### **Bisolvon® Chesty Oral Liquid**

Active ingredient(s): Bromhexine hydrochloride

#### **Consumer Medicine Information (CMI)**

This leaflet provides important information about using Bisolvon Chesty Oral Liquid. You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Bisolvon Chesty Oral Liquid.

Where to find information in this leaflet:

1. Why am I using Bisolvon Chesty Oral Liquid?

2. What should I know before I use Bisolvon Chesty Oral Liquid?

- 3. What if I am taking other medicines?
- 4. How do I use Bisolvon Chesty Oral Liquid?
- 5. What should I know while using Bisolvon Chesty Oral Liquid?
- 6. Are there any side effects?
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# 1. Why am I using Bisolvon Chesty Oral Liquid?

**Bisolvon Chesty Oral Liquid contains the active ingredient bromhexine hydrochloride.** Bromhexine hydrochloride thins and loosens mucus to help clear chest congestion.

It relieves chesty coughs and breathing difficulties due to excess mucus in cold, flu and respiratory tract infections.

Bisolvon Chesty Oral Liquid is used in conditions where breathing is difficult because there are a lot of secretions (also referred to as mucus) in your air passages. Such conditions include:

- common cold
- flu
- infections of the respiratory tract

# 2. What should I know before I use Bisolvon Chesty Oral Liquid?

#### Warnings

Do not use Bisolvon Chesty Oral Liquid if:

• you are allergic to bromhexine, or any of the ingredients in Bisolvon Chesty Oral Liquid.

If you are not sure if you have these allergies you should raise those concerns with your doctor or pharmacist.

#### Do not take Bisolvon Chesty Oral Liquid if you have fructose intolerance.

If you are not sure if you have this condition you should raise those concerns with your doctor or pharmacist.

- Always check the ingredients to make sure you can use this medicine.
- Do not use Bisolvon Chesty products in children under 6 years of age (see Children).
- You should not use Bisolvon Chesty Oral Liquid after the EXPIRY DATE on the carton or bottle.

If you take this medicine after the expiry date, it may not work as well.

 Do not use Bisolvon Chesty Oral Liquid if the cap seal is broken or the packaging is torn or shows signs of tampering.

#### Check with your doctor or pharmacist if you:

- have a persistent or chronic cough such as coughs occurring with smoking, asthma, chronic bronchitis, emphysema or cough accompanied by excess phlegm, consult your doctor before taking Bisolvon Chesty Oral Liquid.
- have, or have had, any of the following conditions:
  - liver problems
  - kidney problems
  - stomach ulcers.

If you are not sure if you have, or have had, any of these conditions, you should raise those concerns with your doctor or pharmacist.

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

Bisolvon Chesty Oral Liquid may increase the amount of antibiotic penetration. Antibiotics are medicines used to treat infections.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section <u>6. Are there any side effects</u>?

#### Pregnancy and breastfeeding

## Check with your doctor or pharmacist if you are pregnant or intend to become pregnant.

Special care is recommended during pregnancy. The benefits of Bisolvon Chesty Oral Liquid must be assessed against any risks. Your doctor will discuss the risks and benefits of using Bisolvon Chesty Oral Liquid while you are pregnant.

The use of Bisolvon Chesty Oral Liquid during the first trimester is not recommended.

## Talk to your doctor or pharmacist if you are breastfeeding or intend to breastfeed.

Bisolvon Chesty Oral Liquid is expected to enter the breast milk.

It is not recommended that Bisolvon Chesty Oral Liquid be taken by women who are breastfeeding.

#### Children

 Do not use Bisolvon Chesty Oral Liquid in children under 6 years of age. Use in children 6 – 11 years only on the advice of a doctor, pharmacist or nurse practitioner.

#### 3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Bisolvon Chesty Oral Liquid.

# 4. How do I use Bisolvon Chesty Oral Liquid?

Use the enclosed measuring cup to measure the doses correctly.

#### How much to take

Adults and children 12 years and over:

- 10 mL three times a day when necessary.
- This dose can be increased to 20 mL three times a day for the first 7 days.

Children 6 - 11 years:

• 10 mL three times a day when necessary.

## Ask your doctor or pharmacist for more information if you have been advised to take a different dose.

- Follow the instructions provided with the medicine.
- Do not exceed the recommended dosage.

## If you use too much Bisolvon Chesty Oral Liquid

If you think that you have used too much Bisolvon Chesty Oral Liquid, you may need urgent medical attention.

#### You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26 in Australia), or
- contact your doctor or pharmacist, or
- go to the Emergency Department at your nearest hospital.

## You should do this even if there are no signs of discomfort or poisoning.

# 5. What should I know while using Bisolvon Chesty Oral Liquid?

When you take Bisolvon Chesty Oral Liquid, you may notice an increase in thin watery mucus from your air passages. This is common when you take Bisolvon Chesty Oral Liquid and is due to the way Bisolvon Chesty Oral Liquid works, helping to remove mucus by making it easier to cough up.

The maximum recommended daily dose of Bisolvon Chesty Oral Liquid for children 6 - 11 years of age (30 mL) contains at least 7.5 g of maltitol and up to 1.2 g of sorbitol.

The maximum recommended adult daily dose (60 mL) of Bisolvon Chesty Oral Liquid contains at least 15 g of maltitol and up to 2.4 g of sorbitol.

Products containing maltitol and sorbitol may have a laxative effect or cause diarrhoea in some people. This is more likely if several products containing maltitol, sorbitol or related substances are consumed at the same time.

#### Things you should do

## If your symptoms persist, you should contact your doctor for further advice.

Your doctor will assess your condition and decide if you should continue to take Bisolvon Chesty Oral Liquid or if a new treatment plan is needed.

Stop taking Bisolvon Chesty Oral Liquid and contact your doctor immediately if you experience any skin reaction with severe blisters and bleeding in the lips, eyes, mouth, nose or genitals. These may be symptoms of a severe allergic reaction that requires urgent medical attention.

There have been very rare reports of severe skin reactions such as Stevens Johnson Syndrome and Lyell's Syndrome with products containing bromhexine.

Remind any doctor, dentist or pharmacist you visit that you are using Bisolvon Chesty Oral Liquid.

#### **Driving or using machines**

#### Be careful before you drive or use any machines or tools until you know how Bisolvon Chesty Oral Liquid affects you.

When used as recommended, and when there are no side effects, Bisolvon Chesty Oral Liquid is not known to have any effect on the ability to drive or operate machinery.

#### Looking after your medicine

Follow the instructions in the carton on how to take care of your medicine properly.

 Bisolvon Chesty Oral Liquid should be kept in a cool dry place where the temperature stays below 25°C Store in a cool, dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

#### Keep it where young children cannot reach it.

#### Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

#### 6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects from taking Bisolvon Chesty Oral Liquid.

#### Less serious side effects

Less serious side effects	What to do
<ul><li>Gastrointestinal related</li><li>nausea</li></ul>	Speak to your doctor or pharmacist as soon as possible if you have any of these less serious
• diarrhoea	

Less serious side effects	What to do
<ul> <li>vomiting</li> <li>stomach pain</li> <li>other mild stomach problems</li> <li>Head and neurology related</li> </ul>	side effects and they worry you.
<ul> <li>headache</li> <li>dizziness</li> <li>sweating</li> <li>Liver related</li> <li>temporary rise in some liver enzyme levels</li> </ul>	

#### **Serious side effects**

Serious side effects	What to do
Serious allergic reactions have occurred with the use of Bisolvon Chesty Oral Liquid. Symptoms of allergic reactions may include: • skin rashes, including pinkish, itchy swellings (also called hives) • difficulty in breathing	Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.

Serious side effects	What to do
<ul> <li>swelling of the face, lips, mouth, tongue or throat which may cause difficulty swallowing or breathing.</li> </ul>	

#### Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell during or after taking Bisolvon Chesty Oral Liquid.

Other side effects not listed here may occur in some people.

#### **Reporting side effects**

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at <u>www.tga.gov.au/reporting-problems</u>. By reporting side effects, you can help provide more information on the safety of this medicine.

#### 7. Product details

This medicine is available over-the-counter without a doctor's prescription.

#### What Bisolvon Chesty Oral Liquid contains

Active ingredient (main ingredient)	Bromhexine hydrochloride - each 5 mL of Bisolvon Chesty Oral Liquid contains 4 mg bromhexine hydrochloride.
Other ingredients	<ul> <li>maltitol solution</li> <li>sucralose</li> <li>benzoic acid</li> <li>menthol</li> <li>chocolate flavour</li></ul>
(inactive ingredients)	96534-33 <li>cherry flavour 96323-33</li> <li>purified water</li>

Do not take this medicine if you are allergic to any of these ingredients.

#### What Bisolvon Chesty Oral Liquid looks like

Bisolvon Chesty Oral Liquid is the brand name of your medicine. The Oral Liquid is a clear to almost clear and colourless to almost colourless solution with an aroma of chocolate and cherry.

Bisolvon Chesty Oral Liquid is available in bottles containing 200 mL or 250 mL, with a tamper-evident cap.

Each carton is labelled with the Australian Registration Number AUST R 133244.

#### Who distributes Bisolvon Chesty Oral Liquid

Bisolvon Chesty Oral Liquid is made in France.

Bisolvon Chesty Oral Liquid is supplied in Australia by:

Sanofi Consumer Healthcare,

87 Yarraman Place, Virginia,

Qld 4014 Australia.

Toll-free: 1800 818 806

Registration No AUST R 133244

Date of preparation: August 2024

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