Package leaflet: Information for the patient

/…/ 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.
Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist have 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. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to your doctor if you do not feel better or if you feel worse within 5 days (within 3 days in children).

What is in this leaflet

1. What /…/ is and what it is used for

This product is used for acute and chronic respiratory diseases. These are acute and recurrent bronchitis, laryngitis and tracheitis and chronic diseases such as chronic bronchitis and chronic obstructive pulmonary disease.

Patients with acute respiratory disease can use this product without consulting a doctor. Patients suffering from chronic respiratory diseases can use this product for long-term treatment only after consulting with a doctor.

Initially acute diseases are usually accompanied by a dry irritating cough or even by burning sensation in chest due to bronchitis and by hoarseness in laryngitis. In next phase the wet mucus formation and successive expectoration occurs. Both kinds of cough can occur in chronic diseases - dry irritant cough and wet (productive) cough with mucus expectoration.

Ambroxol, the active ingredient of /…/, increases mucus secretion in airways, the formation of pulmonary surfactant (substance covering inner walls of alveoli) and stimulates cilia activity ensuring mucus transport. These effects result in more substantial liquefaction, better transport and secretion of mucus (mucociliary clearance), which leads to expectoration facilitating and cough relief.

/…/ is used to treat especially children younger than 12 years but it can also be used by adults and adolescents.

You must talk to a doctor if you do not feel better or if you feel worse within 5 days (within 3 days in children).

2. What you need to know before you take /…/

Do not take /…/:
- if you are allergic to ambroxol hydrochloride or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions
Talk to your doctor or pharmacist before taking /…/:
- if you have had a cough for a long time;
- if you have asthma or suffer from serious asthma attacks;
- if you have or have had liver or kidney problems;
- if you have peptic or duodenal ulcers.

There have been reports of severe skin reactions associated with the administration of ambroxol. If you develop a skin rash (including lesions of the mucous membranes such as mouth, throat, nose, eyes, genitals), stop using /…/ 15 mg/5 ml and contact your doctor immediately.

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

The administration of /…/ with antibiotics (amoxicillin, cefuroxim, and erythromycin) leads to increase of antibiotics concentrations in mucus formed in the airways which may be considered as desirable effect.

The concomitant use of /…/ with medicines that inhibit cough (e.g. codeine) is not recommended since these medicines supress the mucus expectoration.

There were no reports of clinically significant adverse interactions with other drugs.

Pregnancy, breast-feeding and fertility
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.

It is not recommended to use /…/ syrup during pregnancy, especially during the first 3 months.

It is not recommended to use /…/ if you are breast-feeding since ambroxol is excreted in breast milk.

Driving and using machines
The medicinal product has no or negligible influence on the ability to drive and use machines.

/…/ contains sorbitol
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine. Each ml of the product /…/ contains 0.35 g of sorbitol. The maximal recommended daily dose (30 ml) contains 10.5 g of sorbitol. Sorbitol may have a mild laxative effect. Caloric value is 2.6 kcal/g sorbitol.

/…/ is suitable for diabetics.

3. How to take /…/

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

- Adults and adolescents above 12 years: 10 ml 3 times a day
- Children 6-12 years: 5 ml 2 - 3 times a day
- Children 2-5 years: 2.5 ml 3 times a day
- Children up to 2 years: 2.5 ml 2 times a day

Use the enclosed measuring syringe for correct dosing.

/…/ may be administered to children less than 12 years of age only upon recommendation of a doctor.

/…/ syrup is for oral use only.
/…/ syrup can be taken with or without food. It is recommended to drink a glass of water after administration and plenty of liquid during the day.

Duration of treatment with /…/ is determined individually depending on the indication and type of disease. However, if an acute respiratory illness symptoms do not improve or worsen within 5 days (within 3 days in children), consult your doctor.

Do not take medicine without consulting your doctor for more than 10 days.

Long-term use of /…/ in chronic respiratory diseases is possible only after consulting your doctor.

If you take more /…/ than you should
If you take more /…/ than you should, consult your doctor or pharmacist. No specific symptoms of overdose have been reported for humans so far. Based on reports of accidental overdose and/or treatment mistakes observed signs are consistent with known side effects of /…/ in recommended doses and may require appropriate symptomatic treatment.

If you forget to take /…/
If you forget to take a dose, take it as soon as you remember unless it is nearly time for your next dose. If this happens skip the missed dose and take the remaining dose as normal. Do not take a double dose to make up for a forgotten dose.

If you stop taking /…/
/…/ should be used only when it is necessary and its use should be discontinued if you experienced relief from symptoms.

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

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Common (may affect less than 1 in 10 patients)

- Taste disturbance
- Numbness in throat
- Nausea
- Numbness in mouth and tongue

Uncommon (may affect less than 1 in 100 patients)

- Diarrhoea
- Vomiting

- Indigestion
- Dry mouth
- Abdominal pain

Rare (may affect less than 1 in 1 000 patients)
- Hypersenzitivity reactions
- Rash
- Urticaria

Not known (frequency cannot be estimated from the available data)
- Anaphylactic reactions including anaphylactic shock, angioedema (rapidly developing swelling of the skin, subcutaneous, mucosa or submucosal tissues) and pruritus
- Severe cutaneous adverse reactions (including erythema multiforme, Stevens-Johnson syndrome/toxic epidermal necrolysis and acute generalised exanthematous pustulosis).
- Itching of the skin
- Dry throat

Reporting of suspected adverse reactions
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed in Appendix V*. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store /…/

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

Do not use this medicine after the expiry date which is stated on the label and carton after EXP. The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

After first opening use within 6 months.

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

What /…/ contains
- The active substance is ambroxol hydrochloride 3 mg in 1 ml of syrup.
- The other ingredients (excipients) are Sodium benzoate (E 211), Sorbitol (E 420), Sucralose, Hydroxyethylcellulose, Citric acid monohydrate (E 330), Strawberry flavour 501 440 T (composed of propylene glycol (E 1520) and flavouring substances) and Purified water.

What /…/ looks like and contents of the pack
/…/ is colourless or pale yellow liquid with strawberry odour.

/…/ syrup is packed in amber glass bottle closed with plastic screw child proof cap, outer caps and adaptor in carton box. Each package contains plastic oral dosing syringe.

Pack size: 100 ml, 200 ml

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

[To be completed nationally]

This medicinal product is authorised in the Member States of the EEA under the following names:

[To be completed nationally]

This leaflet was last revised in .