IRISH MEDICINES BOARD ACTS 1995 AND 2006

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

(S.I. No.540 of 2007)

PA0441/007/002
Case No: 2069833

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

Procter & Gamble (Health & Beauty Care) Ltd

The Heights, **Brooklands**, **Weybridge**, **Surrey KT13 0XP**, **United Kingdom**

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

Vicks Original Cough Syrup Chesty

Guaifenesin 50mg/5ml

Cetylpyridinium Chloride 1.25mg/5ml

Sodium Citrate 200mg/5ml

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 **13/05/2010**.

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

Vicks Original Cough Syrup Chesty

Guaifenesin 50mg/5ml

Cetylpyridinium Chloride 1.25mg/5ml

Sodium Citrate 200mg/5ml

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5 ml of the syrup contains Gaifenesin 50 mg, Cetylpridinium Chloride 1.25 mg and Sodium Citrate 200 mg.
Excipients: Each 5ml of syrup contains glucose 1.8g, sucrose 1.8g, ethanol 0.4g.
For full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Syrup.
A clear reddish-pink syrup having a characteristic cherry/aromatic aroma and taste.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Treatment of nasopharyngeal irritation and relief of productive cough.

4.2 Posology and method of administration

Adults and children over 12years: 10 ml (2 teaspoons)

to be repeated every three hours as needed

4.3 Contraindications

None.

4.4 Special warnings and precautions for use

If symptoms persist consult your doctor

4.5 Interaction with other medicinal products and other forms of interaction

None.

4.6 Pregnancy and lactation

No specific data available

4.7 Effects on ability to drive and use machines

None

4.8 Undesirable effects

Guaifenesin has been reported occasionally to cause gastrointestinal discomfort.

4.9 Overdose

Treatment of overdose
Symptomatic management

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Guaifenesin and sodium citrate are expectorants which are believed to work by increasing bronchial secretion and reducing the viscosity of sputum. Cetylpyridinium chloride is a surfactant and antibacterial agent, having a local antiseptic effect.

5.2 Pharmacokinetic properties

Guaifenesin is rapidly metabolised and excreted in the urine mainly as -(2-Methoxy Phenoxy) Lactic acid.

Sodium citrate is oxidised to bicarbonate and excreted in the urine.

Cetylpyridinium chloride acts locally and, being cationic in nature would not be expected to be absorbed systematically. It would therefore be excrete unchanged in the faeces.

5.3 Preclinical safety data

Not applicable.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium benzoate (E211)
Citric acid monohydate
Glycerol
Liquid Glucose
Sucrose
Ethanol 96 %
Tingle flavour EAD 2576
Propylene glycol
Cochineal
Levomenthol
Camphor
Eucalyptus oil

Vicks flavour (FD&O 23143)
Purified water

6.2 Incompatibilities

Not applicable.

6.3 Shelf Life

2 years

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

100 ml coated amber glass bottle with wadless polypropylene screw cap or polypropylene child resistant closure.

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

Shake well before use.

7 MARKETING AUTHORISATION HOLDER

Procter & Gamble (Health & Beauty Care) Ltd.
The Heights
Brooklands
Weybridge
Surrey
KT13 0XP
United Kingdom

8 MARKETING AUTHORISATION NUMBER

PA 441/7/2

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 29 September 1982

Date of last renewal: 29 September 2007

10 DATE OF REVISION OF THE TEXT

May 2010