## SUMMARY OF PRODUCT CHARACTERISTICS

### **1** NAME OF THE MEDICINAL PRODUCT

Veno's Honey & Lemon Syrup

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Glucose, liquid 4.00 g, Purified Honey 0.29 g, Lemon Juice Concentrate 0.25 g (equivalent to Lemon Juice 0.9 ml).

For excipients, see 6.1.

## 3 PHARMACEUTICAL FORM Syrup

## 4 CLINICAL PARTICULARS

**4.1 Therapeutic indications** For the symptomatic relief of tickly coughs and sore throats.

### 4.2 **Posology and method of administration**

#### **Route of Administration** Oral

## **Dosage Instructions**

Adults (including the elderly) and children aged 12 years and over: Take a 15 ml dose (three 5 ml spoonfuls) and repeat every two to three hours. Do not exceed 8 doses in any 24 hours.

*Children aged 6 to under 12 years:* Take a 10 ml dose (two 5 ml spoonfuls) and repeat every two to three hours. Do not exceed 6 doses in any 24 hours.

Children aged 2 to under 6 years:

Take a 5 ml dose (one 5 ml spoonful) and repeat every two to three hours. Do not exceed 4 doses in any 24 hours. Do not exceed the stated dose.

Consult a pharmacist or other healthcare professional before use in children under 6 years.

Do not take with any other cough and cold medicine.

Not to be given to children under two years of age.

#### 4.3 Contraindications

Known hypersensitivity to any of the constituents.

#### 4.4 Special warnings and precautions for use

<u>Labelling</u> Keep all medicines out of the sight and reach of children. If symptoms persist, consult your doctor. Carbohydrate content: 3.5 g per 5 ml.

*Children aged 2 to under 6 years:* Consult a pharmacist or other healthcare professional before use in children under 6 years. Do not take with any other cough and cold medicine.

# **4.5** Interaction with other medicinal products and other forms of interaction None known

#### 4.6 Fertility, Pregnancy and lactation

The product is not contraindicated during pregnancy and lactation. However, the advice of a doctor should be sought before use.

### **4.7 Effects on ability to drive and use machines** None known

#### 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 the Yellow Card Scheme at: <u>www.mhra.gov.uk/yellowcard</u>.

#### 4.9 Overdose

The product does not contain any ingredient in a high enough concentration to cause toxic effects; therefore no special symptoms of overdosage would be anticipated and no antidotes would be required.

## **5 PHARMACOLOGICAL PROPERTIES**

#### 5.1 Pharmacodynamic properties

Glucose liquid, honey and lemon juice are demulcents.

#### 5.2 Pharmacokinetic properties

Pharmacokinetic considerations do not arise since the pharmacological action is local to the oropharyngeal cavity and the constituents are systematically innocuous in the concentration used.

#### 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

Ammonium chloride, citric acid monohydrate, xanthan gum, sodium metabisulfite, sodium benzoate, sodium citrate, levomenthol, propylene glycol, water, lemon flavour 730024E, honey flavour 510553E and caramel colour.

#### 6.2 Incompatibilities

None known

#### 6.3 Shelf life

Unopened: Three years Opened: Six months

# 6.4 Special precautions for storage None

#### 6.5 Nature and contents of container

Cylindrical glass bottle with a roll-on, pilfer proof, aluminium cap, containing a melinex-coated, aluminium-faced pulp-board wad. Each bottle is packed in a boxboard carton together with a graduated, polypropylene measuring cup. Pack sizes: 100 or 160 ml.

Not all pack sizes may be marketed.

## 6.6 Special precautions for disposal Not applicable

## 7 MARKETING AUTHORISATION HOLDER

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

## 8 MARKETING AUTHORISATION NUMBER(S) PL 00108/0337

## 9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION 06/10/2005

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

13/06/2016