

## PACKAGE LEAFLET: INFORMATION FOR THE USER

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### BISOLVON

8 mg tablets

BROMHEXINE

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*• 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.*

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*• 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 •*

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#### 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,
- In children under 6 years of age.

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 or your child have or have had a stomach ulcer, it would be good to consult a doctor.
- If difficulties with coughing last longer or are often repeated it is necessary to see a doctor.
- You must be aware of the increased amount of mucus released in the airways.

#### ***Taking other medicines***

Before using BISOLVON Tablets, 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 tablets 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 tablets 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 tablets should not be used during breastfeeding.

There are no studies on the effect of BISOLVON on fertility in humans. The available results of animal studies do not indicate the possible effects of bromhexine on fertility.

#### ***Driving and using machines***

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

#### ***Other warnings***

Each tablet contains 74 mg of lactose. If you have been told by your doctor that you have intolerance to some sugars, contact, contact your doctor before taking this medicinal product.

### ***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.

**Adults and children over 12 years:** 1 tablet (8 mg) 3 times a day  
**Children from 6-12 years:** ½ tablet (4 mg) three times a day

At the beginning of treatment, the daily dose for adult patients may be increased to 48 mg.

#### **Children**

BISOLVON Tablets should not be used in children under 6 years of age.  
For children the use of liquid pharmaceutical forms is more appropriate (BISOLVON syrup 4 mg / 5 ml and BISOLVON solution of 4 mg / 2 mL).

Take whole tablets with fluid. The tablet can be broken into two halves.

#### **Note**

During treatment BISOLVON increase in the secretion of mucus in the airways is anticipated.

It is necessary to consult a doctor if symptoms do not improve quickly or if they get worse.

#### ***If you take more BISOLVON than you should***

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

#### ***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***

Sudden discontinuation of taking the tablets does not cause problems.

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).

\* In very rare cases serious skin diseases occur, such as severe hypersensitivity reaction with (high) fever, red spots on the skin, joint pain and / or inflammation of the eye (Stevens Johnson syndrome) and severe, acute reactions (hypersensitivity) accompanied by fever and bubble formation / peeling skin (Lyell's syndrome). If you experience any of these, stop taking BISOLVON tablet and immediately inform your doctor.

#### ***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.

Do not use **BISOLVON** after the expiry date which is stated on the label.

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**

Each BISOLVON tablet contains bromhexine hydrochloride 8 mg. BISOLVON Chesty Forte Tablets also contain: • lactose • maize starch • magnesium stearate

### **What BISOLVON looks like and contents of the pack**

20 tablets (2x10) in white PVC / PVDC / Al – blisters, in a box.

The tablets are round, white and bevel-edged. One side is scored and impressed with '51B' on both sides of the score. The other is impressed with the company logo.

### **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**

Delpharm Reims, 10, rue Colonel Charbonneaux, 51100 Reims, France