

PACKAGE LEAFLET

PACKAGE LEAFLET: INFORMATION FOR THE USER

ARKOVOX Syrup

Ivy leaf dry extract

Caramel flavour

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you. Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor or pharmacist. It includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor if you do not feel better or if you feel worse after 1 week.

What is in this leaflet

1. What ARKOVOX Syrup is and what it is used for
2. What you need to know before you take ARKOVOX Syrup
3. How to take ARKOVOX Syrup
4. Possible side effects
5. How to store ARKOVOX Syrup
6. Contents of the pack and other information

1. WHAT ARKOVOX SYRUP IS AND WHAT IT IS USED FOR

ARKOVOX Syrup is an herbal medicinal product used as an expectorant in case of productive cough.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE ARKOVOX SYRUP

Do not take ARKOVOX Syrup :

- If you are allergic to ivy leaf, to plants of the Araliaceae family or to any of the other ingredients of ARKOVOX Syrup (listed in section 6).

Do not give ARKOVOX Syrup:

- To your children below 4 years of age because of the risk of aggravation of the respiratory symptoms.

Warnings and precautions

Talk to your doctor or pharmacist before using ARKOVOX Syrup if:

- you have gastritis (inflammation of lining of the stomach) or gastric ulcer (stomach ulcer),
- you are already taking other cough medicines such as those containing codeine or dextromethorphan.

Consult your doctor or pharmacist if you develop difficulties breathing (shortness of breath), have fever or green sputum.

Other medicines and ARKOVOX Syrup

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Pregnancy, breast-feeding and fertility

Do not take ARKOVOX Syrup 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, ARKOVOX Syrup is unlikely to affect your ability to drive and use machines.

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

Important information about some of the ingredients of ARKOVOX Syrup

ARKOVOX Syrup contains sucrose: if you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

ARKOVOX Syrup contains sodium methyl parahydroxybenzoate and sodium propyl parahydroxybenzoate which may cause allergic reactions (possibly delayed).

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

3. HOW TO TAKE ARKOVOX Syrup

For oral use only.

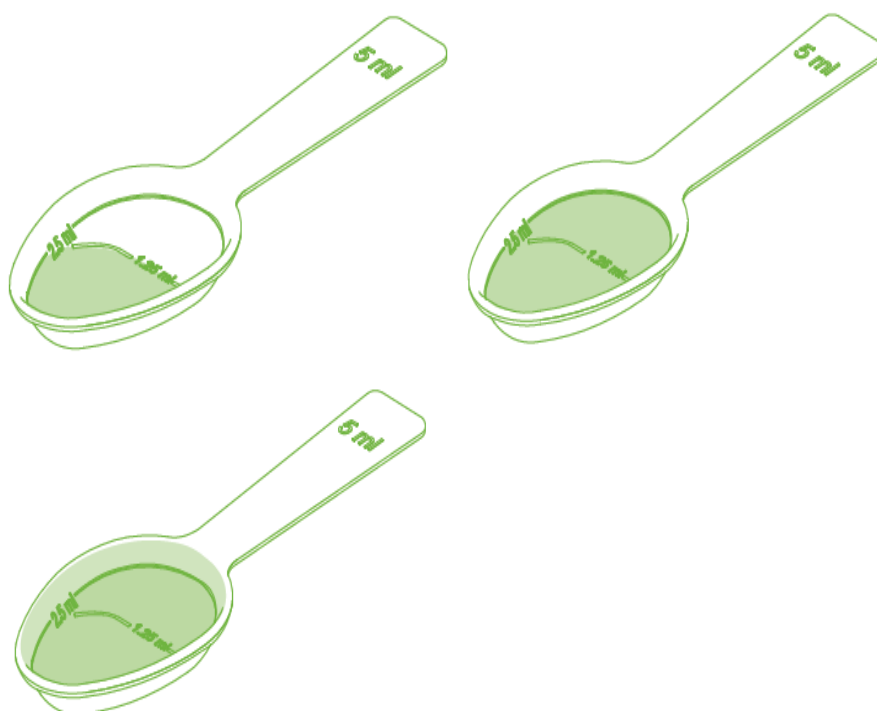
Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose is:

- For adults and adolescents: 5 ml 2 times daily, morning and evening;
- For children between 6 and 12 years old :2.5 ml 2 times daily, morning and evening;
- For children between 4 and 5 years old : 1.25 ml 2 times daily, morning and evening.

Shake the bottle before use.

Please fill the measuring spoon following the explanations hereafter :



1.25 ml : fill the spoon up to the mark 1.25 ml line in the middle of the spoon, while inclining the spoon,

2.5 ml : fill the spoon up to the mark 2.5 ml on the side of the spoon,

5 ml : fill the spoon completely (which corresponds to a 5 ml dose).

Duration of use

Consult your doctor or pharmacist, if the symptoms persist longer than 1 week during the use of ARKOVOX Syrup.

If you take more ARKOVOX Syrup than you should

If you take more than the recommended dose, you can have nausea, vomiting, diarrhoea or you may feel excitable. In this case, consult your doctor or pharmacist and take this leaflet with you.

If you forget to take ARKOVOX Syrup

Do not take a double dose to make up for a forgotten dose but continue to take the usual dose at the usual time.

If you stop taking ARKOVOX Syrup

You can stop taking ARKOVOX Syrup at any time.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, ARKOVOX Syrup can cause side effects, although not everybody gets them.

Uncommon side effects (may affect up to 1 in 100 people): allergic reactions (urticaria, skin rash, couperoses, dyspnoea). If you get any of these side effects, stop taking the medicine immediately and seek urgent medical advice.

Common side effects (may affect up to 1 in 10 people): gastrointestinal complaints such as nausea, vomiting, diarrhoea.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly 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

By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE ARKOVOX Syrup

Keep out of the reach and sight of children.

There are no specific storage conditions.

Do not use ARKOVOX Syrup after the expiry date which is stated on the carton and on the label after "Exp". The expiry date refers to the last day of that month.

Do not keep more than 3 months after opening.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to dispose of medicines you no longer use. These measures will help protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What ARKOVOX Syrup contains

The active substance is ivy leaf (*Hedera helix* L.) dry extract (DER 4-6:1), extraction solvent ethanol 30% (V/V). Each 5 ml of syrup contains 50 mg of dry extract.

The other ingredients are purified water, sucrose, citric acid monohydrate, sodium carmellose, caramel flavour*, caramel colour, sodium methyl parahydroxybenzoate, sodium propyl parahydroxybenzoate and potassium sorbate.

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

What ARKOVOX Syrup looks like and contents of the pack

Pharmaceutical form: brown syrup.

Each bottle contains 100, 150 or 200 ml of syrup.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer:

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This leaflet was last approved in {MM/YYYY}.