IRISH MEDICINES BOARD ACT 1995

MEDICINAL PRODUCTS(LICENSING AND SALE)REGULATIONS, 1998

(S.I. No.142 of 1998)

PA0329/009/001
Case No: 1999987

The Irish Medicines Board in exercise of the powers conferred on it by the above mentioned Regulations hereby grants to

Pierre Fabre Medicament

45, Place Abel Gance, **F-92654 BOULOGNE, Cedex**, , **France**

an authorisation, subject to the provisions of the said Regulations, in respect of the product

PectroDrill for chesty coughs 250mg/5ml oral solution

The particulars of which are set out in Part I and Part II of the attached Schedule. The authorisation is also subject to the general conditions as may be specified in the said Regulations as listed on the reverse of this document.

This authorisation, unless previously revoked, shall continue in force from **24/03/2006** until **23/03/2011** .

Signed on behalf of the Irish Medicines Board this

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A person authorised in that behalf by the said Board.

Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

PectoDrill for chesty coughs 250mg/5ml oral solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

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

For excipients, see 6.1

3 PHARMACEUTICAL FORM

Oral solution
A yellow to light brown, clear syrup with a weak odour suggesting 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 adminstration

Oral route

Adults and children 12 years and over:
The usual dose is three 5ml three times daily initially, reducing to two 5ml 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

Known hypersensitivity to carbocisteine or any other constituents
Active peptic ulcer disease

4.4 Special warnings and precautions for use

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.
Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine.
In the event of either diabetes mellitus, or low-sugar diet, the content of 6 g of sucrose per 15 ml measure should be taken into account.

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

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).

4.6 Pregnancy and lactation

Pregnancy
Studies in animals have not revealed any teratogenic effect. In the absence of available clinical data, the administration of this drug should be avoided during pregnancy as a precautionary measure.

Breast-feeding
The use of this drug is not recommended while breast-feeding.

4.7 Effects on ability to drive and use machines

None known.

4.8 Undesirable effects

Side effects seen with carbocisteine are rare.
Possibility of signs of digestive intolerance (gastric pain, nausea, diarrhoea). In this event, it is recommended that the dose be reduced.
Allergic reactions (possibly delayed) caused by methyl parahydroxybenzoate (E218) may occur.

4.9 Overdose

Gastrointestinal disturbance is the most likely symptom of overdosage.
The treatment should be symptomatic and supportive. Gastric lavage may be beneficial.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

MUCOLYTIC
ATC code: R05CB03
(R: respiratory system)

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

Carbocisteine is rapidly absorbed following oral administration; the plasma peak is reached in two hours.
The bioavailability is low– less than 10% of the dose administered – probably due to intraluminal metabolism and a marked liver first-pass effect.
The elimination half-life is approximately 2 hours.
Both it and its metabolites are mainly eliminated via the kidneys.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sucrose solution
Methyl parahydroxybenzoate (E218)
Caramel flavour*
Sodium hydroxide
Purified water

*Caramel flavour: aromatic caramel, coffee extract, vanillin

6.2 Incompatibilities

Not applicable.

6.3 Shelf Life

2 years 6months

6.4 Special precautions for storage

Do not store above 30oC. Do not refrigerate or freeze

6.5 Nature and contents of container

150ml glass bottle
200ml glass bottle
150ml glass bottle with a measuring cup (15ml)
200ml 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
France

8 MARKETING AUTHORISATION NUMBER

PA 329/9/1

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of First Authorisation: 24th March 2006.

10 DATE OF REVISION OF THE TEXT