

PACKAGE LEAFLET: Information for the patient

BRONAX

Syrup – 4 mg / 5 ml

(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 Bronax is and what it is used for
2. Before you take Bronax
3. How to take Bronax
4. Possible side effects
5. How to store Bronax
6. Other information

1. WHAT BRONAX IS AND WHAT IT IS USED FOR

Bronax contains bromhexine hydrochloride as active substance, which is a mucolytic agent used in the treatment of respiratory disorders associated with viscous or excessive mucus. It helps in expectoration of tracheobronchial secretion and in fluidizing those secretions, so you can breathe more easily.

Bronax is used to:

- fluidize the secretions of the respiratory mucosa in cases of acute or chronic bronchopulmonary diseases like: bronchitis, emphysema, tracheobronchitis and chronic

asthmatic bronchitis;

- prevent respiratory complications after a surgery;
- accelerate the expectoration of any tracheobronchial foreign substance (for example the contrast means used in radiology).

If acute bronchitis gets worse, an antibiotic should be added to the current syrup treatment.

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

2. BEFORE YOU TAKE BRONAX

Do not take Bronax if:

- you are hypersensitive to bromhexine hydrochloride or to any of the excipients of the syrup;
- you suffer of active gastroduodenal ulcer;
- you have a severe impairment of hepatic function.

It should not be used in children under 2 years old.

Take special care with Bronax

Talk to your doctor or pharmacist before taking Bronax!

Bromhexine should be used under special care in patients with active tuberculosis.

Special care should be taken in asthmatic patients treated with bromhexine.

It is not advisable to use this medicine during pregnancy, especially the first trimester of pregnancy and during breastfeeding.

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 Bronax and contact your doctor immediately.

In some cases, the use of bromhexine can increase the volume of the fluidized bronchial secretions that cannot be drawn with cough. In such cases it is preferred the patient to be intubated in order to maintain the respiratory airways free.

Clearance of bromhexine or its metabolites may be reduced in patients with severe hepatic or renal impairment.

Since mucolytics may disturb the gastric mucosal barrier, bromhexine should be used with caution in patients with a history of peptic ulcer disease.

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.

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

Concomitant use of Bronax with certain antibiotics (such as ampicillin, amoxicillin, erythromycin and oxytetracyclin) increases antibiotic concentration into the bronchial secretions.

Taking Bronax with food and drinks

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

Pregnancy

Talk to your doctor or pharmacist for advice before taking this medicine.

Bromhexine crosses placenta in small amounts.

It is not advisable to use Bronax in the first trimester of pregnancy. In the other trimesters also you should act according to medical advice.

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

Breastfeeding

Bromhexine is excreted in breast milk.

Since there are no informations available regarding safety, it is preferable to avoid its use.

If it is necessary to use it, avoid breastfeeding while you are using this medicine.

Driving and using machines

No data available.

Important information about some of the excipients of Bronax

Bronax 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;
- sucrose; if you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. HOW TO TAKE BRONAX

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

Bromhexine hydrochloride general recommended dose is: 4 – 16 mg three times daily.

2 – 5 years old: 2.5 ml (1/2 teaspoon), 3 times daily.

6 – 12 years old: 5 ml (1 teaspoon), 3 times daily.

Adults and children over 12 years old: 10 ml (2 teaspoons), 3 times daily.

In adults, at commencement of treatment, it may be necessary to increase the total daily dose up to 4 tablespoons (60 ml; 48 mg).

Bromhexine should not be used in children under 2 years old.

If you have taken more Bronax

If you have taken more Bronax 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 Bronax

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 medicinal product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all other medicines, bromhexine may cause side effects, although not everybody manifests them. Sometimes they are serious, mostly they are not. Do not get worried from this list of possible side effects. No one of them might appear to you.

In general Bronax is well tolerated.

Gastrointestinal disorders that are usually mild might appear in sensitive patients.

In some cases, an increase of aminotransferase value in serum has been observed.

There have also been reported other side effects, including: headache, dizziness, sweating and skin rash.

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

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, mucosal or submucosal tissues) and pruritus.

Severe cutaneous adverse reactions (including erythema multiforme, Stevens-Johnson syndrome / toxic epidermal necrolysis and acute generalised exanthematous pustulosis).

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

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

5. HOW TO STORE BRONAX

Keep out of the reach and sight of children!

Do not use Bronax after the expiry date which is stated on the package!

Store below 25°C!

6. OTHER INFORMATION

What Bronax contains

The active substance is bromhexine hydrochloride.

5 ml of syrup contain 4 mg of bromhexine hydrochloride.

The excipients are: tartaric acid, benzoic acid, glycerol, sorbitol 70%, sucrose, sodium hydroxide, banana essence, purified water.

Content of the pack:

Carton box with one amber glass bottle with 100 ml.

Marketing Authorisation Holder (MAH) and Manufacturer:

PROFARMA sh.a.,

St. “Skënder Vila”,

Tirana, Albania.

Tel.: +355 4 23 89 602

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