Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

PectoDrill sugar-free for chesty coughs 250mg/5ml oral solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Carbocisteine 5.00 g per 100 ml of oral solution
Each 5ml contains 250mg carbocisteine

Excipients with known effect: Each 5ml contains
Methylparahydroxybenzoate (E218) 7.5mg
Sodium 33.3mg
Ethanol (alcohol) <100mg.

For the full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Oral solution
Slightly brownish, clear solution.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Mucolytic agent for use in lower respiratory tract disorders characterised by excessive or viscous mucus.
PectoDrill is indicated in adults and children over 6 years of age.

4.2 Posology and method of administration

Posology

Adults and children 12 years and over:
The usual dose is 15 ml three times daily initially, reducing to 10 ml three times daily when a satisfactory response has been obtained.
The maximum daily dose for adults and children over 12 years of age is 45 ml.
15 ml of the syrup/oral solution contains 750 mg of carbocisteine.

Children aged 6 to 12 years:
One 5 ml (250 mg) measure three times daily.
The maximum daily dose for children aged 6 to 12 years is 15 ml.

Method of administration
For oral use

Treatment duration
Duration of treatment must be restricted to five days after which time if symptoms continue, medical advice must be sought.

4.3 Contraindications

- Hypersensitivity to the active substance (carbocisteine) or to any of the excipients listed in section 6.1.
- Active peptic ulcer.
- Administration of carbocisteine to infants and toddlers under the age of 2.

4.4 Special warnings and precautions for use

A productive cough must not be suppressed since this is a fundamental part of the bronchopulmonary defence mechanism.

It must be administered with caution to patients with severe respiratory insufficiency, as it could increase airway obstruction (see section 5.1).

The association of a bronchial mucus modifier with an antitussive and/or with a substance which dries the secretions (atropinic) is not advisable.

It must be administered with caution in patients with a history of peptic ulcer disease.

Management should be re-assessed if there are signs of pulmonary superinfection.

This medicinal product contains small amounts of ethanol (alcohol), 89.7 mg (i.e. less than 100 mg) per 15 ml dose (ethanol content: 0.8 % v/v).

This medicinal product contains 101 mg (about 0.1g) of sodium per 15 mL dose. To be taken into consideration by patients on a controlled sodium diet.

This medicine contains methyl parahydroxybenzoate (E218) which may cause allergic reactions (possibly delayed).

4.5 Interaction with other medicinal products and other forms of interaction

No specific study for pharmacokinetic interaction has been conducted. Based on our knowledge of carbocisteine, no interactions are expected (see section 5.2).

4.6 Fertility, pregnancy and lactation

Pregnancy
There are no or limited amount of data from the use of carbocisteine in pregnant women. Animal studies are insufficient with respect to reproductive toxicity.
PectoDrill is not recommended during pregnancy and in women of childbearing potential not using contraception.

Breastfeeding
There is insufficient information on the excretion of carbocisteine and/or its metabolites in human milk or in animal milk.
A risk to the newborns/infants cannot be excluded.
Therefore, PectoDrill is not recommended during breast-feeding.

Fertility
Experimental data did not demonstrate any effect on male and female fertility in rat (see section 5.3).

4.7 Effects on ability to drive and use machines

PectoDrill has no or negligible influence on the ability to drive and use machines.

4.8 Undesirable effects

Undesirable effects are classified by their frequency, according to the following convention: very common (≥1/10), common (≥1/100 to <1/10), uncommon (≥1/1000 to <1/100), rare (≥1/10,000 to <1/1000), very rare (<1/10,000), not known (cannot be estimated from the available data). The incidence based on the MedDRA frequency convention and system organ class database is not known.

Body system	**Adverse reactions (frequency not known)**
Gastrointestinal disorders	Upper abdominal painNausea Vomiting Diarrhoea
Skin and subcutaneous tissue disorders	Allergic skin reactions, such as erythematous rash, pruritus, urticaria, angio-edema and fixed drug eruption.

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: www.hpra.ie; E-mail: medsafety@hpra.ie.

4.9 Overdose

Symptoms
There is no experience on the poisoning following overdose. Due to the low toxicity of the product, it is unlikely that an overdose will have toxic effects.
Excessive doses could result most often in gastrointestinal disorder symptoms (nausea, vomiting, diarrhoea, stomach ache).

Treatment
In the event of a massive accidental ingestion, gastric lavage should be performed and symptomatic treatment administered.
There is no known antidote.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: MUCOLYTICS, ATC code: R05CB03 (R: respiratory system)

Carbocisteine (5-carboxymethyl L-cysteine) is a mucoregulator mucolytic-type that acts by altering the structure of the mucus. Carbocisteine stimulates sialomucin synthesis, and consequently modifies mucus composition, reduces mucus viscosity and facilitates expectoration.

Clinically, Carbocisteine treatment induces a decrease in sputum viscosity and an increase in sputum volume.

5.2 Pharmacokinetic properties

Absorption
After oral administration, carbocisteine is almost completely and rapidly absorbed from the gastrointestinal tract. Peak plasma concentration is reached 1 to 2 hours after dosing. After repeat-dose, no accumulation of carbocisteine is evidenced.

Distribution
The apparent volume of distribution of carbocisteine is approximately 60 litres. No information is available on the extent of protein binding.
Carbocisteine appears to penetrate into lung tissues and respiratory mucus, suggesting a local action.

Biotransformation
Acetylation, decarboxylation and sulfoxidation have been identified as the major metabolic pathways of carbocisteine. Pronounced inter-individual variation in metabolic patterns has been observed.

Elimination
The plasma elimination half-life ranges between 1.5 and 2.1 hours.
Renal excretion is the principal route of elimination (96% of the administered dose after 168 hours), the dose being excreted as unchanged drug and metabolites.

5.3 Preclinical safety data

Preclinical safety data in literature have not revealed any relevant findings that have not been mentioned elsewhere in this SmPC.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium Saccharin
Methyl parahydroxybenzoate (E218)
Hydroxyethylcellulose
Aromatic flavour*
Sodium hydroxide (for pH adjustment)
Water purified

*Composition of the Aromatic flavour: Rum, honey, cocoa tincture, orange tincture, cherry tincture, hart`s tongue leaves, tonka bean, liquorice, vanillin, ethylvanillin, maltol, acetylmethylcarbinol, ethyl acetate, caramel colouring, propylene glycol.

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

30 months

6.4 Special precautions for storage

Do not store above 30°C. Do not refrigerate or freeze

6.5 Nature and contents of container

150ml & 200ml Type III amber glass bottle

150ml & 200ml Type III amber glass bottle with a measuring cup (15ml)

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

Pierre Fabre Medicament
45, Place Abel Gance
92100 Boulogne
Cedex
France

8 MARKETING AUTHORISATION NUMBER

PA0329/009/002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 24th March 2006

Date of last renewal: 24th March 2011

10 DATE OF REVISION OF THE TEXT

May 2016