Package leaflet: Information for the user

Broxivan 3 mg/ml oral solution
ambroxol 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 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 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 (within 3 days in children aged less than 6 years).

What is in this leaflet

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

1. What Broxivan is and what it is used for

Ambroxol, the active ingredient of this medicine, belongs to a group of medicines called mucolytics, which reduces the viscosity of mucus, fluidizing it and facilitating its elimination.

This medicine is indicated for mucous-dissolving treatment in diseases of the bronchi and the lungs with thick mucus, in adults and children from 2 years old.

You must talk to a doctor if you do not feel better or if you feel worse after 5 days (within 3 days in children aged less than 6 years).

2. What you need to know before you take Broxivan

Do not take Broxivan
- If you are allergic to ambroxol hydrochloride or any of the other ingredients of this medicine (listed in section 6).
- For children under 2 years of age.

Warnings and precautions
Talk to your doctor or pharmacist before taking Broxivan.
- if you have kidney or severe liver problems, this medicine should only be used after asking a doctor;
- if you have a bronchial motor activity disorder (problems with your lungs) along with a large production of secretion (risk of a mucous plug), you should not take this medicine;
- if you develop a skin rash (including lesions of the mucous membranes such as mouth, throat, nose, eyes, genitals), stop using Broxivan and contact your doctor immediately. There have been reports of severe skin reactions associated with the administration of ambroxol.

- if you suffer from histamine intolerance (allergy to histamine-rich foods). You should then avoid long-term therapy, as the active substance of this medicine influences the histamine metabolism and may lead to symptoms of intolerance (such as headache, runny nose, itching).
- if you have a predilection for the development of peptic ulcers as mucolytics (such as this medicine) may disrupt the gastric mucosal barrier. In this case you should not take this medicine.

Children
Do not give this medicine to children under 2 years of age.
In children from 2 to 4 years with persistent or recurrent cough a doctor must check before treatment.

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

There are no known interactions of ambroxol with other medicines.

While taking Broxivan, you should not use any medicines that suppress the cough reflex (so-called antitussives). The cough reflex is important in order to cough up the liquefied mucus and thus remove it from the lungs.

Broxivan with food and drink
Broxivan can be taken with or without food.

Pregnancy, breast-feeding and fertility
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

There is no evidence of side effects during pregnancy. However, you should not take ambroxol during the first three months of pregnancy.

Ambroxol hydrochloride is excreted in breast milk, therefore Broxivan is not recommended during breast-feeding.
Animal studies do not indicate direct or indirect harmful effects on fertility.

Driving and using machines
No studies on the effects of ambroxol on the ability to drive and use machines have been performed. However, there is no evidence of any effect of this medicine on the ability to drive and use machines.

Broxivan contains benzoic acid
This medicine contains 0.51 mg benzoic acid in each ml.

Broxivan contains sodium
This medicine contains less than 1 mmol sodium (23 mg) per ml, that is to say essentially ‘sodium-free’.

3. How to take Broxivan

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.

Do not take this medicine for more than 5 days (within 3 days in children aged less than 6 years) without asking your doctor.

The recommended dose

Use in adults
10 ml, 3 times a day (every 8 hours), which means a daily maximum of 90 mg of ambroxol hydrochloride.

Use in children and adolescents

Adolescents over 12 years old
10 ml, 3 times a day (every 8 hours), which means a daily maximum of 90 mg of ambroxol hydrochloride.

Children from 6 to 12 years old
5 ml, 2-3 times a day, (every 8-12 hours, as needed), which means a daily maximum of 45 mg of ambroxol hydrochloride. After 2-3 days, once the patient improves, the dosage regimen can be reduced to 2 times a day every 12 hours.

Children from 2 to 5 years old
2.5 ml, 3 times a day (every 8 hours), which means a daily maximum of 22.5 mg ambroxol hydrochloride. After 2-3 days, once the patient improves, the dosage regimen can be reduced to twice a day every 12 hours.

Broxivan can be taken with or without food.

To facilitate administration of the oral solution the package contains a volume measuring device.

You must talk to a doctor if you do not feel better or if you feel worse after 5 days (within 3 days in children aged less than 6 years).

If you take more Broxivan than you should
There are no known poisoning situations with ambroxol.
If you accidentally take more medicine than recommended the side effects of ambroxol may occur. The symptoms of overdose are consistent with the side effects of ambroxol when taken at the recommended doses and symptomatic treatment may be required.

If you forget to take Broxivan
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.

The following side effects may occur:
Common (may affect up to 1 in 10 people):
- taste alteration,
- nausea,
- decreased sensitivity at the mouth and pharynx (the tubes going down to the stomach and the lungs)

Uncommon (may affect up to 1 in 100 people):
- diarrhoea,
- vomiting, dyspepsia,
- dry mouth,
- abdominal pain

Rare (may affect up to 1 in 1,000 people):
- allergic reactions,
- rash,
- urticaria,
- dry throat

Not known (frequency cannot be estimated from the available data)
- anaphylactic reactions including anaphylactic shock (life-threating allergic reactions),
- angioedema (fast swelling of the skin, tissues under the skin, mucosa or submucosa),
- pruritus (itchy skin),
- severe skin reactions (including erythema multiforme, Stevens-Johnson syndrome/toxic epidermal necrolysis and acute generalized exanthematous pustulosis).

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 the:

Cyprus
Pharmaceutical Services
Ministry of Health
CY-1475 Nicosia
Tel: +357 22608607
Fax: + 357 22608669
Website: www.moh.gov.cy/phs

Malta
ADR Reporting Website: www.medicinesauthority.gov.mt/adrportal

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Broxivan

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 after EXP. The expiry date refers to the last day of that month. After opening the bottle for the first time, the medicine remains stable for 6 months.

This medicine does not require any special storage conditions.
Do not freeze.

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 Broxivan contains
- The active substance is ambroxol hydrochloride. Each 1 ml of oral solution contains 3 mg ambroxol hydrochloride.
- The other ingredients are: sucralose, benzoic acid, hydroxyethylcellulose 10900-20300 mPA.s, disodium edetate, cherry flavour powder, vanilla dry flavour powder, hydrochloric acid, concentrated, sodium hydroxide, water, purified.

What Broxivan looks like and contents of the pack
Colourless to slightly yellowish, clear, vanilla and cherry flavoured liquid.

Brown type III glass bottles of 100 ml, 125 ml or 150 ml filling volume, sealed with child proof plastic caps, which are also tamper evident. The bottles are packed in carton box together with a plastic measuring cup.

The capacity of the plastic measuring cups is 2.5 ml, 5 ml and 10 ml.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and
Medochemie Ltd., 1-10 Constantinoupoleos street, 3011 Limassol, Cyprus

Manufacturer
Medochemie Ltd. (Cogols Facility), 1-10 Constantinoupoleos street, 3011 Limassol, Cyprus

For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder.

This medicine is authorised in the Member States of the EEA under the following names:

Portugal	Broxivan
Bulgaria	Broxivan
Cyprus	Broxivan
Lithuania	Broxivan
Malta	Broxivan
Romania	Broxivan
Slovakia	Broxivan
Spain	Broxivan

This leaflet was last revised in August 2021.