SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Beechams Chesty Cough Oral Solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Guaifenesin 100 mg, Glucose, liquid 3.0 g, Treacle 1.35 g

For full list of excipients, see section 6-1

3 PHARMACEUTICAL FORM

Oral solution

A dark, brown, viscous liquid with the odours of liquorice and aniseed.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

An expectorant for the symptomatic relief of coughs (including bronchial cough) and chesty catarrh, particularly associated with colds and flu.

The product also has a soothing, protective, demulcent action on a sore, irritated, tickling and inflamed throat.

4.2 Posology and method of administration

Adults and children over the age of 12: Take one 10ml dose (two 5ml spoonfuls) and repeat every 2 to 3 hours.

Route of Administration

Oral

4.3 Contraindications

Known hypersensitivity to guaifenesin, treacle or glucose or to any of the Excipients.

4.4 Special warnings and precautions for use

Patients suffering from chronic cough or asthma should consult a physician before taking this product.

Patients should stop using the product and consult a health care professional if cough lasts for more than 5 days or comes back, or is accompanied by a fever, rash or persistent headache.

Do not take with a cough suppressant.

Special Label Warnings

Keep out of the reach and sight of children.

If symptoms persist, consult your doctor.

Do not exceed the stated dose.

Do not use with other cough and cold medicines.

Contains 6.68 g total sugars per 10 ml dose. This should be taken into account in patients with diabetes mellitus.

Patients with rare glucose-galactose malabsorption should not take this medicine.

Contains 9.6 mg sodium per 10 ml dose. This should be taken into consideration in patients on a controlled sodium diet.

Contains sodium benzoate and sodium metabisulphite, which may rarely cause severe allergic reactions and bronchospasm.

4.5 Interaction with other medicinal products and other forms of interaction

None.

4.6 Fertility, Pregnancy and lactation

Pregnancy

The safety of guaifenesin during pregnancy has not been established. Medical advice should be sought before use in pregnancy and this medicine should not be used unless the potential benefit to the mother outweighs the possible risk to the developing foetus.

Lactation

No relevant data available. Should not be used whilst breastfeeding without medical advice.

4.7 Effects on ability to drive and use machines

None.

4.8 Undesirable effects

Immune system disorders:

Unknown: allergic reactions, angioedema, anaphylactic reactions

Respiratory, thoracic and mediastinal disorders:

Unknown: Dyspnoea (in association with other symptoms of hypersensitivity)

Skin and subcutaneous disorders:

Unknown: Rash, urticaria

Gatrsointestinal disorders:

Unknown: nausea, vomiting, abdominal discomfort

4.9 Overdose

Very large doses of guaifenesin cause nausea and vomiting. Vomiting would be treated by fluid replacement and monitoring of electrolytes if indicated.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Guaifenesin is an expectorant.

Treacle and liquid glucose are demulcents.

5.2 Pharmacokinetic properties

None Stated.

5.3 Preclinical safety data

There are no preclinical data of any relevance additional to that already included in other sections of the SmPC.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Deionised water, Macrogol 300, Glacial acetic acid, Sodium benzoate (E211), Capsicum tincture (contains ethanol), Sodium metabisulphite (E223), Aniseed oil, Xanthan gum, Levomenthol, Camphor, racemic, Sodium cyclamate, Acesulfame potassium, Liquorice aniseed flavour and Caramel colour (E150).

6.2 Incompatibilities

None.

6.3 Shelf life

Unopened: Three years.

Opened: Six months.

6.4 Special precautions for storage

None.

6.5 Nature and contents of container

Amber cylindrical glass bottle fitted with a child resistant and tamper evident plastic screw cap.

Pack size: 100 or 160 ml.

6.6 Special precautions for disposal

None.

7 MARKETING AUTHORISATION HOLDER

Haleon UK Trading Limited
The Heights
Weybridge
Surrey
KT13 0NY
United Kingdom

8 MARKETING AUTHORISATION NUMBER(S)

PL 44673/0025

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

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10 DATE OF REVISION OF THE TEXT

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