

# Summary of Product Characteristics

## 1 NAME OF THE MEDICINAL PRODUCT

Veno's Honey and Lemon oral solution

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5ml dose contains lemon Juice 1.0ml, Honey 250 mg, Ammonium Chloride Ph. Eur. 30 mg, Ipecacuanha Liquid Extract BP 3.0 microlitres and Liquid Glucose Ph.Eur. 4.0g.

Excipients with known effects:

Each 5ml dose contains 2.5mg sodium metabisulphite.

For the full list of excipients, see section 6.1.

## 3 PHARMACEUTICAL FORM

Oral solution

A gold coloured, viscous clear syrup, with a lemon and honey flavour.

## 4 CLINICAL PARTICULARS

### 4.1 Therapeutic Indications

In the treatment of productive cough, in adults and children over 12 years of age.

### 4.2 Posology and method of administration

#### Posology

*Adults and Children aged 12 years and over:* Fill measure cup to 15 ml mark (three 5 ml spoonfuls) and repeat every 2 to 3 hours.

Do not exceed 8 doses in any 24 hours.

*Elderly population:* The normal adult dose may be taken.

*Paediatric population:* The safety and efficacy in children under 12 years of age have not been established.

#### Method of administration

For oral administration.

Shake the bottle before use.

### 4.3 Contraindications

Hypersensitivity to any of the active ingredients or to any of the excipients listed in section 6.1.

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.

Prolonged use without medical supervision may be harmful.

Do not exceed the stated dose.

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

Contains 4.00g of sugars per 5ml. This equates to 12 g of sugar per 15 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 medicine.

## 4.5 Interaction with other medicinal products and other forms of interaction

No interaction studies have been performed.

## 4.6 Fertility, pregnancy and lactation

Use in pregnancy and lactation is not contraindicated.

## 4.7 Effects on ability to drive and use machines

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

## 4.8 Undesirable effects

There are no side-effects associated with normal use of the product.

### 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](http://www.hpra.ie); E-mail: [medsafety@hpra.ie](mailto:medsafety@hpra.ie).

## 4.9 Overdose

The symptoms of overdosage with this product would be mild emesis induced by the content of Ipecacuanha liquid extract and ammonium chloride. However, the contents of a whole bottle of the larger 160ml size do not contain an adult emetic dose of either ingredient, but an additive emetic effect may occur.

# 5 PHARMACOLOGICAL PROPERTIES

## 5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Expectorants, ATC code: R05CA04

Liquid glucose, honey and lemon juice exhibit demulcent properties. Ammonium chloride and Ipecacuanha are well known expectorants.

## 5.2 Pharmacokinetic properties

Ammonium chloride is absorbed from the gastro-intestinal tract. The ammonium ion is converted into urea in the liver, the anion thus liberated into the blood stream and extracellular fluid causes a metabolic acidosis and decreases the pH of the urine; this is followed by transient diuresis. Glucose is rapidly absorbed from the gastro-intestinal tract. It is metabolised to carbon dioxide and water with the release of energy. Ascorbic acid is readily absorbed from the GI tract and is widely distributed in the body tissues, 25% bound to plasma proteins. Ascorbic acid in excess of the body's needs is eliminated in the urine as metabolites.

## 5.3 Preclinical safety data

There are no pertinent data not already described elsewhere in this SPC.

# 6 PHARMACEUTICAL PARTICULARS

## 6.1 List of excipients

Propylene glycol  
Sodium benzoate (E211)  
Sodium citrate (E331)  
Citric acid monohydrate (E330)  
Xanthan gum (E415)  
Sodium metabisulphite (E223)  
Levomenthol  
Caramel YT25 (E150)  
Lemon Flavour 7300244E  
Honey Flavour 510553E  
Purified 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

100 ml and 160 ml cylindrical glass bottle fitted with a roll-on, pilfer-proof, aluminium cap containing a Melinex-coated, aluminium-faced, pulpboard wad. The bottles are packed in boxboard boxes 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**

PA1986/075/001

## **9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

Date of first authorisation: 01 April 1978

Date of last renewal: 01 April 2008

## **10 DATE OF REVISION OF THE TEXT**

August 2018