

PACKAGE LEAFLET: INFORMATION FOR THE USER

Flavamed For children from two years, adolescents and adults

15 mg/5 ml oral solution

AMBROXOL HYDROCHLORIDE

• This leaflet is a copy of the Summary of Product Characteristics and Patient Information Leaflet for a medicine, which outlines the conditions under which the medicine should be used and information on its known safety • The product information may be updated several times within its shelf life, and there could be differences between the version of information shown here and other information in the public domain or in the package insert • This leaflet may not contain all the information about the medicine or the information may not be the most up to date version for this product • If you have any questions or are not sure about anything, ask your doctor or pharmacist • 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 only • Do not pass it on to others • It may harm them, even if their signs of illness are the same as yours • If you get any 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 Flavamed is and what it is used for
2. What you need to know before you take Flavamed
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1. WHAT FLAVAMED IS AND WHAT IT IS USED FOR

Flavamed contains the active substance ambroxol hydrochloride and belongs to the therapeutic group cough and cold preparations, mucolytics. Ambroxol hydrochloride is used to treat productive cough associated with diseases of the lungs and bronchial tubes. Flavamed is indicated in children from two years, adolescents and adults.

Mucus becomes more liquid through Flavamed and can be coughed up more easily.

You must talk to a doctor if you do not feel better or if you feel worse after 4-5 days.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE FLAVAMED

Do not take Flavamed if you are allergic to ambroxol hydrochloride) or any of the other ingredients of this medicine.

Flavamed must not be used in children under two years.

Warnings and precautions

Talk to your doctor or pharmacist before taking Flavamed

- If you have had very severe hypersensitivity reactions of the skin in the past (Stevens-Johnson syndrome, Lyell's syndrome).
- Stevens-Johnson syndrome is a disease in which there is high fever and skin and mucous membrane rash with blistering.
- The life-threatening Lyell's syndrome is also known as scalded skin syndrome. Signs of this are severe blistering of the skin, similar to a burn.
Therefore, if you notice that you have skin or mucous membrane changes, you must stop taking Flavamed immediately. Go to a doctor at once!
- If you suffer from impaired kidney function or from a severe liver disease. You must then only take Flavamed with particular caution (i.e. at greater dose intervals or at a reduced dose – ask your doctor about this). In severe kidney-function disturbance, there may be an accumulation of the breakdown products of the active substance of Flavamed.
- If you suffer from a rare disease of the bronchial tubes with increased mucus formation (e.g. immotile cilia syndrome). Here, the mucus is unable to be transported away from the lungs. In this case, only take Flavamed under the supervision of a doctor.
- If you suffer from histamine intolerance. You should then avoid long-term therapy, as the active substance of Flavamed influences the histamine metabolism and may lead to symptoms of intolerance (e.g. headache, runny nose, itching).
- If you have a history of peptic ulcer disease, you should take advice from your doctor how to take Flavamed, since mucolytics may disrupt the gastric mucosal barrier. Ask your doctor before taking Flavamed.

Children

Persistent or recurrent cough in children between 2-4 years requires medical diagnosis before treatment.

Other medicines and Flavamed

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

Cough-suppressant agents (antitussives)

While taking Flavamed, you should not use any medicines that suppress the cough reflex (so-called antitussives). The cough reflex is important in order to cough up the liquefied mucus and thus remove it from the lungs.

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.

Only take Flavamed during pregnancy and breast-feeding at the explicit direction of your doctor!

There is no adequate experience to date in humans for pregnancy and breast-feeding. However, it has been observed in animals that the active substance of Flavamed crosses into breast milk.

Animal studies did not indicate harmful effects of ambroxol with respect to fertility.

Driving and using machines

There is no evidence for an effect on the ability to drive and use machines.

Studies on the effects on the ability to drive and use machines have not been performed.

Flavamed contains sorbitol

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

Sorbitol may have a mild laxative effect.

3. HOW TO TAKE FLAVAMED

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 following details apply unless your doctor has prescribed Flavamed to you otherwise. Please keep to the instructions for use, as Flavamed is otherwise unable to work properly!

The recommended dose is:

Children from 2 - 5 years:

½ a measuring spoon each with 2.5 ml of oral solution 3 times daily (equivalent to 3 times 7.5 mg ambroxol hydrochloride = 22.5 mg ambroxol hydrochloride/day)

Children from 6 - 12 years:

1 .measuring spoon each with 5 ml of oral solution 2 - 3 times daily
(equivalent to 2 - 3 times 15 mg ambroxol hydrochloride = 30 - 45 mg ambroxol hydrochloride/day)

Adolescents from 12 years and adults:

2 .measuring spoons each with 5 ml of oral solution 3 times daily
(equivalent to 3 times 30 mg ambroxol hydrochloride = 90 mg ambroxol hydrochloride/day) during the first 2 to 3 day, then 2 measuring spoons each with 5 ml of oral solution 2 times daily
(equivalent to 2 times 30 mg ambroxol hydrochloride = 60 mg ambroxol hydrochloride/day)

Note:

With the adult dosage, the daily dose can be increased to 4 measuring spoons each with 5 ml of oral solution 2 times daily
(equivalent to 2 times 60 mg ambroxol hydrochloride = 120 mg ambroxol hydrochloride/day).

Method of use

For oral use. Take Flavamed after meals with the aid of the enclosed measuring spoon.

Duration of use

Flavamed should not be taken for longer than 4 to 5 days without the advice of a doctor.

If your complaints still do not get better after 4 to 5 days or even get worse, you should go to a doctor at once! Please speak to your doctor or pharmacist if you have the impression that the effect of Flavamed is too strong or too weak.

If you take more Flavamed than you should

No serious poisoning symptoms have been observed so far. There may be temporary unrest and diarrhoea. Increased salivation, retching, vomiting and drop in blood pressure with circulatory disturbances may occur in extreme overdose.

Contact a doctor. Immediate measures like causing vomiting and a stomach pump are normally not necessary and are only to be considered in extreme overdose. A treatment according to the occurring signs of the overdose is recommended.

If you forget to take Flavamed or have taken too little, simply take the medicine in the prescribed dosage at the next dose time.

Do not take a double dose to make up for a forgotten dose.

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.

Undesirable effects

Common (may affect up to 1 in 10 people):

- Nausea
- Changed taste
- Numbness of the mouth and throat (hypoesthesia)

Uncommon (may affect up to 1 in 100 people):

- vomiting
- Dry mouth
- Diarrhoea
- Digestive Complaints (dyspepsia)
- Abdominal pain
- Fever

Rare (may affect up to 1 in 1,000 people):

- Rash
- Hives (urticaria)

Very rare (may affect up to 1 in 10,000 people):

- Severe skin reactions like Lyell's syndrome and Stevens-Johnson syndrome (see Section 2 "Warnings and precautions")

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

- Severe allergic (anaphylactic) reactions up to shock
- Swelling of the face (angioedema)
- Itching and other hypersensitivity
- Dry throat

If you get any side effects talk to your doctor or pharmacist. This includes any side effects not listed in this leaflet.

5. HOW TO STORE FLAVAMED

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 folding box after "EXP". The expiry date refers to the last day of that month.

This medicinal product does not require any special storage conditions.

Shelf life after first opening:

You must discard the opened bottle with the remaining solution after 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 Flavamed contains

The active substance is ambroxol hydrochloride. 1 ml of oral solution contains 3 mg ambroxol hydrochloride. One measuring spoon with 5 ml of oral solution contains 15 mg ambroxol hydrochloride.

This leaflet was last revised in 04/2013