

PACKAGE LEAFLET: INFORMATION FOR THE USER

Flavamed Forte

30 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 Forte is and what it is used for
2. Before you take Flavamed Forte
3. How to take Flavamed Forte
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1. WHAT FLAVAMED FORTE IS AND WHAT IT IS USED FOR

Flavamed Forte is used to treat productive cough associated with diseases of the lungs and bronchial tubes. Mucus becomes more liquid through Flavamed Forte and can be coughed up more easily.

2. BEFORE YOU TAKE FLAVAMED FORTE

Do not take Flavamed Forte

if you are allergic (hypersensitive) to the active substance of Flavamed Forte (ambroxol hydrochloride) or any of the other ingredients of Flavamed Forte (see Section 6 "What Flavamed Forte contains").

Take special care with Flavamed Forte:

- If you have got very severe hypersensitivity reactions of the skin (Stevens-Johnson syndrome, Lyell's syndrome) in the past.
- Stevens-Johnson syndrome is a disease in which there is high fever and skin and mucousmembrane rash with blistering.

- The life-threatening Lyell's syndrome is also known as scalded skin syndrome. A sign of this is 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 Forte 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 Forte 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 Forte;

- if you suffer from a rare disease of the bronchial tubes with increased mucus formation (e.g. primary ciliary dyskinesia). Here, the mucus is unable to be transported away from the lungs. In this case, only take Flavamed Forte under the supervision of a doctor;

- If you have a history of peptic ulcer disease, you should take advice from your doctor how to take Flavamed Forte, since mucolytics may disrupt the gastric mucosal barrier. Ask your doctor before taking Flavamed Forte.

- If you suffer from histamine intolerance, you should then avoid long-term therapy, as the active substance of Flavamed Forte influences the histamine metabolism and may lead to symptoms of intolerance (e.g. headache, runny nose, itching).

Children

The safety and efficacy of Flavamed Forte in children under 12 years have not yet been established.

Taking other medicines

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

Cough-suppressant agents (antitussives)

While taking Flavamed Forte, 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 and breast-feeding

Ask your doctor or pharmacist for advice before taking any medicine.

Only take Flavamed Forte 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 Forte crosses into breast milk.

Driving and using machines

Flavamed Forte has no, or negligible, influence on driving and the ability to use machines.

Important information about some of the ingredients of Flavamed Forte

This medicinal product 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.

Each measuring spoon with 5 ml of oral solution contains sorbitol 1.75 g (= 0.15 bread unit). Sorbitol may have a mild laxative effect.

3. HOW TO TAKE FLAVAMED FORTE

Always take Flavamed Forte exactly according to the instructions in this package leaflet. You should check with your doctor or pharmacist if you are not sure.

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

Unless otherwise prescribed by the doctor, the usual dose is:

Age	Single dose	Max. daily dose
Adolescents above 12 years and adults	1 measuring spoon each with 5 ml of oral solution 3 times daily (equivalent to 3 times 30 mg	3 measuring spoons (equivalent 90 mg ambroxol hydrochloride)
	ambroxol hydrochloride) during the first 2 to 3 days, then 1 measuring spoon each with 5 ml of oral solution 2 times daily (equivalent to 2 times 30 mg ambroxol hydrochloride).	

Note:

Daily dose may be increased to 2 measuring spoons each with 5 ml of oral solution 2 times daily.

The safety and efficacy of Flavamed Forte in children under 12 years have not yet been established.

Method of use

Take Flavamed Forte after meals with the aid of the enclosed measuring spoon.

Duration of treatment

Flavamed Forte 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 Forte is too strong or too weak.

If you take more Flavamed Forte 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 Forte 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 product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Flavamed Forte can cause side effects, although not everybody gets them. The following frequencies are taken as a basis when evaluating side effects:

Very common:	affects more than 1 users in 10
Common:	affects 1 to 10 users in 100
Uncommon:	affects 1 to 10 users in 1,000
Rare:	affects 1 to 10 users in 10,000
Very rare:	affects less than 1 user in 10,000, not known (frequency cannot be estimated from the available data)

Undesirable effects

Gastrointestinal disorders

Uncommon: Nausea, stomachache, vomiting

Skin and subcutaneous tissue disorders:

Very rare: Severe skin reactions like Lyell's syndrome and Stevens-Johnson syndrome (see Section 2 "Take special care with Flavamed Forte")

General disorders and administration site conditions:

Uncommon: Hypersensitivity reactions as skin rash, swelling of the face (oedema), breathlessness, itching, fever

Very rare: Severe allergic (anaphylactic) reactions up to shock

Counter-measures

If you notice that you have one or more of the side effects set out above, discontinue treatment with Flavamed Forte at once.

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 FORTE

Keep out of the reach and sight of children.

Do not use Flavamed Forte 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.

Note on stability after first opening

Discard the opened bottle with any remaining solution after 6 months.

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 Forte contains

The active substance is ambroxol hydrochloride. 1 ml of oral solution contains 6 mg ambroxol hydrochloride. Each measuring spoon with 5 ml of oral solution contains 30 mg ambroxol hydrochloride.

The other ingredients are:

Sorbitol (E 420), liquid 70 per cent (non-crystallising), benzoic acid (E 210), glycerol (85 per cent), hydroxyethylcellulose, raspberry flavouring concentrate No. 516028 (Miltitz Duft und Aroma GmbH), purified water.

What Flavamed Forte looks like and contents of the pack

Clear, colourless to slightly yellow liquid with a fruity odour of raspberry.

Flavamed Forte comes in packages with 1x 100 ml of oral solution.

A measuring spoon is enclosed in the package.

Marketing Authorisation Holder and Manufacturer

Berlin-Chemie AG
Glienicke Weg 125
D-12489 Berlin

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

Bulgaria	Flavamed max
Czech Republic	Flavamed forte
Denmark	Flavamed 6 mg/ml
Estonia	Flavamed 30 mg/5 ml
Finland	Flavamed 6 mg/ml
Germany	Flavamed Hustenlöser 30 mg/5ml Lösung zum Einnehmen
Latvia	Tusmed 30 mg/5 ml šķīdums iekšķīgai lietošanai
Lithuania	Tussisol 30 mg/5 ml geriamasis tirpalas
Poland	Flavamed max
Slovenia	Flavamed 6 mg/ml peroralna raztopina

This leaflet was last approved in September 2013.