

IRISH MEDICINES BOARD ACTS 1995 AND 2006

MEDICINAL PRODUCTS(CONTROL OF PLACING ON THE MARKET)REGULATIONS,2007

(S.I. No.540 of 2007)

PA0251/001/001

Case No: 2050603

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

Sinclair Pharmaceuticals Limited

Borough Road, Godalming, Surrey GU7 2AB, United Kingdom

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

Visclair Tablets 100mg

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 **22/05/2008** until **03/08/2008**.

Signed on behalf of the Irish Medicines Board this

A person authorised in that behalf by the said Board.

Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Visclair Tablets 100mg

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains Mecysteine Hydrochloride (Methylcysteine Hydrochloride) 100 mg.

For excipients, see 6.1.

3 PHARMACEUTICAL FORM

Coated gastro-resistant tablets
Round, biconvex yellow tablets with no markings.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

As an adjunct in the management of conditions characterised by thick viscid or glutinous mucus including the symptomatic relief of cough with sputum.

4.2 Posology and method of administration

Adults (including the elderly)

1-2 tablets three to four times daily before meals with a little water.

A rapid clinical effect can be achieved by giving 2 tablets 4 times daily for the first 2 days of therapy.

The standard dose, 2 tablets three times a day, is given for 6 weeks and thereafter the dose should be reduced to 2 tablets twice daily.

Children over 5 years

One tablet 3 times daily.

Children under 5 years

Not recommended.

The tablets should be swallowed whole.

4.3 Contraindications

VISCLAIR is contra-indicated in patients with known hypersensitivity to Methylcysteine, Carbocysteine or N-acetylcysteine.

4.4 Special warnings and precautions for use

VISCLAIR is well tolerated and serious toxic effects have not been reported. It is important that the tablets, which are enteric coated, should be swallowed whole.

Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose –galactose malabsorption should not take this medicine.

4.5 Interaction with other medicinal products and other forms of interaction

None known.

4.6 Pregnancy and lactation

VISCLAIR is not recommended during pregnancy and lactation.

4.7 Effects on ability to drive and use machines

Not applicable.

4.8 Undesirable effects

None known.

4.9 Overdose

Overdosage may cause excessive production of bronchial secretions and hence result in respiratory embarrassment. In such cases postural drainage and suction would be advisable.

Experience regarding overdosage is limited and treatment in such cases should comprise general supportive symptomatic measures.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Methylcysteine Hydrochloride is a systemically active mucolytic agent. Double blind clinical trials have demonstrated a significant reduction of cough and sputum in bronchitic patients.

5.2 Pharmacokinetic properties

The sulphhydryl groups in mecysteine are a readily assimilable supply of sulphur which can intervene in the synthesis of mucoproteins to produce mucus of a more normal viscosity. As the tissue becomes saturated with the drug, the disulphide bonds uniting glucoprotein molecules can be severed, breaking down the mucin gel responsible for sputum viscosity.

5.3 Preclinical safety data

Not applicable.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Core
Lactose Anhydrous
Povidone
Magnesium Stearate

Core Seal

Shellac
Kaolin Heavy

Gastro-resistant Coating

Stearic Acid (1973)
Polyvinylacetate Phthalate

Sugar Coating

Acacia
Gelatin
Sucrose
Calcium Carbonate
Talc
Titanium Dioxide (E171)
Quinoline Yellow (E104)
Sunset Yellow (E110)
Aluminium Hydroxide
White Beeswax
Carnauba Wax

6.2 Incompatibilities

Not applicable.

6.3 Shelf Life

2 years.

6.4 Special precautions for storage

Store below 25°C.

6.5 Nature and contents of container

Aluminium/Polythene foil laminate to take 10 tablets.
10 laminates per carton. Pack size 100 tablets.

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

Sinclair Pharmaceuticals Limited
Borough Road
Godalming
Surrey
GU7 2AB
England

8 MARKETING AUTHORISATION NUMBER

PA 251/1/1

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 04 August 1978

Date of last renewal: 04 August 2003

10 DATE OF REVISION OF THE TEXT

September 2006