SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Veno's Expectorant

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Guaifenesin BP 100mg, Liquid Glucose BPC (1963) 3.0g, Treacle 1.35g

3 PHARMACEUTICAL FORM

Oral Solution

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

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

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

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

4.5 Interaction with other medicinal products and other forms of interaction

None

4.6 Pregnancy and lactation

Use in pregnancy and lactation is not contraindicated. However, as with all medicines, caution should be exercised during pregnancy and lactation.

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

Gastrointestinal disorders:
Unknown: nausea, vomiting, abdominal discomfort

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard.

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 SPC.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Macrogol
Glacial acetic acid
Sodium benzoate (E211)
Capsicum tincture
Sodium metabisulfite (E223)
Star anise oil
Xanthan gum
Levomenthol
Camphor
Sodium cyclamate
Acesulfame potassium
Liquorice aniseed flavour
Caramel colour (E150)
Water

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 160ml.

6.6 Special precautions for disposal

None

7 MARKETING AUTHORISATION HOLDER

Forest Laboratories UK Limited,
Whiddon Valley,
Barnstaple,
North Devon,
EX32 8NS,
United Kingdom.

8 MARKETING AUTHORISATION NUMBER(S)

PL 00108/0338

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

31/01/1983 / 06/09/2004

10 DATE OF REVISION OF THE TEXT

17/01/2017