

PACKAGE LEAFLET: INFORMATION FOR THE USER

BISOLVON

4 mg / 2 ml oral solution

BROMHEXINE

• This leaflet is a copy of the Summary of Product Characteristics and Patient Information Leaflet for a medicine, which outlines the conditions under which the medicine should be used and information on its known safety • The product information may be updated several times within its shelf life, and there could be differences between the version of information shown here and other information in the public domain or in the package insert • This leaflet may not contain all the information about the medicine or the information may not be the most up to date version for this product • If you have any questions or are not sure about anything, ask your doctor or pharmacist • Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

• 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 only • Do not pass it on to others • It may harm them, even if their signs of illness are the same as yours • If you get any side effects, talk to your doctor or pharmacist • This includes any possible side effects not listed in this leaflet •

What is in this leaflet?

1. What BISOLVON is and what it is used for
2. Before you take BISOLVON
3. How to take BISOLVON
4. Possible side effects
5. How to store BISOLVON
6. Further information

1. WHAT BISOLVON IS AND WHAT IS IT USED FOR

BISOLVON contains bromhexine hydrochloride which is a synthetic derivative of the herbal active ingredient vasicine. This belongs to a group of medicines called mucolytic agents which are used in conditions where breathing is difficult because there are a lot of secretions (also referred to as mucus) in your air passages.

Bromhexine facilitates expectoration and reduces cough.

BISOLVON works by making your mucus thinner and increasing the secretion of mucus from the respiratory tract in acute and chronic diseases of the bronchi and lungs with disorders of excretion and transmission of mucus.

Be sure to contact your doctor if you do not feel better or if you feel worse after 3 days.

2. BEFORE YOU TAKE BISOLVON

Do not take BISOLVON

- If you are allergic (hypersensitive) to bromhexine or any of the other ingredients of BISOLVON (listed in Section 6. Further information),

- If you are pregnant, likely to get pregnant or are breast-feeding,
- If you have a rare hereditary disease, which could be incompatible with any of the excipients of the medicine

Do not take this medicine if any of the above applies to you. If you are not sure, talk to your doctor or pharmacist.

Take special care with BISOLVON

Warnings and precautions

- If you notice any changes in the skin or mucous membranes (eg, blisters on the skin and / or mucous membranes, skin peeling). If this happens, immediately contact your doctor and, as a precaution, stop the treatment. There are very few reported cases of severe skin reactions such as Stevens-Johnson syndrome (Severe skin disease due to which the top layer of skin is dying out, and it peels off) and toxic epidermal necrolysis (TEN, a rare and sometimes life-threatening reaction to the medicines, due to which the large surface area of the upper layer of the skin separates from the deeper layers of the skin and can also affect the eyes, mouth, throat and bronchi), and are associated with the use of substances as bromhexine. Their appearance is in most cases explained by the severity of the disease of a person and / or concomitant use of other medicines.

- If you are taking other cough medicines.

Taking other medicines

Before using BISOLVON Oral solution, it is important to tell your doctor or pharmacist if you are taking any other medicines, obtained with or without a doctor's prescription.

Do not take BISOLVON oral solution simultaneously with other medicines that facilitate coughing up or medicines that suppress the cough reflex. Reports do not indicate clinically significant adverse interactions with other medicines.

Pregnancy and breast-feeding

Ask your doctor or pharmacist for advice before taking any medicine. Previous limited experience has not shown harmful effects on the fetus during pregnancy. As a precaution, it is recommended to avoid taking BISOLVON oral solution during pregnancy.

It is not known whether bromhexine is excreted into breast milk. Available data from animal studies indicate excretion into the milk. The risk for the infant cannot be excluded. BISOLVON oral solution should not be used during breastfeeding.

Driving and using machines

No studies on the effect on the ability to drive and use machines have been performed with BISOLVON.

Other warnings

BISOLVON 4 mg / 2 ml oral solution / inhalable solution contains methylparahydroxybenzoate.

Oral solution: may cause allergic reaction (possibly delayed).

Inhalable solution: may cause allergic reaction (possibly delayed).

3. HOW TO TAKE BISOLVON

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist have told you. Check with your doctor or pharmacist if you are not sure.

BISOLVON oral solution contains no sugar so it can be taken by diabetics.

There is a dropper in the throat of the bottle. There is also a measuring cup (with measuring marks 1-6 mL). 1 ml of a solution contains 2 mg of bromhexine hydrochloride corresponding to 15 drops.

Oral use (through the mouth)

Solution 4 mg / 2 ml (4 ml = 60 drops)

Adults and children over 12 years: 4 ml (60 drops), 3 times a day

Children from 6-12 years: 2 mL (30 drops), 3 times a day

Children from 2-6 years: 20 drops, 3 times a day

Children under 2 years: 10 drops, 3 times a day

Measure the correct amount of solution with the supplied measuring cup (mL) or using dropper and drink with plenty of fluids!

Inhalation:

Adults: 4 ml (60 drops), 2 times a day

Children over 12 years: 2 mL (30 drops) 2 times a day

Children 6-12 years: 1 mL (15 drops) 2 times a day

Children from 2-6 years: 10 drops, 2 times a day

Children under 2 years: 5 drops, 2 times a day

Warm to body temperature before inhalation.

Measure the correct amount of solution with the supplied measuring cup (mL) or using dropper, and inhale using a nebulizer!

Before using it, dilute a solution with physiological saline at a ratio of 1: 1. To avoid the creation of particles in diluted solution, inhale BISOLVON solution immediately after preparation.

If you suffer from bronchial asthma, first take a regular dose of bronchodilators which you are usually taking, and only then inhale BISOLVON.

Combined treatment of inhalation and oral form of the medicine increases the effect of BISOLVON, and is particularly suited to start treating patients who need to achieve full effect of the medicine in a short time.

Note:

Patients taking BISOLVON should be warned that they can expect an increased secretion of mucus.

BISOLVON solution starts to work after about five hours. When the airways cleanse by releasing the mucus, cough will decrease and breathing will become easier. It will take several days to achieve optimal effect. For this reason, you should not stop taking BISOLVON solution too soon.

Be sure to contact your doctor if you do not feel better or if you feel worse after 3 days.

If you take more BISOLVON than you should

Seek medical advice if you have taken more than the recommended or prescribed dose of BISOLVON.

Until now there were no reported specific symptoms of overdose in people. Based on data of reported cases of accidental overdose or with errors in treatment, symptoms correspond to the known side effects at the recommended doses of the medicine, and it is sometimes necessary to treat them symptomatically.

If you forget to take BISOLVON

If you miss a dose, take the next dose at the usual time and continue to take the medicine as instructed by a doctor.

Do not take a double dose to make up for a forgotten dose.

If you stop taking BISOLVON

BISOLVON is taken only when necessary.

Talk to your doctor or pharmacist if you have any additional questions.

4. POSSIBLE SIDE EFFECTS

Like all medicines, **BISOLVON** can cause side effects, although not everybody gets them.

Very common: more than 1 treated person of 10
Common: 1 to 10 treated persons of 100
Uncommon: 1 to 10 treated persons of 1000
Rare: 1 to 10 treated persons of 10000
Very rare: less than 1 treated person of 10000
Not known: frequency cannot be estimated from the available data

The following side effects have been reported:

Uncommon: nausea, vomiting, diarrhea and pain in the upper abdomen.

Rare: hypersensitivity, skin rash

Unknown: Acute hypersensitivity reactions (anaphylactic reaction), including anaphylactic shock, bronchial spasm (bronchospasm), swelling (angioneurotic edema), hives (urticaria), itching (pruritus).

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. By reporting side effects, you can help provide more information on the safety of this medicine.

5. HOW TO STORE BISOLVON

Keep out of the reach and sight of children.

Do not store above 30 °C.

Shelf life: 3 years.

After opening the package, BISOLVON solution may be used for 6 months.

Medicines should not be disposed of via waste water or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What BISOLVON contains

2 ml of a solution containing 4 mg of bromhexine-hydrochloride.

The other ingredients are: tartaric acid, methyl parahydroxybenzoate, purified water.

What BISOLVON looks like and contents of the pack

A brown glass bottle with 40 ml of solution with the measuring cup (with measuring marks from 1 to 6 ml) on the cap, in a box. there is a dropper in the throat of the bottle.

Regime of dispensing

The medicine is issued without doctor's prescription.

Manufacturer

Boehringer Ingelheim RCV GmbH & Co.KG, Dr. Boehringer Gasse 5-11, Vienna, Austria

Manufacturer of the medicinal product

Instituto de Angeli srl, Loc. Prulli 103 / C, Reggello, Italy