

Package leaflet: information for the user  
Bromhexine HCl cough tablets Sanias 8 mg, tablets  
Bromhexine hydrochloride

Read the entire 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, pharmacist, or nurse has told you.

- Keep this leaflet. You may need to read it again.
- Do you have any questions? Then contact your doctor or pharmacist.
- Does your complaint not improve after 14 days, or does it even get worse? Then contact your doctor.
- Do you experience any of the side effects listed in section 4? Or do you experience a side effect not listed in this leaflet? Then contact your doctor, pharmacist, or nurse.

#### Contents of this leaflet

1. What is Bromhexine HCl cough tablets Sanias and what is it used for?
2. When should you not use this medicine or be extra careful with it?
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1. What is Bromhexine HCl cough tablets Sanias and what is it used for?

#### Medicinal group

Bromhexine makes the mucus in the lungs less viscous, making it easier for you to cough up this mucus. This allows you to breathe more easily.

#### Application of the medicine

For persistent cough, to facilitate the expectoration of mucus in the airways when this is hindered by thick mucus.

Does your complaint not improve after 14 days, or does it even get worse? Then contact your doctor.

2. When should you not use this medicine or be extra careful with it?

#### When should you not use this medicine?

- You are allergic to any of the ingredients in this medicine. You can find these ingredients in section 6 of this leaflet.
- In children under 2 years.

#### When should you be extra careful with this medicine?

- If you or your child has or has had a stomach ulcer. In that case, contact your doctor.
- You should be aware of an increase in the amount of mucus released in the airways.

- If the cough symptoms persist, recur frequently, or increase during use, it is advisable to contact your doctor.

There have been reports of serious skin reactions related to the administration of bromhexine hydrochloride. If you develop a rash (including damage to the mucous membranes, for example of the mouth, throat, nose, eyes, or genitals), stop using bromhexine and contact your doctor immediately.

Are you taking any other medicines?

Are you taking any other medicines besides Bromhexine HCl cough tablets Sanias 8 mg, have you recently taken any, or are you planning to take any soon? Then tell your doctor or pharmacist. This also applies to medicines you can obtain without a prescription.

Simultaneous use of bromhexine and antibiotics (amoxicillin, erythromycin, doxycycline, cefuroxime) leads to higher antibiotic levels in lung tissue.

Pregnancy and breastfeeding

Are you pregnant, do you think you might be pregnant, do you want to become pregnant, or are you breastfeeding? Then contact your doctor or pharmacist before using this medicine.

Pregnancy

There is no indication that the use of bromhexine during pregnancy can be harmful to the unborn child. However, bromhexine does pass into the body of the unborn child. As a precaution, you should not use bromhexine if you are pregnant.

Breastfeeding

It is not known whether bromhexine passes into breast milk. An effect on the infant cannot be excluded. Therefore, it is better not to use bromhexine when breastfeeding.

Driving and using machines

It is not known whether the use of bromhexine affects the ability to drive or use machines. Dizziness may occur when using this medicine (see section 4 "Possible side effects"). This should be taken into account when engaging in activities such as driving vehicles and operating machines.

Bromhexine HCl cough tablets Sanias 8 mg contains lactose

Bromhexine HCl cough tablets Sanias 8 mg contains, among other things, the excipient lactose. If your doctor has told you that you or your child cannot tolerate certain sugars (lactose), contact your doctor before you or your child takes this medicine.

Contact your doctor if any of the above warnings apply to you or have applied in the past.

### 3. How to use this medicine?

This medicine contains no sugar and can therefore also be taken by diabetics.

Consult your doctor if the symptoms of an acute respiratory condition do not improve quickly.

Always use this medicine exactly as described in this leaflet or as your doctor, pharmacist, or nurse has told you. Are you unsure about the correct use? Then contact your doctor, pharmacist, or nurse.

The usual dosage is:

Adults and children over 10 years  
3 times daily ½ - 2 tablets.

Children aged 5 - 10 years  
3 times daily ½ - 1 tablet.

This medicine should not be used in children under 2 years. This medicine is not suitable for use in children under 5 years.

This medicine starts to work after about five hours. As the mucus loosens and the airways are cleared, coughing decreases and breathing becomes easier. It takes a few days for this effect to be optimal. Therefore, do not stop taking this medicine too soon.

Method of use

Take the tablets with some water. You can divide the tablet into equal doses.

Have you used too much of this medicine?

It is unlikely that symptoms will occur. If you or your child do experience any symptoms, contact your doctor.

Did you forget to use this medicine?

If you or your child miss a dose, you or your child can simply continue with the next dose. Do not take a double dose to make up for a forgotten dose.

If you stop using this medicine

Stopping the use of this medicine suddenly does not cause problems.

Do you have any other questions about the use of this medicine? Then contact your doctor, pharmacist, or nurse.

#### 4. Possible side effects

Like any medicine, this medicine can cause side effects. Not everyone experiences them.

Some side effects can be serious. If you experience any of the following side effects, contact your doctor immediately or go to the emergency department of a nearby hospital immediately:

- Anaphylactic reactions including anaphylactic shock, angioedema (rapid swelling of the skin, subcutaneous tissue, mucous membranes, or tissues under the mucous membranes), and itching.

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

Common side effects (occur in 1 to 10 out of 100 users):

- Mild gastrointestinal side effects.

Uncommon side effects (occur in 1 to 10 out of 1000 users):

- Dizziness.
- Pain in the upper abdomen.
- Nausea.
- Vomiting.
- Diarrhea.
- Sweating.
- Temporarily increased levels of transaminases (certain enzymes), detected via a blood test.

Rare side effects (occur in less than 1 in 1000 users):

- Hypersensitivity reactions.
- Skin rash.
- Hives.

Not known: based on available data, the frequency cannot be determined:

- Anaphylactic reactions, including anaphylactic shock, angioedema (rapid swelling of the skin, subcutaneous tissue, mucous membranes, or tissues under the mucous membranes), and itching.
- Severe skin reactions (including erythema multiforme, Stevens-Johnson syndrome/toxic epidermal necrolysis, and acute generalized exanthematous pustulosis).
- Shortness of breath due to spasm of the airway muscles (bronchospasm).

#### Reporting side effects

If you experience side effects, contact your doctor or pharmacist. This also applies to side effects not listed in this leaflet. You can also report side effects via the Netherlands Pharmacovigilance Centre Lareb, website [www.lareb.nl](http://www.lareb.nl).

By reporting side effects, you help us obtain more information about the safety of this medicine.

#### 5. How to store this medicine?

Store below 25°C, in the original packaging to protect against moisture. Keep out of the sight and reach of children.

Do not use this medicine after the expiry date. You will find this on the blister pack and on the box after "Exp.". It includes a month and a year. The last day of that month is the expiry date.

Do not flush medicines down the sink or toilet and do not throw them in the trash. Ask your pharmacist what to do with medicines you no longer use. Proper disposal of medicines ensures they are destroyed correctly and do not enter the environment.

#### 6. Contents of the package and other information

What substances are in this medicine?

- The active substance in this medicine is bromhexine hydrochloride. Broomhexine HCl cough tablets Sanias 8 mg contains 8 mg bromhexine hydrochloride per tablet.
- The other ingredients in this medicine are: corn starch, lactose, gelatin (E485), talc (E553b), and magnesium stearate (E470b).

What do Broomhexine HCl cough tablets Sanias 8 mg look like and what is in a package?  
The tablets are white, have a score line and the inscription "8 mg" on one side and "BROOMHEXINE" on the other side.

The tablets are registered in blister packs of 10, 20, 30, 40, 50, 60, 90, 100, 250, and 500 pieces and in bottle packs of 50, 100, 250, and 500 pieces.

It is possible that not all mentioned pack sizes are marketed.

Marketing authorization holder and manufacturer

Marketing authorization holder

Aurobindo Pharma B.V.

Baarnsche Dijk 1

3741 LN Baarn

Netherlands

Manufacturer

APL Swift Services (Malta) Ltd

HF26, Hal Far Industrial Estate, Hal Far

Birzebbugia, BBG 3000

Malta

This medicine is registered under:

RVG 56954 Broomhexine HCl cough tablets Sanias 8 mg, tablets.

For all information regarding this medicine, contact the aforementioned company.

Information for the user

You or your child is suffering from a persistent cough. This occurs in our climate, for example, as a result of a cold. A persistent cough arises when more mucus is produced in the airways than normal. Inhaling irritating substances, such as tobacco smoke and exhaust fumes, can also cause increased mucus production. This mucus can be thicker and more viscous than normal. To get rid of the excess mucus, we use a natural mechanism: coughing. But if the mucus is too thick and viscous, coughing is insufficient. You or your child is coughing, but not enough mucus is coming up. It is stuck. "Persistent cough" is actually "stuck mucus." To help with coughing up, the mucus needs to be thinned. Broomhexine HCl cough tablets Sanias 8 mg, tablets is a mucolytic. The thick, viscous mucus loosens and can be coughed up much more easily.

This leaflet was last approved in April 2024.