Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Venos Expectorant, Oral Solution
Guaifenesin 100 mg/5 ml
Liquid glucose 3 g/5 ml
Treacle 1.35 g/5 ml

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Constituents	**Quantity/5ml**
Guaifenesin	100.00 mg
Liquid Glucose	3.00 g
Treacle	1.35 g

Excipients with known effects
Contains 2.5 mg/5 ml sodium metabisulphite.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Oral solution.
Dark brown viscous oral solution.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

For use as an expectorant and demulcent in the treatment of productive cough in adults and children over 12 years of age.

4.2 Posology and method of administration

Posology

Adults (including elderly) and children aged 12 years and over:
Fill the measure cup to the 10ml mark (two 5ml teaspoonfuls) and repeat every 2 - 3 hours.

Not more than 4 doses should be given in any 24 hours.

Paediatric population
The safety and efficacy in children under 12 years of age have not been established.No data are available.

Method of administration

Shake the bottle before use.

Oral administration only.

Do not exceed the stated dose.

Should not be used with other cough and cold medicines.

4.3 Contraindications

Hypersensitivity to guaifenesin, treacle, glucose or to any of the excipients listed in section 6.1.

Contraindicated in children under 12 years of age.

4.4 Special warnings and precautions for use

Do not take with any other cough and cold medicine.

If symptoms persist consult your doctor.

Do not exceed the stated dose.

This product should only be used when clearly necessary.

Contains sodium metabisulphite which may rarely cause severe hypersensitivity reactions and bronchospasm.

Contains 3.34g of sugars per 5ml. This equates to 6.68 g of sugar 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.

Patients with rare hereditary problems of fructose intolerance should not take this.

4.5 Interaction with other medicinal products and other forms of interaction

No interaction studies have been performed.

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.

Breast-feeding
No relevant data available. Should not be used whilst breast-feeding without medical advice.

4.7 Effects on ability to drive and use machines

Veno's Expectorant has no or negligible influence on the ability to drive and use machines.

4.8 Undesirable effects

Adverse events from historical clinical trial data are both infrequent and from small patient exposure. Adverse events reported from extensive post-marketing experience at therapeutic/labelled dose and considered attributable are tabulated below by System Organ Class. As these reactions are reported voluntarily from a population of uncertain size, the frequency of these events is unknown but likely to be rare.

Immune system disorders:
Unknown: allergic reactions, angioedema, anaphylactic reactions

Respiratory, thoracic and mediastinal disorders:
Unknown: dyspnoea*
*dyspnoea has been reported in association with other symptoms of hypersensitivity

Gastrointestinal disorders:
Unknown: nausea, vomiting, abdominal discomfort

Skin and subcutaneous tissue disorders:
Unknown: rash, urticaria

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 HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; e-mail: medsafety@hpra.ie.

4.9 Overdose

Very large doses of guaiphenesin can cause nausea and vomiting. Vomiting may be treated by fluid replacement and monitoring of electrolytes if indicated. In the unlikely event of emesis not occurring, gastric lavage should be carried out. Thereafter, treatment is symptomatic.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Expectorants, ATC code: R05CA03
Guaifenesin is a well known expectorant which reduces the viscosity of tenacious sputum.

Treacle and Liquid Glucose exhibit demulcent properties.

5.2 Pharmacokinetic properties

Guaifenesin is absorbed from the gastrointestinal tract. It is rapidly metabolised by oxidation to β-(2 methoxy-phenoxy) lactic acid which is excreted via the urine.

5.3 Preclinical safety data

There is no preclinical data of relevance to the prescriber which is additional to that already included in other sections of the SmPC.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Macrogol 300
Caramel SCS 20 (E-150)
Glacial acetic acid
Sodium benzoate
Capsicum tincture
Sodium metabisulphite (E223)
Anise oil
Xanthan gum
Levomenthol
Racemic camphor
Sodium cyclamate
Acesulfame K
Liquorice aniseed flavour 510877E
Water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

Unopened: 3 years
Opened: 6 months

6.4 Special precautions for storage

Do not store above 25°C.

For storage conditions after first opening of the medicinal product, see section 6.3.

6.5 Nature and contents of container

The product is packaged in 100ml and 160ml cylindrical glass bottles fitted with a roll-on, aluminium cap containing a Melinex-coated, aluminium-faced, pulpboard wad, packaged in a carton with a PP measuring cup.

Not all pack sizes may be marketed.

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

Teva B.V.
Swensweg 5
2031GA Haarlem
Netherlands

8 MARKETING AUTHORISATION NUMBER

PA1986/074/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 10th November 1987
Date of last renewal: 10th November 2007

10 DATE OF REVISION OF THE TEXT

August 2018