

Package leaflet: Information for the user

Bisolvon® 4 mg/5 ml Oral Solution (bromhexine hydrochloride)

Read all of 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 troublesome or serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What BISOLVON 4 mg/5 ml Oral Solution is and what it is used for
2. Before you take BISOLVON 4 mg/5 ml Oral Solution
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1. WHAT BISOLVON 4 MG/5 ML ORAL SOLUTION IS AND WHAT IT IS USED FOR

The name of your medicine is BISOLVON 4 mg/5 ml Oral Solution (called BISOLVON in this leaflet). BISOLVON contains a medicine called bromhexine. This belongs to a group of medicines called mucolytic agents.

BISOLVON helps you to breathe more easily when you have breathing problems such as bronchitis or sinusitis. It works by making your mucus thinner so that you can get rid of it more easily.

2. BEFORE YOU TAKE BISOLVON 4 MG/5 ML ORAL SOLUTION

Do not take BISOLVON if:

- You are allergic (hypersensitive) to bromhexine or any of the other ingredients of BISOLVON (listed in Section 6 below)
- You are pregnant, likely to get pregnant or are breast-feeding

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

Take special care with BISOLVON

Check with your doctor or pharmacist before taking your medicine if:

- You have or have ever had a stomach ulcer

If this applies to you (or you are not sure), talk to your doctor or pharmacist before taking BISOLVON.

There have been reports of severe skin reactions associated with the administration of bromhexine hydrochloride. If you develop a skin rash (including lesions of the mucous membranes such as mouth, throat, nose, eyes, genitals), stop using BISOLVON and contact your doctor immediately.

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines. This includes medicines that you buy without a prescription and herbal medicines. This is because BISOLVON can affect the way some other medicines work. Also some other medicines can affect the way BISOLVON works.

In particular tell your doctor or pharmacist if you are taking any:

- Antibiotics such as ampicillin, amoxicillin, erythromycin or oxytetracycline

Pregnancy and breast-feeding

Do not take BISOLVON if you are pregnant, likely to get pregnant or if you are breast-feeding.

Driving and using machines

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

Important information about some of the ingredients of BISOLVON

BISOLVON contains maltitol liquid (E965). When taken according to the dosage recommendations, each 5 ml dose supplies up to 2.5 g of maltitol liquid which has a calorific value of 5.75 Kcal.

The maltitol liquid in the product may have a mild laxative effect.

This medicine contains 6.35 mg benzoic acid in each 5 ml.

You should not take this product if you have been told by your doctor that you have an intolerance to fructose (a type of sugar). If in doubt ask your doctor or pharmacist.

3. HOW TO TAKE BISOLVON 4 MG/5 ML ORAL SOLUTION

Always take this medicine exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Taking this medicine

Take this medicine only by mouth. It can be taken with or without food.

- To make sure you use the right amount, use the measuring cup provided to measure your dose
- If you prefer, you can ask your pharmacist for a 5 ml plastic spoon to use instead
- Remove the measuring cup from the bottle cap before use
- Fill the measuring cup up to the 5 ml line
- Rinse the measuring cup with water after use

How much to take**Children from 2 up to and including 5 years**

- The usual dose is 5 ml two times a day

Children over 5 up to and including 12 years

- The usual dose is 5 ml four times a day

Adults and children over 12 years

- The usual dose starts from 10 ml three times a day
- However, you could be asked to take up to 15 ml four times a day. Your doctor will tell you exactly how much you need to take

If you think this medicine is not working well enough

If your medicine does not seem to be working for you, talk to your doctor as soon as possible. Do not take extra BISOLVON unless your doctor tells you to.

If you take more BISOLVON than you should

If you take more of this medicine than you should, talk to a doctor or go to a hospital straight away. Take the medicine container with you even if there is no BISOLVON left.

If you forget to take BISOLVON

- If you forget a dose, take it as soon as you remember it
- However, if it is nearly time for the next dose, skip the missed dose
- Do not take a double dose to make up for a forgotten dose

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them. The following side effects may happen with this medicine:

Stop taking BISOLVON and see a doctor straight away if you notice any of the following serious side effects – you may need urgent medical treatment:

- Serious allergic reactions that may cause swelling of face or throat, wheezing or sudden difficulties in breathing
- Skin lesions such as severe blistering or peeling of your skin, mouth, throat, nose, eyes and genitals

If you notice any of the above, stop taking BISOLVON and see a doctor straight away.

Other side effects**Uncommon**

(affects less than 1 in 100 people)

- Feeling sick (nausea) or being sick (vomiting)
- Pain in the upper part of your abdomen
- Diarrhoea

Rare

(affects less than 1 in 1000 people)

- Hypersensitivity reactions
- Rash
- Urticaria

The following side effects can also happen but the frequency of these is not known

- Anaphylactic reactions including anaphylactic shock, angioedema (rapidly developing swelling of the skin, subcutaneous, mucosa or submucosal tissues)
- Severe cutaneous adverse reactions (including erythema multiforme, Stevens-Johnson syndrome/toxic epidermal necrolysis and acute generalised exanthematous pustulosis)
- Tightness of your chest
- Pruritus

In addition, an expected increase in the flow of mucus secretion will result from taking BISOLVON.

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. You can also report side effects directly (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

Ireland

HPRA Pharmacovigilance

Website: www.hpra.ie

Malta

ADR Reporting Website:

www.medicinesauthority.gov.mt/adrportal

5. How to store BISOLVON 4 MG/5 ML ORAL SOLUTION

Keep out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the packaging. The expiry date refers to the last day of that month.

Do not use this medicine if the bottle has been open for 12 months.

BISOLVON should be kept in the original container.

Medicines should not be disposed of via wastewater 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**

- Each 5 ml of your medicine contains 4 mg of the active substance bromhexine hydrochloride
- The other ingredients are maltitol liquid (E965), sucralose (E955), benzoic acid (E210), cherry aroma, chocolate aroma, levomenthol and purified water.

What BISOLVON looks like and contents of the pack

BISOLVON is a clear, almost colourless solution with a fruity odour. Your bottle contains either 100 ml, 200 ml or 250 ml of liquid. Each bottle is provided with a measuring cup, together in a carton.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

The Marketing Authorisation for BISOLVON is held by:

Ireland

Opella Healthcare France SAS
157 avenue Charles de Gaulle
92200 Neuilly-sur-Seine
France.

Malta

Opella Healthcare France SAS
157 avenue Charles de Gaulle
92200 Neuilly-sur-Seine
France.

and the BISOLVON is manufactured by:

Delpharm Reims S.A.S.
10 Rue Colonel Charbonneaux
51100 Reims
France

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

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