# ACTIVOX Ivy syrup

THR 12297/0017

## UKPAR

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ACTIVOX IVY SYRUP

THR 12297/0017

LAY SUMMARY

The Medicines and Healthcare products Regulatory Agency (MHRA) granted LABORATOIRES ARKOPHARMA a Traditional Herbal Registration Certificate for the traditional herbal medicinal product ACTIVOX Ivy syrup (Traditional Herbal Registration number: THR 12297/0017) on 20 September 2012. This product is available without prescription and can be bought from pharmacies and other outlets.

ACTIVOX Ivy syrup is a traditional herbal medicinal product used to relieve chesty coughs associated with the common cold, based on traditional use only. The active ingredient in ACTIVOX Ivy syrup comes from the leaf of the Ivy plant, which is also known as *Hedera helix* L.

This registration is based exclusively upon evidence of the use of Ivy leaf as a traditional herbal medicine and not upon data generated from clinical trials. There is no requirement under the Traditional Herbal Registration Scheme to prove scientifically that the product works.

No new or unexpected safety concerns arose from this application and it was, therefore, decided that a Traditional Herbal Registration Certificate could be granted.
# ACTIVOX IVY SYRUP

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## SCIENTIFIC DISCUSSION

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INTRODUCTION

The MHRA granted a Traditional Herbal Registration Certificate for the traditional herbal medicine ACTIVOX Ivy syrup (THR 12297/0017) to LABORATOIRES ARKOPHARMA on 20 September 2012. This product is on the general sales list (GSL).

This application was submitted according to Article 16.c of Directive 2001/83 EC, as amended, as part of the Traditional Herbal Medicines Registration Scheme. ACTIVOX Ivy syrup is used to relieve chesty coughs associated with the common cold, based on traditional use only.

The data supplied by the applicant demonstrate 30 years of traditional use of Ivy leaf in the European Union. A satisfactory review of the available safety data on Ivy leaf has also been provided, together with an Expert Safety Report supporting the proposed product.
PHARMACEUTICAL ASSESSMENT

HERBAL SUBSTANCE: IVY LEAF

Scientific name of plant:  
Common name of plant: Climbing ivy
Plant family: Araliaceae

Manufacture of Herbal Substance
The Ivy leaf is collected from the wild in Bulgaria during spring. It is dried under natural conditions, protected from sunlight.

No pesticides are used before or after collection and there is no use of piperonyl butoxide. The supplier of the herbal substance has provided confirmation that the herbal substance is produced in accordance with the principles of Good Agricultural and Collection Practice (GACP) (EMEA/HMPC/246816/20050) and that the herbal substance is not treated with ethylene oxide or irradiation following collection.

Hedera helix L. is the only species from the genus Hedera sp. that grows in Bulgaria and suitable identification tests are applied to the herbal substance. Therefore, there is no risk of adulteration by other species into batches of this easily identifiable herbal substance.

Control of Herbal Substance
A suitable specification based on the Ph Eur monograph for Ivy leaf is applied and is acceptable. The specification is supported by the batch data provided.

Container Closure System
Satisfactory details of the container closure system are provided and confirmation has been given that all components of the container closure system comply with current legislation relating to plastic materials and articles intended to come into contact with foodstuffs.

Stability of Herbal Substance
Confirmation is given that the herbal substance will be tested prior to being used to make the herbal preparation. A shelf-life for the herbal substance is not necessary because it is only a precursor of the active substance, the herbal preparation. The guideline requires stability testing data for the herbal preparation and the herbal product and not for the herbal substance.

HERBAL PREPARATION: IVY LEAF DRY EXTRACT

Extract solvent: Ethanol 30% V/V
Drug extract ratio (native): 4-6:1

Manufacture of Herbal Preparation
A satisfactory description of the manufacturing process of the herbal preparation and flow diagram have been provided. The in-process controls are satisfactorily detailed.
The manufacture of the herbal preparation is considered a standard procedure.

Certificates of Analysis for all materials used in the manufacture of the herbal preparation have been provided.

**Control of Herbal Preparation**
A satisfactory specification with appropriate tests and limits has been provided for the herbal preparation.

Suitable analytical procedures are used to control the quality of the herbal preparation. Analytical procedures have been validated, as appropriate.

Certificates of Analysis have been provided for production batches of the herbal preparation, demonstrating satisfactory compliance with the proposed specification.

**Container Closure System**
Satisfactory details of the container closure system are provided and confirmation has been given that all components of the container closure system comply with current legislation relating to plastic materials and articles intended to come into contact with foodstuffs.

**Stability of Herbal Preparation**
Stability studies have been carried out under ICH conditions. The results support the proposed retest period of the herbal preparation.

**HERBAL PRODUCT: ACTIVOX IVY SYRUP**

**Description and Composition of Herbal Product**
The herbal product is a brown syrup. 5 ml of syrup contains 50 mg of dry extract from Ivy leaf and the excipients sucrose, citric acid monohydrate, carmelllose sodium, caramel flavour, caramel colour, sodium methyl parahydroxybenzoate, sodium propyl parahydroxybenzoate, potassium sorbate and purified water. The compatibility of the herbal preparation with the excipients is demonstrated by the stability testing results. All excipients are controlled in line with their respective Ph Eur monograph with the exception of caramel flavour and caramel colour, which are controlled in line with suitable in-house specifications; in the absence of Ph Eur monographs for these excipients this is acceptable. Satisfactory Certificates of Analysis are provided for all excipients.

**Manufacture of Herbal Product**
A description and flow-chart of the manufacturing method have been provided. The manufacturing method is a standard, uncomplicated procedure. In-process controls are appropriate considering the nature of the product and the method of manufacture. Process validation has been carried out on product batches and the results are satisfactory.

**Control of Herbal Product**
The finished product specification is satisfactory. Acceptance limits have been justified with respect to conventional pharmaceutical requirements and, where
appropriate, safety. Test methods have been described and have been adequately validated, as appropriate. Batch data have been provided and comply with the release specification.

**Container Closure System**
ACTIVOX Ivy syrup is stored in brown PET bottles enclosed by a white high density polyethylene cap. The bottles are packed into cardboard cartons along with a graduated measuring spoon and Patient Information Leaflet.

Pack sizes of 100 ml, 150 ml and 200 ml have been authorised, although not all pack sizes may be marketed. Suitable specifications have been provided by the packaging suppliers and it has been confirmed that all primary packaging materials comply with current regulations.

**Stability of Herbal Product**
Finished product stability studies have been conducted in accordance with current guidelines. Based on the results, a product shelf-life of 3 years is appropriate for herbal product stored in unopened bottles. Once the bottle is first opened a product shelf-life of 3 month applies.

**Pharmaceutical Expert**
The Quality Overall Summary has been written by a professional with suitable experience.

**Summary of Product Characteristics, product labels and Patient Information Leaflet**
All product literature is satisfactory.

A package leaflet has been submitted to the MHRA along with results of consultations with target patient groups ("user testing"), in accordance with Article 59 of Council Directive 2001/83/EC. The results indicate that the package leaflet is well-structured and organised, easy to understand and written in a comprehensive manner. The test shows that the patients/users are able to act upon the information that it contains.

**Conclusion**
There are no objections to granting of a Traditional Herbal Registration from a quality point of view.
NON-CLINICAL ASSESSMENT

NON-CLINICAL OVERVIEW
An Expert Safety Report was provided, which included reviews of some non-clinical data. The Expert Safety Report was written by a suitably qualified professional.

Due to a shortage of published data on Ivy leaf, it is not possible to assess if the safety package for the phytochemical constituents of Ivy leaf is acceptable to the standards of today’s GLP and safety testing requirements. However, the information supplied demonstrating traditional use is acceptable and, thus, the lack of provision of a complete standard safety package is acceptable and in compliance with guideline EMEA/HMPC/32116/05.

The genotoxic potential of the herbal preparation was investigated in a bacterial reverse mutation test and it was not found to be mutagenic at concentrations of up to 5000 ug/plate, under the test conditions described. The product excipients were not evaluated in this assay; however, they are controlled by either Ph Eur or appropriate in-house specifications and there is no cause for concern regarding mutagenicity. The genotoxicity study was performed in accordance with GLP and OECD guidelines and is considered acceptable.

The non-clinical overview submitted in support of this application is satisfactory.

SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)
The SmPC for this product is satisfactory from a non-clinical point of view.

ENVIRONMENTAL RISK ASSESSMENT
An environmental risk assessment is not required for herbal medicinal products according to guidance CPMP/SWP/4447/00.

CONCLUSION
There are no objections to granting of a Traditional Herbal Registration Certificate from a non-clinical point of view.
CLINICAL ASSESSMENT

PROPOSED INDICATION
The applicant has proposed the following indication:

“Traditional herbal medicinal product used to relieve chesty coughs associated with the common cold based on traditional use only.”

The indication is acceptable.

POSOLOGY AND METHOD OF ADMINISTRATION
The applicant has proposed the following:

“For oral use only.
In adults, the elderly, children aged 12 years and over: 1 measuring spoon (5 ml) 2 times daily, morning and evening.

Duration of use
If symptoms worsen or persist after 7 days, a doctor or qualified healthcare practitioner should be consulted.

The product should not be used for more than 2 weeks.
The use in children under 12 years of age is not recommended (see section 4.4 Special warnings and precautions for use).”

This is acceptable.

EFFICACY
No clinical efficacy data are required for registration of Traditional Herbal Medicinal Products.

EVIDENCE OF TRADITIONAL USE
Article 16 c 1 (c) requires the applicant to provide bibliographic or expert evidence to show that the medicinal product in question, or a corresponding product, has been in medicinal use throughout a period of at least 30 years, including at least 15 years within the EU.

The applicant has provided a bibliographic review as evidence for the use of Ivy leaf within the EU for a period exceeding 30 years. In addition, the published Committee on Herbal Medicinal Products (HMPC) assessment report and monograph for Ivy leaf adequately cover the evidence for traditional use of the herbal preparation in the product under assessment in the EU for at least 30 years. The requirements of the Directive are, therefore, considered to be met.

SAFETY REVIEW
Article 16 c 1 (d) requires the applicant to provide a bibliographic review of the safety data together with an Expert Safety Report.

A satisfactory safety review has been provided as well as an Expert Safety Report.
written by a suitably qualified professional with experience in herbal medicines. In addition, the HMPC assessment report for Ivy leaf covers the bibliographic safety data available.

**PRODUCT LITERATURE**
The product literature (Summary of Product Characteristics, Patient Information Leaflet and labelling) for this product is medically satisfactory.

**CONCLUSION**
There are no objections to granting of a Traditional Herbal Registration Certificate from a clinical point of view.
OVERALL CONCLUSION AND RISK ASSESSMENT

QUALITY
The quality data submitted with this application are satisfactory.

NON-CLINICAL
The results of genotoxicity testing are acceptable. No other new non-clinical data were submitted or are required for an application of this type.

Efficacy and Safety
No clinical efficacy data are required for registration of Traditional Herbal Medicinal Products.

The applicant has provided a bibliographic review which shows ample evidence for the use of Ivy leaf within the EU for a period exceeding 30 years and a satisfactory review of the safety data has been provided.

Furthermore, the published assessment report and monograph for Ivy leaf adopted by the HMPC adequately cover the evidence for traditional use of the extract in the product under assessment for at least 30 years and the safety issues associated with Ivy leaf.

The SmPC, PIL and labelling are satisfactory.

RISK ASSESSMENT
The quality of the product is acceptable and no new non-clinical or clinical safety concerns have been identified. The risk: benefit balance is acceptable and a Traditional Herbal Registration Certificate may be granted.
ACTIVOX IVY SYRUP

THR 12297/0017

STEPS TAKEN FOR ASSESSMENT

1 The MHRA received the Traditional Herbal Registration application on 28 February 2011
2 Following standard checks and communication with the applicant the MHRA considered the application valid on 5 April 2011
3 Following assessment of the application the MHRA requested further information relating to the clinical dossier on 29 July 2011 and the quality dossier on 11 August 2011
4 The applicant responded to the MHRA’s requests, providing further information on the clinical and quality dossiers on 17 February 2012
5 Following assessment of the response the MHRA requested further information relating to the quality dossier on 23 March 2012
6 The applicant responded to the MHRA’s request, providing further information on the quality dossier on 22 June 2012
7 A THR was granted on 20 September 2012
SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT
ACTIVOX Ivy syrup

2 QUALITATIVE AND QUANTITATIVE COMPOSITION
5 ml of syrup contains 50 mg of extract (as dry extract) from ivy leaf (Hedera helix L.) (DER 4-6:1).
Extraction solvent: ethanol 30% (V/V)

For a full list of excipients, see section 6.1.

Contains the following excipients (see Section 4.4):
Sucrose (1.7 g/ 5 ml)
Potassium (3 mg/ 5 ml)
Sodium methyl and sodium propyl parahydroxybenzoates.

3 PHARMACEUTICAL FORM
Syrup, brown

4 CLINICAL PARTICULARS

4.1 Therapeutic indications
Traditional herbal medicinal product used to relieve chesty coughs associated with the common cold based on traditional use only.

4.2 Posology and method of administration
For oral use only.
In adults, the elderly, children aged 12 years and over: 1 measuring spoon (5 ml) 2 times daily, morning and evening.

Duration of use
If symptoms worsen or persist after 7 days, a doctor or qualified healthcare practitioner should be consulted.

The product should not be used for more than 2 weeks. The use in children under 12 years of age is not recommended (see section 4.4 Special warnings and precautions for use).

4.3 Contraindications
Hypersensitivity to the active substance or to any of the excipients.

4.4 Special warnings and precautions for use
Do not exceed the stated dose.
The use of this product in children under 12 years of age is not recommended because data are not sufficient and medical advice should be sought.

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

Caution is recommended in patients with gastritis or gastric ulcer.

If dyspnoea, fever or purulent sputum occurs, a doctor or a qualified healthcare practitioner should be consulted.
If symptoms worsen or persist for more than 7 days, a doctor or a qualified healthcare practitioner should be consulted.

This product contains 1.7 g of sucrose per 5ml spoonful. This should be taken into consideration in the daily intake, in case of low-sugar diet or in case of diabetes mellitus.
Patients with rare hereditary problems of fructose intolerance, glucose, galactose malabsorption or sucrase/isomaltase insufficiency should not take this medicine.
This product contains potassium less than 1 mmol and is essentially 'potassium-free'.

This product contains sodium methyl parahydroxybenzoate and sodium propyl parahydroxybenzoate that could induce allergic reactions (possibly delayed).

4.5 **Interaction with other medicinal products and other forms of interaction**
None reported.

4.6 **Fertility, pregnancy and lactation**
Safety during pregnancy and lactation has not been established. The use during pregnancy and lactation is not recommended.
Studies on the effects 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**
Allergic reactions (urticaria, skin rash, dyspnoea, couperoses) and gastrointestinal reactions (nausea, vomiting, diarrhoea) have been reported.

The frequency is not known.

If other adverse side effects not mentioned above occur, a doctor or a qualified healthcare practitioner should be consulted.

4.9 **Overdose**
Overdose can provoke nausea, vomiting, diarrhoea 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
Tests on carcinogenicity and reproductive toxicity have not been performed.

Ivy leaf dry extract (DER 4-6:1), extraction solvent ethanol 30% (V/V) contained in the medicinal product showed no mutagenic potential in the Ames test.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients
Sucrose
Citric acid monohydrate
Carmellose sodium
Caramel flavour*
Caramel colour
Sodium methyl parahydroxybenzoate
Sodium propyl parahydroxybenzoate
Potassium sorbate
Water purified

Caramel flavour*: mixture of flavouring substances, identical to the natural ones, and of flavouring preparations (cacao extract) on a maltodextrin support.

6.2 Incompatibilities
None reported

6.3 Shelf life
Unopened:
3 years

Opened:
3 months

6.4 Special precautions for storage
No special requirement

6.5 Nature and contents of container
Brown PET bottle of 100, 150 or 200 ml pack sizes, made of brown PET with a white high density polyethylene cape and a graduated measuring spoon. Not all pack sizes may be marketed.
6.6 **Special precautions for disposal**
No special requirements

7 **MARKETING AUTHORITY \&持证人**
LABORATOIRES ARKOPHARMA
Lid de Carros Le Broc-1st avenue, 2709 m
06510 CARROS
FRANCE
Tél.: +33 (0)4 93 29 11 28
Fax.:+33 (0)4 93 29 11 62

8 **MARKETING AUTHORITY NUMBER(S)**
THR 12297/0017

9 **DATE OF FIRST AUTHORIZATION/RENEWAL OF THE AUTHORIZATION**
20/09/2012

10 **DATE OF REVISION OF THE TEXT**
20/09/2012
ACTIVOX
Ivy Syrup

IVY LEAF EXTRACT 50 mg

Read all of this leaflet carefully because it contains important information for you.
This medicine is available without prescription. However, you still need to take ACTIVOX Ivy syrup carefully to
get the best results from it.
• Keep this leaflet. You may need to read it again.
• Ask your pharmacist, doctor or qualified healthcare practitioner if you need more information or advice.
• You must contact a doctor or qualified healthcare practitioner if your symptoms worsen or do not improve
after 7 days.
• If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your
doctor or pharmacist.

IN THIS LEAFLET:
1. What ACTIVOX Ivy syrup is and what it is used for
2. Before you take ACTIVOX Ivy syrup
3. How to take ACTIVOX Ivy syrup
4. Possible side effects
5. How to store ACTIVOX Ivy syrup
6. Further information

1. WHAT ACTIVOX IVY SYRUP IS AND WHAT IT IS USED FOR
ACTIVOX Ivy syrup is a traditional herbal medicinal product used to relieve chesty coughs associated with the
common cold based on traditional use only.

2. BEFORE YOU TAKE ACTIVOX IVY SYRUP
DO NOT TAKE ACTIVOX IVY SYRUP IF:
- You are allergic (hypersensitive) to ivy leaf or any of the other ingredients of ACTIVOX Ivy syrup (see section 6).
- You are under 12 years old.

TAKE SPECIAL CARE WITH ACTIVOX IVY SYRUP:
- Tell your doctor or a healthcare practitioner before taking ACTIVOX Ivy Syrup if you:
  • suffer from gastritis (inflammation of the lining of the stomach) or from stomach ulcer,
  • are already taking a medicine to help stop your coughing such as codeine or dextromethorphan,
  • suffer from diabetes.
- Consult your doctor or qualified healthcare practitioner if you have difficulties breathing (shortness of breath),
have fever or bloody phlegm.

TAKING OTHER MEDICINES:
Studies investigating the effects of ACTIVOX Ivy syrup on other medicines have not been performed.
Please tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines,
including medicines obtained without prescription.

PREGNANCY BREAST-FEEDING AND FERTILITY:
Do not take this medicine if you are pregnant or breastfeeding. Ask your doctor or pharmacist for advice before
taking any medicine.

DRIVING AND USING MACHINES:
No studies have been performed. However it is unlikely to affect your ability to drive or use machines.

ACTIVOX Ivy syrup contains sucrose: if you have been told by your doctor that you have an intolerance to some
sugars, please contact your doctor before taking this medicinal product.
ACTIVOX Ivy syrup contains sodium methyl parahydroxybenzoate and sodium propyl parahydroxybenzoate: they may cause allergic reactions (possibly delayed).
ACTIVOX Ivy syrup contains potassium less than 1 mmol and is essentially “potassium free”.

3. HOW TO TAKE ACTIVOX IVY SYRUP
For oral use only. Shake the bottle well each time before use. Take this medicine as follows. If you are not sure what to do, consult your doctor, pharmacist or qualified healthcare practitioner. The recommended dose is:
Adults, the elderly, children aged 12 years and over: One 5 ml spoonful 2
times per day, morning and evening.

For a 5 ml dose the measuring spoon should be filled completely.
Duration of use: ACTIVOX Ivy Syrup should not be used for more than 2 weeks.
Consult your doctor or qualified healthcare practitioner if your symptoms worsen or if symptoms do not improve
after using the product for 7 days, if shortness of breath, fever or bloody phlegm occur, if side-effects listed in section 4
become serious or if side-effects not listed in section 4 occur. Do not take more than the stated dose.
IF YOU TAKE MORE ACTIVOX IVY SYRUP THAN YOU SHOULD
If you take more than the recommended dose, you may experience nausea, vomiting, diarrhoea, or you may feel excitable. In this case, consult your doctor, pharmacist or qualified healthcare practitioner and take this leaflet with you.

IF YOU FORGET TO TAKE ACTIVOX IVY SYRUP
Do not take twice the dose but continue to take the usual dose at the usual time.

IF YOU STOP TAKING ACTIVOX IVY SYRUP
You can stop taking ACTIVOX IVY syrup at any time.
If you have any questions or are unsure about anything, please ask your doctor, pharmacist or qualified healthcare practitioner.

4. POSSIBLE SIDE EFFECTS
Like all medicines ACTIVOX IVY syrup can cause side effects, although not everybody gets them.
They are listed below:
Mild gastro-intestinal complaints such as nausea, vomiting, diarrhoea; allergic reactions such as skin rash, red itchy skin, red enlarged capillaries on the face and other parts of the body and shortness of breath may occur when using ACTIVOX IVY syrup.
If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.
You can help to make medicines safer by reporting any side effects to the Yellow Card Scheme at www.mhra.gov.uk/yellowcard. Alternatively you can get a paper Yellow Card form from your GP’s surgery or pharmacy, or call free phone 0808 100 3352 (available 10am-2pm Monday-Friday).

5. HOW TO STORE ACTIVOX IVY SYRUP
Keep out of the reach and sight of children. There are no specific storage conditions.
Do not use ACTIVOX IVY syrup after the expiry date which is stated on the carton after “Exp”. The expiry date refers to the last day of that month. After the first opening of the bottle, the product must be used within 3 months.
Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION
What ACTIVOX IVY syrup contains
- The active substance is an ivy leaf extract. Each 5 ml of syrup contains 50 mg of extract (as dry extract) from ivy leaf (Hedera helix L.).
The extraction solvent is ethanol 30% (V/V).
- The other ingredients are: Sucrose, Citric acid monohydrate, Carmellose sodium, Caramel flavour, Caramel colour, Sodium methyl parahydroxybenzoate, Sodium propyl parahydroxybenzoate, Potassium sorbate, Water purified.
Each 5 ml of syrup contains 1.7 g sucrose and 3 mg potassium.

What ACTIVOX IVY syrup looks like and contents of the pack
ACTIVOX IVY syrup is a brown liquid with a caramel odour.
Each bottle contains 100, 150 or 200 ml of syrup.
Not all pack sizes may be marketed.

Traditional Herbal Registration Holder and Manufacturer
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Traditional Herbal Registration Number: THR 12297/0017
This leaflet was last revised in August 2012.
For large print, call +44 (0) 1782 564512 or email to enquiries@wfbm.co.uk

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LABELLING

Label:

ACTIVOX
Ivy syrup
Ivy leaf extract 50 mg

TRADITIONAL HERBAL MEDICINAL PRODUCT USE TO RELIEVE CHESTY COUGHS ASSOCIATED WITH THE COMMON COLD BASED ON TRADITIONAL USE ONLY.

DOSAGE
Traditional herbal medicinal product used to relieve chesty coughs associated with the common cold based on traditional use only.

DIRECTIONS FOR USE:
For oral use only. Read label carefully before use. Adults, the elderly, children aged 12 years and over: One 5 ml spoonful 2 times per day, morning and evening. If the symptoms worsen or do not improve after 7 days, a doctor or a qualified healthcare practitioner should be consulted. Keep out of the reach and sight of children.

WARNINGS:
For oral use.
Do not use if you are pregnant or breastfeeding.
Not for use in children under 12 years.
Do not exceed the stated dose.
Do not use if you are allergic to any of the active substances or to any of the other ingredients.

No specific precautions for storage. After the first opening of the bottle, the product must be used within 3 months.

ACTIVE INGREDIENT: Each 5 ml of syrup contains 50 mg of extract (dry extract) from Ivy leaf (Hedera Helix). Each 5 ml of syrup contains 50 mg of extract (dry extract) from Ivy leaf (Hedera Helix). Also contains Sucrose, preservatives, sorbates, sodium methylparaben, and sodium propylparaben and its benzylates. See enclosed leaflet for further information.

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Expiration date: see on the side.

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Carton with Braille: