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 5.00g per 100ml
Each 5ml contains 250mg carbocisteine

Excipients with known effect: Each 5ml contains Methyl parahydroxybenzoate (E218) 7.5mg, sodium 33.3mg and ethanol (alcohol) <100mg.

For the full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Oral solution
A slightly brownish, clear solution with odour of caramel.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Mucolytic agent for use in lower respiratory tract disorders characterised by excessive or viscous mucus.

4.2 Posology and method of administration

Posology

Oral route

Adults and children 12 years and over:
The usual dose is 15ml three times daily initially, reducing to 10mls three times daily when a satisfactory response has been obtained.

Children aged 6 to 12 years:
One 5 ml measure two to three times daily.

4.3 Contraindications

Hypersensitivity to carbocisteine, the active substance or to any of the excipients listed in section 6.1.

Active peptic ulcer disease.

4.4 Special warnings and precautions for use

Special warnings

Productive coughs are a fundamental component of the bronchopulmonary defences and should not be suppressed.

Special precautions

Caution is recommended in subjects suffering from gastroduodenal ulcers.

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

This medicine contains 0.1g of sodium per 15 ml measure. To be taken into consideration by patients on a controlled sodium diet.

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

4.5 Interaction with other medicinal products and other forms of interaction

An expectorant or mucolytic medicinal product should not be combined with an antitussive medicinal product or a medicinal product indicated for use to dry secretions (such as anticholinergics).

No interaction studies have been performed.

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. Therefore, the use of PectoDrill during pregnancy is not recommended unless under the guidance of a medical practitioner.

Lactation

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

4.7 Effects on ability to drive and use machines

No studies on the effects on the ability to drive and use machines have been performed.

4.8 Undesirable effects

Undesirable effects are classified by their frequency, according to the following convention: 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), not known (cannot be estimated from the available data).

Body system	Adverse reactions (frequency not known)
Gastrointestinal disorders	Abdominal pain upper Nausea Diarrhoea
Skin and subcutaneous tissue disorders	Skin allergic reactions including erythematous rash, pruritus, urticaria, angioedema 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 IMB Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.imb.ie; e-mail: imbpharmacovigilance@imb.ie

4.9 Overdose

Symptoms and signs:
Gastrointestinal disturbance is the most likely symptom of overdosage.

Treatment
The treatment should be symptomatic and supportive. Gastric lavage may be beneficial.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

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

Mechanism of action

Carbocisteine is a mucolytic-type mucomodifier. It exerts its action on the gel phase of the mucus, probably by breaking the disulphide bonds of the glycoproteins and thus aids expectoration.

Moreover, carbocisteine has effects on bronchial secretion by normalization of mucus hyperviscosity.

5.2 Pharmacokinetic properties

Absorption
Carbocisteine is rapidly absorbed following oral administration; the plasma peak is reached in two hours.

Distribution and biotransformation
The bioavailability is low, less than 10% of the dose administered which is probably due to intraluminal metabolism and a marked liver first-pass effect.

Elimination
The elimination half-life is approximately 2 hours.
Both it and its metabolites are mainly eliminated via the kidneys.

5.3 Preclinical safety data

No information further to that contained in other sections of the SPC is included.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

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

*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 clear glass bottle

150ml & 200ml Type III 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: 24 March 2011

10 DATE OF REVISION OF THE TEXT

March 2014