IRISH MEDICINES BOARD ACT 1995

MEDICINAL PRODUCTS(LICENSING AND SALE)REGULATIONS, 1998

(S.I. No.142 of 1998)

PA0043/042/001
Case No: 1999891

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

Crookes Healthcare Ltd

1 Thane Road West, **Nottingham**, **NG2 3AA**, **United Kingdom**

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

Strepsils chesty cough 100mg/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 **27/04/2007** until **26/04/2012**.

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

Strepsils Chesty Cough 100mg/5ml Oral solution.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5ml oral solution contains Guaifenesin 100mg.
For a full list of excipients see section 6.1

3 PHARMACEUTICAL FORM

Oral solution
A clear, bright green viscous oral solution with a lemon/lime odour.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

An expectorant for the symptomatic relief of chesty coughs, and to soothe and coat the throat.

For oral administration.

4.2 Posology and method of administration

Adults and children over 12 years:
10ml to be taken every four hours up to four times a day.

Children 6 to 12 years:
5ml to be taken every four hours up to four times a day.

Elderly:
There is no need for dosage reduction in the elderly.

4.3 Contraindications

Hypersensitivity to any of the ingredients.

4.4 Special warnings and precautions for use

Keep all medicines out of the reach and sight of children.

4.5 Interaction with other medicinal products and other forms of interaction

There are no clinically significant interactions.

4.6 Pregnancy and lactation

The safety of Strepsils Chesty Cough Max Strength during pregnancy and lactation has not been established. However guaifenesin is not considered to constitute a hazard during pregnancy since there is no evidence of an association with foetal malformations. There are no data available on use of guaifenesin during breast feeding.

4.7 Effects on ability to drive and use machines

No adverse effects known.

4.8 Undesirable effects

Gastrointestinal discomfort has been reported.

4.9 Overdose

Overdosage may give rise to nausea and vomiting.

Treatment need only be symptomatic and supportive.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Guaifenesin reduces the viscosity of tenacious sputum and is used as an expectorant. The oral liquid (containing glycerol, liquid sucrose and hydroxyethylcellulose) has demulcent properties and will soothe and coat irritated throats.

5.2 Pharmacokinetic properties

Guaifenesin is readily absorbed from the gastrointestinal tract. It is metabolised and excreted in the urine.

5.3 Preclinical safety data

Not applicable.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Glycerol
Liquid sucrose.
Sucrose
Hydroxyethylcellulose
Citric acid
Sodium Citrate
Acesulfame Potassium
Potassium sorbate
Lemon lime flavour 11903-56
Mint cool flavour 79770-36
Quinoline yellow 14031 (E104)
Patent blue V (E131)
Purified water

6.2 Incompatibilities

Not applicable.

6.3 Shelf Life

Unopened: 2 years
After first opening the product should be used within 6 months.

6.4 Special precautions for storage

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

6.5 Nature and contents of container

A squeezable amber polyethylene terephthalate (PET) bottle with a polypropylene plug insert including silicon and polyethylene components, and a child-resistant/tamper evident closure with an expanded polyethylene liner (contact material).
Pack size: 125ml
A graduated dosing cup is provided, allowing measures of 5ml and 10ml.

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

Crookes Healthcare Limited
1 Thane road west
Nottingham NG2 3AA
United Kingdom

8 MARKETING AUTHORISATION NUMBER

PA 43/42/1

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of First Authorisation 27th April 2007.

10 DATE OF REVISION OF THE TEXT