

PACKAGE LEAFLET: INFORMATION FOR THE USER

FLAVAMED

30 mg tablets

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. Before you take Flavamed
3. How to take Flavamed
4. Possible side effects
5. How to store Flavamed
6. Further information

1. WHAT FLAVAMED IS AND WHAT IT IS USED FOR

Flavamed belongs to a class of medicines to treat coughs and colds (mucolytics). It contains the active substance ambroxol.

Flavamed is used for the treatment of productive cough associated with lungs and bronchial tubes diseases accompanied by secretion of viscous mucus.

2. BEFORE YOU TAKE FLAVAMED

Do not take FLAVAMED

- If you are allergic (hypersensitive) to the active ingredient of Flavamed (ambroxol hydrochloride) or to any of other constituents of Flavamed

Take special care with FLAVAMED

There have been a very small number of cases of severe skin disorders such as Stevens-Johnson syndrome and toxic epidermal necrolysis (TEN) associated with the use of agents for dissolving the mucus (expectorant) such

as ambroxol hydrochloride. Most of their occurrence can be explained by the weight of the underlying disease and / or concomitant use of other drugs. In addition, in the initial stages of Stevens • Johnson syndrome or TEN a initially occur non-specific flu-like symptoms such as fever, joint pain, rhinitis, cough and sore throat. Due to the occurrence of these non-specific symptoms it is possible to wrongly treating symptoms with medicines for coughs and colds.

Therefore, if any lesions on skin or mucous membranes become apparent, you should stop taking Flavamed immediately. In such case, contact your doctor immediately!

Patients with impaired renal and liver function

If you have impaired kidney function, or severe liver disease you can take Flavamed solely on the recommendation of a doctor. Like all medicines that are metabolized in the liver and then excreted by the kidneys, in case of severe kidney failure can be expected accumulation of metabolites of ambroxol in the liver.

In some rare diseases of the bronchi associated with the accumulation of excessive secretions (eg. Malignant ciliary syndrome), Flavamed is used exclusively under medical supervision because of possible obstruction of secretion.

Children

Flavamed should only be used by children over 6 years.

Taking other medicines

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

Cough-suppressing medicines (antitussive agents)

No medicines that suppress the coughing reflex (so called antitussive medicines) should be used concomitantly with Flavamed. The coughing reflex is important for expectoration of liquefied mucus and its removal from the lungs.

Pregnancy and breast-feeding

Ask your doctor or pharmacist for advice before taking any medicine. In pregnancy and breast-feeding Flavamed may be used only if the doctor expressly recommends its use! There are reports that in animals the active ingredient contained in Flavamed is secreted into mother's milk.

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.

Important information about certain ingredients of Flavamed

This medicine contains lactose (milk sugar). If your doctor told you that you have intolerance to some sugars, inform your doctor before taking this medicine.

3. HOW TO TAKE FLAVAMED

Flavamed should be always used in compliance with the instructions contained in this patient information leaflet. If you are not sure, please re-check with your doctor or pharmacist. The instructions for use shall be followed; otherwise Flavamed will not be efficacious.

The usual dosage of the medicine is as follows:

Children from 6 • 12 years:

½ effervescent tablets 2 to 3 times a day (or 15 mg of ambroxol hydrochloride 2 to 3 times)

Adults and adolescents older than 12 years:

Usually during the first 2 to 3 days takes 1 tablet 3 times a day (equivalent to 3 x 30 mg ambroxol hydrochloride per day), and then 1 tablet 2 times a day (equivalent to 2 x 30 mg of ambroxol hydrochloride per day).

In adults, if needed, the dose may be increased to 2 tablets twice a day, (equivalent to 120 mg ambroxol hydrochloride per day).

Method of administration

Flavamed is administered orally.

Flavamed tablets are taken with or without meals with plenty of fluids (eg. Water, tea or juice).

Duration of administration

Flavamed should not be taken for more than 4-5 days without consulting a doctor.

If your symptoms do not improve after 3 days, or even if they worsen, immediately contact a doctor!

If you have an impression that Flavamed has too strong or too weak effect on you, then you should consult your doctor or pharmacist.

If you take more Flavamed than you should

No symptoms of severe poisoning have been reported. In case of accidental overdose or incorrect administration, there have been reported symptoms that may occur with the recommended doses (see section 4). In case of overdose, immediately consults a doctor as it may be necessary to treat the symptoms of an overdose.

If you forget to take Flavamed

If you have missed a dose or taken too little of the medicine, you should take the next prescribed dose at the scheduled time. Do not take a double dose to make up for a forgotten one.

Talk to your doctor or pharmacist if you have any additional questions.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Flavamed can cause side effects, although not all patients experience them. Assessment of side effects is based upon the following description of their incidence:

Very common: Affect more than 1 in 10 treated patients

Common: Affect less than 1 in 10, but more than 1 in 100 treated patients

Uncommon: Affect less than 1 in 100, but more than 1 in 1,000 treated patients

Rare: Affect less than 1 in 1,000 but more than 1 in 10,000 treated patients

Very rare: Affect less than 1 in 10,000 treated patients or unknown incidence (incidence could not be determined by using available data).

Side effects

Common:

- Nausea

Uncommon:

- Vomiting, diarrhea, indigestion, abdominal pain
- Fever, reaction on the mucosa

Rare:

- Skin rash, hives

Very rare:

- Constipation, excessive salivation
- Increased secretion from the nose
- Difficulty urinating.

Not known:

- Swelling of the skin and mucous membranes, itching, severe allergic (anaphylactic) reactions that can go all the way to the state of shock, other hypersensitivity reactions
- Dry throat
- Dyspnea (as a sign of hypersensitivity reactions)

If you experience one or more of the adverse reactions listed above, you should immediately discontinue taking Flavamed.

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.

5. HOW TO STORE FLAVAMED

Keep out of the reach and sight of children.

Do not store above 25 °C.

Do not use Flavamed after the expiration date shown on the packaging after the symbol “EXP”. The expiration date refers to the last day of the month indicated.

Shelf life is 2 years from the date of manufacture.

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 FLAVAMED contains

The active substance is ambroxol hydrochloride.

Each tablet contains 30 mg of ambroxol hydrochloride.

The other ingredients are lactose monohydrate, maize starch, powdered cellulose, croscarmellose sodium, povidone K 30, magnesium stearate.

What FLAVAMED looks like and contents of the pack

Round, white tablets, with a break-line on one side.

Tablets can be split into two equal parts.

Flavamed comes in packages of 20 tablets.

Regime of dispensing

The medicine is issued without a doctor's prescription.

Manufacturer

Berlin-Chemie AG

Glienicker Weg 125

12489 Berlin, Germany

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