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 T½ is 1.46 ± 0.60 h and 1.62 ±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 of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

No special requirements

7 MARKETING AUTHORISATION HOLDER

Galen Pharma Ireland Limited
Finnabair Industrial Estate
Dundalk
Louth
Ireland

8 MARKETING AUTHORISATION NUMBER

PA22680/004/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 13th October 2006
Date of last renewal: 27th September 2011

10 DATE OF REVISION OF THE TEXT

June 2019