Package leaflet: Information for the user

BROMHEXINE-GRINDEKS, 8 mg tablets:
Bromium hexidine hydrogen chloride

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.
Always use 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.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to with your doctor or pharmacist. 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 5 days.

What is in this leaflet

1. What Bromhexine-Grindeks is and what it is used for

Bromhexine-Grindeks is an expectorant that liquefies the sputum and makes it easier to cough it out.
The medicine is used in adults and adolescents over 14 years of age

2. What you need to know before you use Bromhexine-Grindeks

Do not use Bromhexine-Grindeks:
- if you are allergic to bromium hexidine or any of the other ingredients of this medicine (listed in section 6);
- if you have gastric or duodenal ulcers;
- along with cough medicines that inhibit the cough reflex (e.g. codeine), especially before going to sleep; this combination inhibits coughing out sputum.

Warnings and precautions
Talk to your doctor or pharmacist before taking any Bromhexine-Grindeks:
- if you have a weakened body;
- if you have bronchial asthma or mechanical narrowing of bronchial lumen (inhibited excretion of secretions from the bronchi);
- if you have a history of gastric or duodenal ulcer; bromium hexidine irritates the gastrointestinal mucosa; therefore, this medicine should be used with caution.

It should be taken into account that patients with severe liver or kidney failure have a decreased excretion of bromium hexidine and its metabolites from the body.

Severe skin reactions have been reported in connection with bromhexin administration. If you develop blemishes (including ulcers on mucous membranes, such as your mouth, throat, nose, eyes, genitals), stop using Bromhexine-Grindex and contact your doctor immediately.

Children and adolescents
This medicine is not suitable for children under 14 years of age.

Other medicines and Bromhexine-Grindeks
Tell your pharmacist if you are taking, have recently taken or might take any other medicines.
Bromhexine-Grindeks enhances the adsorption of antibiotics (erythromycin, cefalexine) into the lung parenchyma if used concomitantly.
Bromhexine-Grindeks may be used along with bronchial dilators and cardiac medicines. Concomitant use of various anti-inflammatory and anti-rheumatic medicines (e.g. salicylates, phenylbuthazone and oxyphenylbuthazone) may increase its irritation effect on the gastric mucosa.

Pregnancy and breast-feeding
Ask your doctor or pharmacist for advice before taking this medicine.
The safety of using bromium hexidine in pregnant women has not been established, therefore the use of Bromhexine-Grindeks during pregnancy is contraindicated.
Bromium hexidine is excreted into breast milk in small quantities; therefore the use of the medicine must be stopped during breastfeeding.

Driving and using machines
Bromhexine-Grindeks does not affect the ability to drive or use machines.

Bromhexine-Grindeks saccharose and lactose
If you have been told by your doctor that you have intolerance to some sugars, contact your doctor before taking this medicine.

3. How to take Bromhexine-Grindeks

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.

This medicine is taken orally independent of eating with water if necessary

One-time regular dose for adults and adolescents at least 14 years old is 8-16 mg three times per day.
The treatment effect is usually evident on the 2^{nd} to 5^{th} day of administration. If the symptoms are not better or are worse with 5 days, the patient should consult with his/her doctor, who will determine the further treatment.
If you feel that the effect of the medicine is too strong or too weak, talk to your doctor.

If you take more Bromhexine-Grindeks than you should
No cases of overdose with bromium hexidine have been described to date. Turn to the doctor immediately if you suspect overdose.

If you forget to take Bromhexine-Grindeks
Do not take a double dose to make up for a forgotten dose.
If you have any further questions on the use of 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.
Bromhexine-Grindeks is usually well tolerated.

Stop using this medicine and turn to a doctor **immediately**, if you experience any of the following symptoms:
- Breathing difficulties; swelling of lips, tongue or larynx, increased heart rate, low blood pressure, itching or swelling of skin, rash. These may be a sign of a very rare (in up to 1 person per 10,000) severe allergic reaction – anaphylactic shock.

Uncommon (can influence up to 1 person in 1,000):
- Hypersensitivity reactions (skin and mucous membrane rash, swelling of the face, difficulty in breathing, fever).
- Rash, urticaria.

Unknown (frequency cannot be estimated from the available data):
- Anaphylactic reactions including anaphylactic shock, angioedema (rapid onset of swelling of the skin, subcutaneous tissue, mucous membranes or mucous membranes) and itching.
- Severe skin reactions (including erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis and acute generalized exanthematosus pustulosis).
- Headache, vertigo, sweating (usually disappear after the discontinuation of the medicine).
- Loss of appetite, nausea, abdominal pain and discomfort.
- Brief elevation of serum aminotransferases.

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.
You can also report side effects directly via www.ravimiamet.ee. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Bromhexine-Grindeks

Store below 25 °°C.
Store in original package, protected from light and moisture.

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 carton.

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

6. Contents of the pack and other information

What Bromhexine-Grindeks contains:
- The active substance is bromium hexidine (*Bromhexini hydrochloridum*).
  One tablet contains 8 mg of bromium hexidine hydrogen chloride.
- The other ingredients are saccharose, lactose monohydrate, potato starch, magnesium stearate.

What Bromhexine-Grindeks looks like and contents of the pack
White, round sliding edge tablet.
10 tablets in blister package. 5 blisters in a carton box.

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This leaflet was last revised in August 2018.