PACKAGE LEAFLET: Information for the patient

BROMHEKSINE

Tablets – 8 mg

(Bromhexine hydrochloride)

Read this leaflet carefully before you start taking this medicine.

- 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. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- 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.

In this leaflet:

1. WHAT BROMHEKSINE IS AND WHAT IT IS USED FOR

Bromheksine contains the active substance bromhexine hydrochloride, which is a mucolytic medicine used in the treatment of respiratory disorders, when they are associated with viscous or excessive mucus. It helps to expectorate tracheobronchial secretions and to decrease the viscosity of these secretions, which leads in improved breathing.

Bromheksine is used for:

- fluidizing the secretions of the respiratory tract in cases of acute or chronic bronchopulmonary diseases like: bronchitis, emphysema, tracheobronchitis and chronic asthmatic bronchitis;

- preventing respiratory complications after surgical chest interventions;
- accelerating the expectoration of foreign endobronchial substances (contrast means used in radiology).

Your doctor may have prescribed Bromheksine for another intention. Ask your doctor if you want to know why Bromheksine has been prescribed to you.

2. BEFORE YOU TAKE BROMHEKSINE

Do not take Bromheksine if:

- you are hypersensitive to bromhexine hydrochloride or to any of the other excipients of the medicinal product;
- you have a severe impairment of liver function;
- you are breastfeeding.

Take special care with Bromheksine

Ask your doctor or pharmacist before taking Bromheksine!
Bromhexine should be used with special care in active tuberculosis.
Care should be done if bromhexine is used in asthmatic patients.
It is not advisable to use this medicine during pregnancy, especially in the first trimester.
Severe skin reactions have been reported from the use of bromhexine.
If you develop skin rash (including lesions of the mucous membranes such as: mouth, throat, nose, eyes, genitals), stop using Bromheksine and inform your doctor immediately.
In some cases, the use of bromhexine may cause an increase in the volume of fluidized bronchial secretions that cannot be drawn with cough, so it is preferable to intubate the patient in order to mantain the respiratory airways free.
Clearance of bromhexine or its metabolites may be reduced in patients with severe hepatic or renal impairment.
Since bromhexine impairs the gastric mucosa, it should be used with caution in patients with a history of peptic ulcer or suffer from active gastroduodenal ulcer.

Taking other medicines

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

Bromheksine should not be used together with medicines against cough (especially with codeine) or with medicines that act in a way similar to atropine.

Concomitant use of Bromheksine with certain antibiotics (such as ampicillin, amoxicillin, erythromycin or oxytetracyclin) increases the antibiotic concentration in bronchial secretions.

Taking Bromheksine with food and drinks

There are no data for interaction. It can be taken before or after meals.

Pregnancy

Ask for the advice of your doctor or pharmacist before taking this medicine.

Bromhexine crosses placenta in small amounts.

It is advisable to avoid using it during the first trimester of pregnancy. In the other trimesters it is also not recommended, and it should be used only according to medical prescription.

Before taking this medicine inform your doctor if you are pregnant or are planning any pregnancy.

Breastfeeding

Bromhexine is excreted into breast milk.

There are no informations regarding medical safety, therefore the use should be avoided.

If it is necessary for the medicine to be taken by the mother during breastfeeding, the latter should be interrupted.

Driving and using machines

No data available.

Important information about some of the excipients of Bromheksine

Bromheksine tablets contain lactose. If you have been told by your doctor that you have an intolerance to some sugars, talk to your doctor before taking this medicine.

3. HOW TO TAKE BROMHEKSINE

Always take Bromheksine according to the advice of your doctor or pharmacist. You should check with your doctor or pharmacist if you are not sure. If you feel that the effects of Bromheksine are too strong or too weak, talk to your doctor or pharmacist.

Bromhexine hydrochloride is generally taken in doses 4 – 16 mg three times daily.

Children over 12 years old and adults: 8 - 16 mg, 3 times daily.
Children aged 6 – 12 years old: 4 mg, 3 times daily.

If you have taken more Bromheksine

If you have taken more Bromheksine than you should, or if the children have taken this medicine incorrectly, please contact your doctor or call the hospital or emergency to get an opinion for the risk and an advice for the actions to be taken.

If you forget to take Bromheksine

If you forget a dose (or more doses), take the next dose when it is time to take it usually.
Do not take a double dose (or higher) to make up for a forgotten dose (doses).
If you have further questions on the use of this medicine, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all other medicines, bromhexine may cause side effects, although not everybody gets them. Sometimes they are serious, most of the time not. Do not get alarmed from this list of possible side effects. You may not experience any of them.
In general bromhexine is well tolerated.
Mild gastrointestinal disorders may appear in sensitive patients. In some cases an increase in serum aminotransferase values has been observed. Other side effects such as: headache, dizziness, sweating and skin rash have also been reported.

<u>Uncommon (may effect up to 1 in 100 people):</u>
Nausea, vomiting, diarrhea and upper abdominal pain.

Rare (may appear 1 in 1,000 patients):

Hypersensitivity reactions, rash, urticaria.

Unknown (frequency cannot be estimated from the available data):

- Anaphylactic reactions including anaphylactic shock, angioedema (rapid swelling of the skin, subcutaneous, mucosal or submucosal tissues) and pruritus.
- Severe skin reactions (including erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis and acute generalized exanthematous pustulosis).
- Narrowing of the bronchi, which cause difficulty in breathing (bronchospasm).

If you experience allergic or skin reactions, stop the treatment immediately and contact your doctor.

If any of the side effects gets worse, or if you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

5. HOW TO STORE BROMHEKSINE

Keep out of the reach and sight of children.

Do not use Bromheksine after the expiry date which is stated on the package.

Store below 25°C!

6. OTHER INFORMATION

What Bromheksine tablets contain

The active substance is Bromhexine hydrochloride.

Each tablet contains 8 mg of bromhexine hydrochloride

The excipients are: lactose, microcrystalline cellulose, magnesium stearate.

Content of the pack

Carton box with 20 tablets.

Marketing Authorisation Holder (MAH) and Manufacturer:

PROFARMA sh.a.,

St. "Skënder Vila",

Tirana, Albania.

Tel.: +355 4 23 89 602

This leaflet was last revised in August 2023.