

## Information leaflet: User information

### **Ambroxol Fluidox 30 mg tablets** **Ambroxol Fluidox 6 mg/ml syrup**

Ambroxol hydrochloride

Please read this leaflet carefully before you start taking this medicine as it contains important information for you.

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you.

- Keep this leaflet. You may need to read it again.
- If you need clarification or advice, consult your pharmacist.
- 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.
- If you don't feel better or if you get worse, you need to see a doctor.

What does this leaflet contain:

1. What is Ambroxol Fluidox and what is it used for
2. What you need to know before taking Ambroxol Fluidox
3. How to take Ambroxol Fluidox
4. Possible side effects
5. How to store Ambroxol Fluidox
6. Package contents and other information

### **1. What is Ambroxol Fluidox and what is it used for**

Ambroxol belongs to the group of expectorant medicines. It is a drug that reduces viscosity and facilitates the elimination of mucus from the pulmonary alveoli.

Ambroxol Fluidox facilitates expectoration and coughing.

This medication is used to treat acute and chronic bronchopulmonary diseases associated with abnormal secretion and poor transport of mucus.

### **2. What you need to know before taking Ambroxol Fluidox**

Do not take Ambroxol Fluidox

If you are allergic to ambroxol or any of the other ingredients of this medicine (listed in section 6).

Warnings and Precautions

Talk to your doctor or pharmacist before taking Ambroxol Fluidox.

If you are a patient incapable of effective sputum, as the administration of this medicine can lead to accumulation of bronchial secretions.

There have been reports of serious skin reactions associated with the administration of ambroxol. If you develop a skin rash (including lesions on the mucous membranes such as the mouth, throat, nose, eyes, genitals), stop using Ambroxol Fluidox and contact your doctor immediately.

#### Other Medicines and Ambroxol Fluidox

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

Ambroxol Fluidox increases tissue concentration of the following antibiotics: Amoxicillin, Cefuroxime, Erythromycin, Doxycycline. Always talk to your doctor before taking antibiotics with Ambroxol Fluidox.

#### Ambroxol Fluidox with food, drink and alcohol

Ambroxol Fluidox tablets should be taken with liquid.

#### Pregnancy, breastfeeding and fertility

If you are pregnant or breast-feeding, if you think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

During the 1st trimester of pregnancy only prescription drugs should be taken. Studies carried out, as well as an extensive clinical experience after the 28th week, have not shown evidence of side effects during pregnancy.

Ambroxol Fluidox should be used with caution during breastfeeding, as ambroxol is excreted into breast milk.

#### Driving and using machines

There is no description of any effect of this medicine on driving and using machines.

Ambroxol Fluidox 6 mg/ml syrup contains 520 mg/ml Propylene Glycol (E1520). It can cause symptoms similar to those caused by alcohol.

Ambroxol Fluidox 6 mg/ml syrup contains 70% Sorbitol solution. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

### 3. How to take Ambroxol Fluidox

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.

Ambroxol Fluidox is administered orally.

The recommended dose is:

Tablets	Syrup
1 tablet 3 times a day. The therapeutic effect can be increased with the administration of 2 tablets twice a day. You should swallow the tablet with liquid after meals.	5 ml of syrup equals 1 full teaspoon. Ambroxol Fluidox syrup should be taken in the morning, midday, or in the evening after a meal.

The slot is only there to help break the tablet if you have difficulty swallowing it whole.

Use in children and adolescents

Adolescents and children over 12 years old.

10 ml (2 teaspoons) given 2 times a day. For the treatment of acute disorders of the respiratory tract and for the initial treatment of chronic conditions for up to 14 days.

Children under 12 years old

Administration depends on the severity of the disease.

The recommended dose is:

Age	Dose
1 to 2 years	2.5 ml (1/2 teaspoon), 2 times a day
2 to 6 years	2.5 ml (1/2 teaspoon), 3 times a day
6 to 12 years	5 ml (1 teaspoon), 2 to 3 times a day

If you take more Ambroxol Fluidox than you should

If taken in excess, all medications have health risks.

If you take too much Ambroxol Fluidox at one time, see your doctor or go to a hospital. Take the medicine pack with you so that people can see what you have taken.

If you forget to take Ambroxol Fluidox

Do not take a double dose to make up for a forgotten dose. Skip that dose and continue taking the medicine as usual.

If you have any further questions about using this medicine, ask your doctor or pharmacist.

If you stop taking Ambroxol Fluidox

If you have any further questions about using 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.

Side effects that may occur during treatment with Ambroxol Fluidox are:

Mild gastrointestinal effects, heartburn, dyspnoea (difficulty breathing) and occasionally nausea (feeling sick) and vomiting. These effects were mainly observed after injectable administration. Very rarely, allergic reactions, especially skin rash (spots or papules on the skin) have been described.

Extremely rare cases of severe and acute allergic-type reactions have been described but their relationship to ambroxol is uncertain. Some of these patients have also shown allergic reactions to other substances.

Rare: May affect up to 1 in 1,000 people:  
hypersensitivity reactions  
Skin rash, hives

Unknown: frequency cannot be calculated from available data  
Anaphylactic reactions including anaphylactic shock, angioedema (swelling that develops rapidly in the skin, subcutaneous tissues, mucosa or submucosa) and pruritus.

Serious cutaneous adverse reactions (including erythema multiforme, Stevens-Johnson syndrome/toxic epidermal necrolysis, and acute generalized 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. You may also report side effects directly to INFARMED, I.P. through the contacts below. By reporting side effects, you can help provide more information on the safety of this medicine.

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Lisbon Health Park, Av. Brasil 53  
1749-004 Lisbon  
Tel: +351 21 798 73 73  
Medicine Line: 800222444 (free)  
Fax: + 351 21 798 73 97  
Website: <http://extranet.infarmed.pt/page.seram.frontoffice.seramhomepage>  
E-mail: [pharmacovigilancia@infarmed.pt](mailto:pharmacovigilancia@infarmed.pt)

#### 5. How to store Ambroxol Fluidox

Store at a temperature below 25°C.

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 carton after "EXP". The expiry date corresponds to the last day of the indicated month.

Do not use this medicine if you notice visible signs of deterioration.

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

## 6. Package contents and other information

What is the composition of Ambroxol Fluidox

Ambroxol Fluidox 30 mg tablets

The active substance is ambroxol. Each tablet contains 30 mg of ambroxol. Each ml of syrup contains 6 mg of ambroxol.

The other components are:

mannitol (E421), potato starch, methylcellulose, magnesium stearate, cutin HR and croscarmellose sodium.

Ambroxol Fluidox 6 mg/ml syrup

The active substance is ambroxol. Each ml of syrup contains 6 mg of ambroxol.

The other ingredients are: citric acid monohydrate, sodium saccharin (E954), apricot essence, sweet orange essential oil, propylene glycol (E1520), 70% sorbitol solution.

What Ambroxol Fluidox looks like and contents of the pack

White, round, flat-faced tablets, scored on one side – pack of 20 tablets in PVC/Alu blisters.

Syrup, clear or slightly opalescent, slightly yellowish in color – 200 ml amber glass bottle

## Marketing Authorization Holder and Manufacturer

Marketing Authorization Holder

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Manufacturer

Ambroxol Fluidox 30 mg tablets

Farmalabor - Produtos Farmacêuticos, SA. (Fab.)

Zona Industrial de Condeixa-a-Nova

Condeixa-a-Nova

Portugal

Ambroxol Fluidox 6 mg/ml Syrup

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APPROVED IN  
01-03-2016  
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This booklet was last revised in March 2016

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