IRISH MEDICINES BOARD ACTS 1995 AND 2006

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

(S.I. No.540 of 2007)

PA1326/001/003
Case No: 2022247

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

Cadbury Trebor Bassett

Bournville Lane, **Birmingham B30 2QZ**, **United Kingdom**

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

Halls Mentholyptus Blackcurrant Lozenge 0.14% w/w levo-menthol 0.028% w/w Eucalyptus oil

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 **01/02/2008** until **31/01/2013**.

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

Halls Mentholyptus Blackcurrant Lozenge
0.14%w/w levo-menthol 0.028%w/w Eucalyptus oil

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 3.78g lozenge contains: levo-menthol 0.14%w/w and Eucalyptus oil 0.028%w/w.
Also contains sucrose. For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Lozenge
A hard translucent, purple, square-shaped boiled sugar lozenge with the letter “H” embossed in the centre.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

For the symptomatic relief of discomforts caused by head colds, nasal congestion, sore throats and chestiness.

4.2 Posology and method of administration

For oral use only.

Each pack contains 9 lozenges.

Adults and the elderly:

Allow one to dissolve slowly in the mouth. Do not exceed 5 packs in any 24 hour period.

Children over 6 years:

Allow one to dissolve slowly in the mouth. Do not exceed 3 packs in any 24 hour period.

Children under 6 years:

Allow one to dissolve slowly in the mouth. Do not exceed 1 pack in any 24 hour period.

4.3 Contraindications

Hypersensitivity to any of the active ingredients.

4.4 Special warnings and precautions for use

Do not exceed the maximum dosage in any 24 hours. If symptoms persist or worsen seek medical advice.

4.5 Interaction with other medicinal products and other forms of interaction

None known.

4.6 Pregnancy and lactation

No adverse effects on pregnancy or lactation have been reported for any of the ingredients and the product may be used in the short term. Prolonged use is not recommended during pregnancy.

4.7 Effects on ability to drive and use machines

None known.

4.8 Undesirable effects

Rarely side effects may include hypersensitivity characterised by urticaria, flushing and headache.

4.9 Overdose

Acute ingestion:

Nausea, vomiting, abdominal pain, flushed face, ataxia, dyspnoea, glottal spasm, inspiratory stridor, tachycardia or bradycardia, hyponatraemia, metabolic acidosis, muscular rigidity, convulsions, drowsiness and coma.

Treatment:

Due to the low concentrations of menthol and eucalyptus, gastric decontamination is unlikely to be required unless large quantities of these lozenges are ingested. If required, gastric decontamination is only useful within one hour of menthol and/or eucalyptus ingestion due to rapid absorption.

Emesis is contraindicated because of the risk of central nervous system depression and glottal spasm upon aspiration with menthol.

Activated charcoal may be given within an hour of ingestion of a significant quantity of menthol/eucalyptus although there is no data on the efficacy of the adsorption by activated charcoal.

Gastric lavage should only be undertaken with a cuffed endotracheal tube in order to reduce the risk of aspiration.

Oral fluids may help to ease any irritant effects on the gastrointestinal tract. If there is any respiratory distress, oxygen and nebulized bronchodilators may be required. Monitor urea, electrolytes and blood gases and correct if necessary. In severe cases continuous monitoring of ECG and respiratory function may be required with regular measurement of renal and hepatic function.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Menthol

Menthol has the unusual property of producing a sensation of coolness especially when applied to mucous membranes. Because of this, it has been used for symptomatic relief of conditions such as bronchitis and sinusitis. It is also used as a decongestant.
Eucalyptus Oil

Eucalyptus Oil has the general properties of essential oils and has been taken by mouth for catarrh.

The combination of these ingredients as medicated confectionery would therefore be expected to provide for the symptomatic relief of discomforts caused by head colds, nasal congestion, sore throats and chestiness.

5.2 Pharmacokinetic properties

In this dosage form, menthol and eucalyptus oil are effectively being used for their topical action. The quantities ingested would not be expected to produce significant systemic levels.

5.3 Preclinical safety data

The active ingredients of Halls Mentholyptus Blackcurrant are well known constituents of medicinal products and their safety profile is well documented.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sucrose.(granulated)
Glucose Syrup
Water
Lactic acid buffered. (lactic acid (E270) & sodium lactate (E325))
Citric acid anhydrous (E330)
Potassium citrate monohydrate (E332)
Cooling flavours (Physcool & WS 3)
Blackcurrant flavour D9515
Ponceau 4R (E124)
Indigo Carmine (E132)

6.2 Incompatibilities

Not applicable.

6.3 Shelf Life

Two years.

6.4 Special precautions for storage

Do not store above 30°C.

6.5 Nature and contents of container

Lozenge stickpack: Each lozenge is wrapped in wax paper overwrapped in foil laminate. Pack size: 9 lozenges.

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

Cadbury Trebor Bassett
Bournville Lane
Birmingham
B30 2QZ
United Kingdom

8 MARKETING AUTHORISATION NUMBER

PA1326/1/3

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of First Authorisation: 1st February 2008

10 DATE OF REVISION OF THE TEXT