Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Arkovox syrup

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Ivy leaf dry extract (DER 4-6:1), extraction solvent ethanol 30% (v/v)

Each 5 ml of syrup contains 50 mg of an Ivy Leaf (*Hedera helix* L.) dry extract (DER 4-6:1), extraction solvent ethanol 30% (v/v)

Excipients:
Sucrose (1.7 mg/5 ml syrup)
Sodium methyl parahydroxybenzoate (3 mg/ 5 ml syrup)
Sodium propyl parahydroxybenzoate (1.5 mg/5 ml syrup)

For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Syrup
Brown syrup

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Herbal medicinal product used as an expectorant in case of productive cough.

4.2 Posology and method of administration

Posology

- In adolescents, adults and elderly, 1 measuring spoon (5 ml) 2 times daily, morning and evening (corresponding to a single dose of 50 mg dry extract and a daily dose of 100 mg dry extract);
- In children between 6-12 years of age, half a measuring spoon (2.5 ml) 2 times daily, morning and evening (corresponding to a single dose of 25 mg dry extract and a daily dose of 50 mg dry extract);
- In children between 4-5 years of age, a quarter of a measuring spoon (1.25 ml) 2 times daily, morning and evening (corresponding to a single dose of 12.5 mg dry extract and a daily dose of 25 mg dry extract).

Paediatric population
The use in children under the age of 4 is contraindicated (see section 4.3 “Contraindications”).

Duration of use
If the symptoms persist longer than 1 week during the use of ARKOVOX Syrup, a doctor or a pharmacist should be consulted.

Method of administration
Oral use.

4.3 Contraindications

ARKOVOX Syrup is contraindicated:

- in case of hypersensitivity to the active substance, to plants of the Araliaceae family or to any of the excipients listed in section 6.1;

- in children under 4 years of age because of the risk of aggravation of respiratory symptoms.

4.4 Special warnings and precautions for use

When dyspnoea, fever or purulent sputum occurs, a doctor or a pharmacist should be consulted.

Concomitant use with antitussives as codeine or dextromethorphane is not recommended without medical advice.

Caution is recommended in patients with gastritis or gastric ulcer.

This product contains small amounts of ethanol (alcohol), less than 100 mg per spoonful.

This medicinal product contains sucrose, patients with rare hereditary problems of fructose intolerance, glucose, galactose malabsorption or sucrase/isomaltase insufficiency should not take this medicine.

This medicinal product contains sodium methyl parahydroxybenzoate and sodium propyl parahydroxybenzoate which may cause allergic reactions (possibly delayed).

4.5 Interaction with other medicinal products and other forms of interaction

None reported.

4.6 Fertility, pregnancy and lactation

No data on fertility are available.
Safety during pregnancy and lactation has not been established. In the absence of sufficient data, the use of ARKOVOX Syrup during pregnancy and lactation is not recommended.

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 with ARKOVOX Syrup, nevertheless no effects are expected.

The amount of alcohol present in ARKOVOX Syrup (less than 100 mg per spoonful) has no or negligible influence on the ability to drive and use machines.

4.8 Undesirable effects

Common (≥ 1/100 to < 1/10): gastrointestinal reactions (nausea, vomiting, diarrhoea) have been reported.

Uncommon (≥ 1/1000 to < 1/100): allergic reactions (urticaria, skin rash, couperoses, dyspnoea) have been reported.

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 national reporting system:

Ireland
Pharmacovigilance Section
Irish Medicines Board
Kevin O'Malley House
Earlsfort Centre
Earlsfort Terrace
IRL - Dublin 2
Tel: +353 1 6764971
Fax: +353 1 6762517
Website: www.imb.ie
e-mail: imbpharmacovigilance@imb.ie

4.9 Overdose

Overdose can provoke nausea, vomiting, diarrhoea and agitation.

Paediatric population
One case of a 4-year old child who developed aggressivity and diarrhoea after accidental intake of an ivy extract corresponding 1.8 g herbal substance has been reported.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: respiratory system (ATC code: RO5 C)

The mechanism of action is not known.

5.2 Pharmacokinetic properties

No data available.

5.3 Preclinical safety data

Preclinical data issued from conventional repeated dose toxicity and genotoxicity (Ames test) studies performed with ivy leaf dry extract (DER 4-6:1) extraction solvent ethanol 30% (V/V), raised no safety concern for human use.
No carcinogenicity and reproductive toxicity studies have been performed

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Purified water
Sucrose
Citric acid monohydrate
Sodium carmellose
Caramel flavour (containing natural flavours, cacao extract and maltodextrin)
Caramel colour
Sodium methyl parahydroxybenzoate
Sodium propyl parahydroxy benzoate
Potassium sorbate

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years.

Once opened: 3 months.

6.4 Special precautions for storage

This medicinal product does not require any special storage conditions.

6.5 Nature and contents of container

Brown polyethylene (PET) bottle of 100, 150 or 200 ml with a white polyethylene cap and a graduated measuring spoon.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Laboratoires Arkopharma
LID de Caroos Le Broc - 1ère avenue, 2709 m
06510 CARROS
France

8 MARKETING AUTHORISATION NUMBER

PA1450/001/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 10th January 2014

10 DATE OF REVISION OF THE TEXT