

Package leaflet: information for the patient

AMBROXOL CINFA 15 MG/5 ML SYRUP

AMBROXOL HYDROCHLORIDE

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

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If you get side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

What is in this leaflet:

1. What ambroxol cinfa 15 mg/5 ml syrup is and what it is used for
2. What you need to know before you take ambroxol cinfa 15 mg/5 ml syrup
3. How to take ambroxol cinfa 15 mg/5 ml syrup
4. Possible side effects
5. How to store ambroxol cinfa 15 mg/5 ml syrup
6. Contents of the pack and other information

1. What ambroxol cinfa 15 mg/5 ml syrup is and what it is used for

Ambroxol belongs to the group of medicines called mucolytic agents. It reduces the viscosity of the bronchial secretions, thereby facilitating expectoration.

Ambroxol is indicated in acute and chronic airway disorders requiring the elimination of secretions.

2. What you need to know before you take ambroxol cinfa 15 mg/5 ml syrup.

Do not take ambroxol cinfa 15 mg/5 ml syrup:

- if you are allergic to ambroxol or any of the other ingredients of this medicine (listed in section 6).
- infants under 2 years of age should not take ambroxol cinfa 15 mg/5 ml syrup.

Warnings and precautions

There have been reports of serious skin reactions associated to the use of ambroxol. In the event of skin reactions (including lesions affecting the mucosal membranes of the mouth, throat, nose eyes and genitals), stop taking Ambroxol cinfa and consult the doctor immediately.

This medicine contains sorbitol (E-420). If your doctor has indicated that you suffer intolerance to certain sugars, ask him or her before taking this medicine. A mild laxative effect may result because this medicine contains 2.25 g of sorbitol per 5 ml of syrup.

Calories: 2.6 kcal/g of sorbitol.

Talk to your doctor or pharmacist before taking ambroxol cina 15 mg/5 ml syrup.

Children

Ambroxol is contraindicated in infants under 2 years of age.

Other medicines and ambroxol cina 15 mg/5 ml syrup

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine. Treatment with ambroxol has not been found to be harmful during pregnancy. Nevertheless, the doctor will assess the benefit / risk of using this medicine.

3. How to take ambroxol cina 15 mg/5 ml syrup

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.

Remember to take your medicine.

If you think the effects of this medicine are too strong or too weak, tell your doctor or pharmacist.

Your doctor will indicate the appropriate dose and the duration of treatment.

The recommended adult dose is one 10 ml measure three times a day.

Use in children:

The recommended dose is:

Children over 5 years of age: one 5 ml measure, 2-3 times a day.

Children between 2-5 years of age: one 2.5 ml measure, 3 times a day.

If you take more ambroxol cina 15 mg/5 ml syrup than you should

If you have taken more ambroxol cina 15 mg/5 ml syrup than you should, consult your doctor or pharmacist immediately. Take this leaflet with you. No symptoms of overdose have been described to date. Treatment in such cases should be symptomatic.

In the event of overdose or accidental ingestion, contact the Toxicology Information Service, telephone: 91 562 04 20.

4. Possible side effects

Like all medicines, ambroxol cina 15 mg/5 ml syrup can cause side effects, although not everybody gets them.

There have been some reports of digestive tract alterations such as nausea, vomiting, acid sensation and gastrointestinal discomfort.

Rare (may affect up to one out of every 1000 people)

Hypersensitivity reactions

Rash, urticaria.

Not known (frequency cannot be estimated from the available data)

Anaphylactic reactions such as anaphylactic shock, angioedema (rapidly progressing swelling of the skin, subcutaneous tissues, mucosal membranes or submucosal tissues) and pruritus.

Serious skin reactions (e.g., erythema multiforme, Stevens-Johnson syndrome / toxic epidermal necrolysis and acute generalised exanthematous pustulosis).

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist, or nurse. This includes any possible side effects not listed in this leaflet. By reporting undesirable effects, you can contribute to provide further information on the safety of this medicine.

5. How to store ambroxol cinfa 15 mg/5 ml syrup

Keep this medicine out of the sight and reach of children.

Do not use this medication after the expiry date which is stated on the container. The expiry date refers to the last day of that month.

Do not store at temperatures above 25°C.

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

6. Contents of the pack and other information

Composition of ambroxol cinfa 15 mg/5 ml syrup

- The active drug substance is ambroxol hydrochloride.
- The other ingredients are raspberry aroma, citric acid monohydrate (E-422), hydroxyethylcellulose, benzoic acid, propyleneglycol, sorbitol 70% (E-420), saccharin sodium and purified water.

What ambroxol cinfa 15 mg/5 ml syrup looks like and contents of the pack

ambroxol cinfa 15 mg/5 ml syrup is supplied in 200 ml containers.

Marketing authorisation holder and manufacturer

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Detailed and updated information on this medicine is available at the website of the Spanish Medicines Agency (AEMPS) <http://www.aemps.gob.es/>