Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Chanelle ivy leaf syrup

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 5ml of syrup contain 35 mg of extract (as dry extract) from *Hedera helix* L.., folium (ivy leaf) (4 – 8: 1). Extraction solvent: Ethanol 30 % w/w.

Each 5 ml of Syrup contain 2.49 g of Sorbitol and 6.7 mg of Potassium sorbate.

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Syrup
Colourless to pale yellow syrup with the odour and flavour of cherry.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

A traditional herbal medicinal product used as an expectorant in case of productive cough exclusively based on long-standing use.
This product is indicated for use in adults and adolescents over 12 years of age.

4.2 Posology and method of administration

Posology
Adults and adolescents over 12 years
5 ml 3 times daily.
The use is not recommended in children under 12 years of age (see 4.4 special warnings and precautions for use)

Duration of use
If symptoms persist, worsen or do not improve after 7 days of use of Chanelle Ivy Leaf Syrup a qualified healthcare professional e.g. a doctor or a pharmacist should be consulted.

Method of administration
For oral short-term use only. Shake bottle well before each use.

4.3 Contraindications

Hypersensitivity to ivy preparations or any of the excipients listed in section 6.1 or to any other plant belonging to the family Araliaceae.

Pregnancy and lactation (see section 4.6 'Fertility, pregnancy and lactation').

4.4 Special warnings and precautions for use

Do not exceeed stated dose.

The use is not recommended in children under 12 years of age because no data on safety is available.

If symptoms persist, worsen or do not improve after 7 days of use of Chanelle Ivy Leaf
Syrup a qualified healthcare professional e.g. a doctor or a pharmacist should be consulted.

If dyspnoea, fever or purulent sputum occurs, a qualified health professional e.g. a doctor or a pharmacist should be consulted.

Caution is recommended in patients with gastritis or gastric ulcer.

This product contains sorbitol. Patients with rare hereditary problems of fructose intolerance should not take this medicine.

4.5 Interaction with other medicinal products and other forms of interactions

No interaction studies have been performed.

4.6 Fertility, pregnancy and lactation

Safety during pregnancy and lactation has not been established. In the absence of sufficient data, Chanelle Ivy Leaf Syrup should not be used during pregnancy and lactation.

Studies on fertility have not been performed.

4.7 Effects on ability to drive and use machines

No studies on the effect on the ability to drive and use machines have been performed.

4.8 Undesirable effects

Gastrointestinal reactions (nausea, vomiting, diarrhoea) have been reported. The frequency is not known.

Allergic reactions (urticaria, skin rash, dyspnoea) have been reported. The frequency is not known.

If other adverse reactions not mentioned above occur, a qualified healthcare professional e.g. a doctor or a pharmacist should be consulted.

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 to 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

Overdose can provoke nausea, vomiting, diarrhea and agitation.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Not required as per Article 16c(1)(a)(iii) of Directive 2001/83/EC as amended.

5.2 Pharmacokinetic properties

Not required as per Article 16c(1)(a)(iii) of Directive 2001/83/EC as amended.

5.3 Preclinical safety data

Adequate tests on reproductive toxicity and tests on genotoxicity and carcinogenicity have not been performed.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Potassium sorbate
Citric acid
Xanthan gum
Cherry flavour
Sorbitol liquid
Purified water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

Unopened: 3 years
Opened: 3 months

6.4 Special precautions for storage

This traditional herbal medicinal product does not require any special storage conditions.

6.5 Nature and contents of container

Amber glass bottle with plastic child proof cap.
The pack is available in sizes 100 ml and 200 ml although not all pack sizes may be marketed.
Measuring plastic dosing cup included.

6.6 Special precautions for disposal

No special requirements.

7 REGISTRATION HOLDER

Chanelle Medical
Dublin Road
Loughrea
Co. Galway
Ireland

8 REGISTRATION NUMBER(S)

TR0688/001/002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 19th July 2019

10 DATE OF REVISION OF THE TEXT