

PACKAGE LEAFLET: INFORMATION FOR THE USER

TOSSEQUE® 0.8 mg/ml syrup

Bromhexine hydrochloride

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

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

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor if you do not feel better or if you feel worse after 7 days.

What is in this leaflet:

1. What TOSSEQUE is and what it is used for
2. What you need to know before you take TOSSEQUE
3. How to take TOSSEQUE
4. Possible side effects
5. How to store TOSSEQUE
6. Contents of the pack and other information

1. WHAT TOSSEQUE IS AND WHAT IT IS USED FOR

Tosseque is a medical product intended to oral use, with bromhexine as active substance, which fluidises bronchial secretions, facilitating expectoration.

Tosseque is indicated as a mucolytic adjuvant (reduces mucus viscosity facilitating its elimination) in antibacterial treatment of respiratory infections in the presence of bronchial hypersecretion.

You must talk to a doctor if you do not feel better or if you feel worse after 7 days.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE TOSSEQUE

Do not take Tosseque:

- if you have allergy (hypersensitivity) to bromhexine hydrochloride or any of the other ingredients of this medicinal product (listed in section 6).
- if you have peptic ulcer.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking Tosseque.

If you are taking other medicines, check with your doctor, pharmacist or nurse before taking Tosseque. Do not take Tosseque concomitantly with antitussives or secretion-drying medications, since these have an opposite effect to that which is intended. Talk to your doctor if symptoms persist.

Since bromhexine can change the mucosal barrier of the stomach, Tosseque should be taken with caution if you have an ulcer in the stomach or duodenum or a history of ulcers in the stomach or duodenum. It should also be taken with caution if you have bronchial asthma.

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

The elimination of bromhexine is decreased in case of severe liver or kidney disease. If you have any of these diseases, talk to your doctor before taking Tosseque.

Other medicines and Tosseque

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

There is no knowledge about interactions between bromhexine and other medicines. You should not take the medicinal product concomitantly with antitussives or secretion-drying medications.

However, as previously mentioned in “Precautions”, you should tell to your doctor or pharmacist what medicines you are taking.

Pregnancy, breastfeeding and fertility

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

Bromhexine crosses the placental barrier in small amounts. For this reason, although no adverse effects are described in pregnant women, you should take Tosseque with caution if you are pregnant, particularly in the first three months of pregnancy.

Since the excretion rate of bromhexine in breast milk is not adequately quantified, you should avoid taking Tosseque if you are breast-feeding.

Driving and using machines

There is no reference to the effects of Tosseque on the ability to drive and use machines.

This medicinal product contains 12% (v/v) of ethanol (alcohol), i.e., until 500 mg per dose (5ml \approx 1 full measuring spoon), equivalent to about 12 ml of beer or approximately 5 ml of wine per dose.

Harmful for those suffering from alcoholism.

To be taken into account in pregnant or breastfeeding women, children and high-risk groups such as patients with liver disease, or epilepsy.

This medicine contains liquid sorbitol (non-crystallising) (E420). If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product. May have a mild laxative effect.

This medicine contains red colouring agent (E122). May cause allergic reactions.

3. HOW TO TAKE TOSSEQUE

Always take this medicine exactly as described in this leaflet or as your doctor, pharmacist or nurse has told you. Check with your doctor, pharmacist or nurse if you are not sure.

TOSSEQUE is intended for oral use.

The recommended dose is as follows:

- Adult and children aged 12 years and older: 10 ml, 3 times a day
- Children aged 6 to 12 years: 5 ml, 3 times a day
- Children aged 2 to 6 years: 2.5 ml, 3 times a day
- Children younger than 2 years: 1.25 ml, 3 times a day

Instructions for use: To open the bottle press the cap and turn it counter-clockwise.

To facilitate the administration of the syrup the package contains a measuring spoon with markings compatible with the dosage indicated above.

1 full measuring spoon = 5 ml

To complete the 10ml dose, 2 full measuring spoon must be taken.

Use in children

TOSSEQUE should only be administered to children younger than 2 years under medical supervision.

If you take more TOSSEQUE than you should

In case of overdose, TOSSEQUE may undesirably increase the volume of secretions.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them.

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

Hypersensitivity reactions

Rash, urticaria

Nausea, vomiting, diarrhoea or epigastric pain.

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

Changes the values of AST and ALT (transient increase in aminotransferases)

Changes the values of GOT and GPT (transient increase in transaminases)

Headache, dizziness.

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).

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 can also report side effects directly via INFARMED, I.P. by the contact information presented below. By reporting side effects you can help provide more information on the safety of this medicine.

INFARMED, I.P.

Direção de Gestão do Risco de Medicamentos

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1749-004 Lisboa

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Product Line: 800222444 (free)

Fax: + 351 21 798 73 97

Internet site: <http://www.infarmed.pt/web/infarmed/submissaoram>

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5. HOW TO STORE TOSSEQUE

Do not store above 30°C.

Keep the bottle in the outer carton in order to protect from light.

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 outer carton, after EXP. The expiry date refers to the last day of that month.

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 TOSSEQUE contains

- The active substance is bromhexine hydrochloride. Each ml of syrup contains 0.8 mg of bromhexine hydrochloride.
- The other ingredients are: glycerol, liquid sorbitol (non-crystallising) (E420), monohydrate citric acid, dihydrate saccharin sodium (E954), povidone, red colouring agent (E122), 96% ethanol, benzoic acid (E210), gooseberry flavour, raspberry flavour, peppermint flavour and purified water.

TOSSEQUE is available in bottles containing 60 ml, 100 ml or 200 ml of clear and transparent syrup, which has a pink colour and characteristic flavour and smell, with child-proof cap.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Medinfar Consumer Health - Produtos Farmacêuticos, LDA.
Rua Henrique Paiva Couceiro, N.º 27, Venda Nova
2700-451 Amadora
Portugal (EU)

Manufacturer

Farmalabor - Produtos Farmacêuticos, S.A.
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