Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Expudyne 250mg/5ml oral solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5ml of oral solution contains 250mg of carbocisteine.

Excipient with known effect
Each 5ml of oral solution contains:
- 32.2mg (1.4mmol) of sodium.
- 7.5mg of sodium methyl parahydroxybenzoate.
- 4.0mg of propylene glycol.
- 0.9mg of glucose.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Oral solution.
Clear, amber-coloured liquid, with raspberry odour.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Expudyne 250mg/5ml oral solution, is a mucolytic agent indicated in adults and children 2 years and above for the adjunctive therapy of respiratory tract disorders characterised by excessive, viscous mucus.

4.2 Posology and method of administration

Mode of administration:
This medicine is for oral use

Posology
Adults including the elderly and adolescents >12 years:

The initial dose is 15ml three times a day; if symptoms improve, the dose may be lowered to 10 ml three times a day. The maximum daily dose is 45ml.

Children:
Children 6 – 12 years: The usual dose is 5 ml two to three times daily
Children 2 – 5 years: The usual dose is 2.5 ml two to three times daily

Expudyne oral solution is not recommended for children younger than 2 years of age.

4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.
Use in patients with active peptic ulceration

4.4 Special warnings and precautions for use

Caution is recommended in the elderly, in those with a history of gastroduodenal ulcers, or those taking concomitant medications known to cause gastrointestinal bleeding. Since mucolytics may disrupt the gastric mucosal barrier, caution should be taken in patients with a history of peptic ulcers. If gastrointestinal bleeding occurs, patients should discontinue medication.

This medicine contains:
- **sodium methyl para-hydroxybenzoate** (E219) and may cause allergic reactions (possible delayed).
- **sodium**: 95.6 mg (4.2 mmol) per 15ml, equivalent to 4.8% of the WHO recommended maximum daily intake of the 2 g sodium for an adult.
- **propyleneglycol:** 4mg per 5ml, which is equivalent to 0.8mg/ml
- **glucose** and patients with rare glucose-galactose malabsorption should not take this medicine.

4.5 Interaction with other medicinal products and other forms of interaction

The combination of mycolytics with antitussives and/or substance that dry out secretions (atropinic) is not recommended.

4.6 Fertility, pregnancy and lactation

Pregnancy
There are no data from the use of carbosisteine in pregnant women.
Animal studies are insufficient with respect to reproductive toxicity (see section 5.3). Expudyne 250mg/5ml oral solution is not recommended during pregnancy.

Breast-feeding
It is unknown whether carbocisteine/metabolites are excreted in human milk. Expudyne 250mg/5ml oral solution should not be used during breast-feeding.

Fertility
There is no known data available on the effects of carbocisteine on fertility.

4.7 Effects on ability to drive and use machines

The medicinal product has negligible influence on the ability to drive and use machines.

4.8 Undesirable effects

Adverse reactions listed by System Organ Class.
Frequencies are defined using the following convention:
very common (≥1/10);
common (≥1/100 to <1/10);
uncommon (≥1/1000 to <1/100);
rare (≥1/10,000 to <1/1,000);
very rare (<1/10,000); not known (cannot be estimated from the available data)

Immune System Disorders
There have been reports of anaphylactic reactions, allergic skin eruption and fixed drug eruption.

Nervous system disorders
Headache

Gastrointestinal disorders
Frequency not known: nausea, gastrointestinal upset, vomiting, gastrointestinal bleeding

Skin and subcutaneous tissue disorders
There have been reports of skin rashes and allergic skin eruptions. Isolated cases of dermatitis bullous such as Stevens-Johnson syndrome and erythema multiforme have also been reported.

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, Website: www.hpra.ie.

4.9 Overdose

The most likely symptoms associated with overdose are gastrointestinal (gastralgia, nausea and vomiting). Supportive therapy should be instituted, and gastric lavage could be considered.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: mucolytic, ATC code: R05CB03

Carbocisteine (S-carboxymethyl L-cysteine) is a mucolytic agent that modifies mucous secretions. It acts during the gel phase of the mucus, most likely by breaking up the disulfide bonds of the glycoproteins, normalizing mucus hyperviscosity and thus favouring expectoration.

5.2 Pharmacokinetic properties

After oral administration, carbocisteine is rapidly absorbed from the GI tract; In an 'in-house' study, at steady state (7 days) Carbocisteine capsules 375 mg given as 2 capsules t.d.s. to healthy volunteers gave the following pharmacokinetic parameters:

Plasma Determinations	Mean	Range
T Max (Hr)	2.0	1.0-3.0
T½ (Hr)	1.87	1.4-2.5
KEL (Hr^{-1})	0.387	0.28-0.50
$AUC0_{0-7.5}$ ($mcg.Hr.ml^{-1}$)	39.26	26.0-62.4
Derived Pharmacokinetic Parameters		
*CL_S ($1\ Hr^{-1}$)	20.2	-
CL_S ($ml.min^{-1}$)	331	-
V_D (L)	105.2	-
V_D ($L\ Kg^{-1}$)	1/75	-

*Calculated from dose for day 7 of study

5.3 Preclinical safety data

Preclinical safety data in the literature do not reveal any findings relevant to the prescriber that have not been mentioned elsewhere in this SmPC.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Glycerol (E 422)
Sodium Saccharin (E 954)
Hydroxyethylcellulose (E 1525)
Xanthan gum (E 415)
Caramel powder (contains glucose syrup, maltodextrin, ammonia and water)
Raspberry flavour (contains propylene glycol (E 1520) and triacetin (E 1518))
Sodium Methyl Parahydroxybenzoate (E 219)
Sodium Hydroxide (E 524)
Purified water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

2 years (unopened)

30 days (opened)

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

Expudyne oral solution is packed in 300ml amber type III glass bottle with child resistant screw cap, which seal is made of HDPE and internal seal is made of PE. Expudyne oral solution comes with a, measuring cup with graduations 1.25 – 2.5 – 3.75 – 5 ml.

6.6 Special precautions for disposal and other handling

No special requirements for disposal.

7 MARKETING AUTHORISATION HOLDER

JED Pharma Limited
Questum Business Park
South Ballingarrane
Clonmel
Co Tipperary
E91 V329
Ireland

8 MARKETING AUTHORISATION NUMBER

PA23183/003/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 10th March 2023

10 DATE OF REVISION OF THE TEXT