

BEFORE USE
CAREFULLY READ ALL DATA
CONTAINED IN THE INFORMATION LEAFLET

This is a medicinal product for SELF-MEDICATION that can be used to treat mild and temporary disorders, easily detected and solved without consulting a doctor.

It can be purchased without prescription but should be properly used to ensure proper action and minimise undesirable effects.

- ask your pharmacist if you need more information or advice
- consult your doctor if after a short period of treatment the condition is not solved.

NAME OF MEDICINAL PRODUCT

FLUTOXIL 4 mg/5 ml – syrup

bromhexine

PRODUCT DESCRIPTION

FLUTOXIL syrup is a mucolytic agent- it dissolves and makes it easier to eliminate thick mucus that deposits within the respiratory tract.

WHAT THIS MEDICINAL PRODUCT IS FOR

FLUTOXIL syrup is used to treat secretion conditions (cough, catarrh) in acute and chronic respiratory diseases.

WHEN IT SHOULD NOT BE USED

Hypersensitivity to the active ingredient or to any of the excipients in this formulation.

It is contraindicated for children under 2 years old.

Lactation (see the “Pregnancy and Lactation” section).

Patients with hereditary conditions that may be compatible with one of the excipients (see the Important “Things You Need” to Know section)

PRECAUTIONS FOR USE

Treatment with FLUTOXIL syrup increases bronchial secretions (that facilitates expectoration).

Do not use in long-term treatments. Consult your doctor if after a short period of treatment there is no significant improvement in the condition.

Serious skin reactions associated with the administration of bromexine have been reported. If you experience a skin rash (including mucous membrane lesions such as mouth, throat, nose, eyes, genitals) stop taking Flutoxil and contact your doctor immediately. Such reactions may be symptoms of severe skin diseases such as Steven Johnson syndrome and Lyell’s Syndrome. Most of

these could be explained by the severity of underlying diseases or other medications taken at the same time.

INTERACTION WITH OTHER MEDICINAL PRODUCTS OR FOOD

There is no evidence of interactions with other medical products.

Consult your doctor or pharmacist for advice if you are taking any other drugs.

IMPORTANT THINGS YOU NEED TO KNOW

Mucolytics may cause bronchial obstruction in children under 2 years old.

Particularly at this age, the ability to eliminate bronchial mucus is limited due to the physiological characteristics of the respiratory tract.

Therefore mucolytics should not be administered to children under 2 years old.

When this medicinal product can be used only after consulting a doctor

There are no absolute contraindications, but in patients with gastroduodenal ulcer it is advisable to use it after consulting the doctor. Pregnancy (see “Pregnancy and Lactation” section).

It is advisable to consult the doctor even in cases where these disorders have occurred in the past.

Pregnancy and Lactation

FLUTOXIL should be administered only after you consult a doctor and together carry out a risk/benefit assessment for your specific case.

Treatment with FLUTOXIL is not recommended in breast-feeding women.

Consult a doctor if you suspect you could be pregnant or if you are planning to become pregnant.

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

Effects on ability to drive and use machines

Bromhexine hydrochloride does not influence the ability to drive or alertness when operating machinery.

Relevant information on some FLUTOXIL excipients

This medicinal product contains **sorbitol**. If your doctor has diagnosed intolerance to some sugars, you should consult him before taking this product. Sorbitol may have a mild laxative effect. Sorbitol calorific value: 2.6 kcal/g

This medicinal product contains 3.7 vol % **ethanol**. One dose may contain up to 0.3 g ethanol per dose, equivalent to 7.4 ml of beer or 3 ml of wine per dose. This alcohol content may be harmful for alcoholics. If you are pregnant or breast-feeding, infant or child, or in a high-risk group - patients with liver disease or epilepsy-, you should consider the alcohol content before taking this product.

Athletes/ sportsmen should be aware that taking medicinal products containing ethyl alcohol may lead to a positive anti-doping test going over the alcohol concentration limits set by some sport federations.

HOW TO TAKE THIS PRODUCT

How much

The following dosages are recommended unless otherwise prescribed:

Adults: 1-2 teaspoonfuls (5-10 ml) 3 times a day.

For adults, at the beginning of treatment, it may be necessary to increase the overall daily dose up to 48 mg (60 ml) divided into three doses.

Children over 2 years age: 1/2 – 1 teaspoonful (2.5 - 5 ml) 3 times a day (= 12 mg per day).

This syrup can be administered to diabetic patients and children as it does not contain fructose or sucrose.

Do not take more than the recommended dose.

When and how long

Take this medicinal product after a meal. Consult your doctor if this disorder is recurrent or if you have noticed symptoms have changed.

Caution: For short treatment only.

Method of administration

Oral administration.

IF YOU TAKE MORE OF THIS PRODUCT THAN YOU SHOULD

No cases of overdosing have been reported. In the event of overdose general symptomatic measures are required.

In case you accidentally swallow an overdose of FLUTOXIL, seek immediate medical advice- call and inform your doctor or go to the nearest hospital.

If you are in any doubt on how to use FLUTOXIL, you should consult your doctor or pharmacist.

UNDESIRABLE EFFECTS

FLUTOXIL can have side effects, like all medicines, although these do not affect everyone.

The following side effects may occur following the use of Flutoxil:

Rare (may affect less than 1 in 1 000 patients)

- Hypersensitivity 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);
- bronchospasm

In such cases stop the treatment.

Diarrhea, nausea, vomiting and mild gastrointestinal disturbance cases have been reported.

Bronchial obstruction with frequency unknown.

These undesirable effects are often temporary. Consult your doctor or pharmacist if they occur. However, it is advisable to consult your doctor or pharmacist when you are present.

Follow the instructions contained in this information leaflet to minimise the risk of undesirable effects.

Reporting of suspected adverse effects

If any undesirable effect is evident, including those not listed in this leaflet, please ask your doctor or pharmacist. Healthcare professionals are required to report any suspected adverse effects directly via the Italian national reporting system to: www.agenziafarmaco.gov.it/it/responsabili. Reporting suspected adverse effects is important and it allows continued monitoring of the benefit/risk balance of this medicinal product.

EXPIRATION DATE AND STORAGE

See the expiration date specified on the package.

The expiration date specified applies if the product is properly stored and its package is not damaged.

Caution: Do not use this medicinal product after the expiration date specified on the package. The product must be consumed within 9 months after the bottle is opened, provided that it is stored at a temperature below 25°C. Once the nine months have elapsed, dispose of any product left. Important: keep the medicinal product information- box or information leaflet- at hand. Keep this medical product out of the reach and sight of children.

COMPOSITION

Each 5ml of syrup contains:

Active ingredient: 4 mg **bromhexine hydrochloride** (equivalent to 3.65 mg bromhexine)
(1 teaspoonful, equivalent to 5 ml, contains: 4 mg bromhexine hydrochloride)

Excipients: Tartaric acid, benzoic acid, carmellose sodium, glycerol, liquid **sorbitol, ethanol** (96%), tutti-frutti flavour, sodium hydroxide, deperated water.

PRODUCT PRESENTATION

FLUTOXIL is a syrup in a 250 ml bottle.

MARKETING AUTHORISATION HOLDER

Aesculapius Farmaceutici S.r.l. – Via Cefalonia, 70 – 25124 Brescia

PRODUCER AND FINAL CONTROLLER

ABC FARMACEUTICI S.P.A. – Canton Moretti, 29 – 10090 San Bernardo d'Ivrea (TO)

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