SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

HILLS BALSAM CHESTY COUGH LIQUID

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Guaifenesin BP 100 mg/5 ml.

For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Brown, viscous, oral solution with aromatic odour

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

For symptomatic relief of productive (chesty) cough.

4.2 Posology and method of administration

For oral use only.

NOT RECOMMENDED FOR CHILDREN UNDER 12 YEARS

Adults and Children over 12 years:

One or Two 5ml spoonfuls to be taken every 2 to 4 hours.

Not more than 12 x 5 ml spoonfuls should be given in any 24 hours. Do not exceed the stated dose.

There are no special requirements for the elderly.

4.3 Contraindications

Known hypersensitivity to guaifenesin or to any of the excipients.

In children under 12 years old.

4.4 Special warnings and precautions for use

Should not be used for persistent or chronic cough, such as occurs with asthma, or where excessive secretions accompany cough, unless directed by a doctor.

If symptoms persist or worsen, seek medical advice.

Do not exceed the stated dose.

Caution should be exercised when using the product in the presence of severe renal or severe hepatic impairment.

Alcohol containing products, should be avoided whilst patients taking this medicine.

Use with extreme caution when other central nervous system depressants are used.

Harmful for those suffering from alcoholism.

This product is not recommended for those who are pregnant, planning to become pregnant or breast-feeding women, children and high-risk groups such as patients with liver disease, or epilepsy. Consult your doctor or pharmacist before taking this medicine.

There are reported cases where excessive consumption of guaifenesin may have contributed to renal stone formation.

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

Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine.

4.5 Interaction with other medicinal products and other forms of interaction

The product contains alcohol. It may enhance the effects of central nervous system depressants.

The product should not be taken with other cough and cold containing products.

If urine is collected within 24 hours of a dose of Hill’s Balsam Chesty Cough Liquid a metabolite of guaifenesin may cause a colour interference with laboratory

determinations of urinary 5-hydroxyindoleacetic acid (5-HIAA) and vanillymandelic acid (VMA).

4.6 Fertility, pregnancy and lactation

Pregnant and lactating women may wish to avoid this product as it contains 5.9 vol % ethanol (alcohol). Guaifenesin has been used for many years without any definite evidence of adverse effect. However, women who are pregnant or breast-feeding are advised to consult their doctor or pharmacist before taking this product.

4.7 Effects on ability to drive and use machines

This product contains 5.9 vol % ethanol (alcohol). The product could cause drowsiness. Patients should be aware of these facts, and should not drive, operate machinery, or perform hazardous tasks if they feel drowsy, or dizzy.

4.8 Undesirable effects

Central nervous system: dizziness, drowsiness, headache

Gastrointestinal: Nausea, vomiting and abdominal pain

Skin: Rashes and allergic reactions.

4.9 Overdose

Overdosage may cause gastrointestinal discomfort. Symptoms of a very large overdose are nausea and vomiting. The drug is however metabolised rapidly and excreted in the urine. Patients should be kept under observation and treated symptomatically.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Expectorants.

ATC code: R05CA03.

Guaifenesin is reported to reduce the viscosity of tenacious sputum and is used as an expectorant.

5.2 Pharmacokinetic properties

Guaifenesin is readily absorbed from the gastrointestinal tract. It is readily metabolised and excreted in the urine. It has a plasma half-life of one hour. The major metabolite in the urine is beta-(2-methoxyphenoxy) lactic acid.

5.3 Preclinical safety data

There are no pre-clinical data of relevance to the prescriber which are additional to that already included in other sections of the SPC.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Acetic acid 80% sodium methyl hydroxybenzoate, sodium propyl hydroxybenzoate, xanthan gum, treacle, capsicum tincture, compound benzoin tincture, ethanol 96%, mint/liquorice flavour GB 2637, anise oil, sucrose (granular), caramel, saccharin sodium, special flavour NI 225892, purified water.

6.2 Incompatibilities

None known.

6.3 Shelf life

36 months.

6.4 Special precautions for storage

Store below 25°C.

6.5 Nature and contents of container

Type 3 round amber glass bottles (with 28mm ROPP neck finish) with a white plastic 28 mm clic-loc tamper evident child resistant cap (with an expanded polyethylene liner). Pack sizes of 100ml and 200ml.

6.6 Special precautions for disposal

None.

7 MARKETING AUTHORISATION HOLDER

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8 MARKETING AUTHORISATION NUMBER(S)

PL 19664/0004

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

20/03/2009

10 DATE OF REVISION OF THE TEXT

04/12/2019