Bisolvon® Chesty Forte Tablets

Active ingredient: Bromhexine hydrochloride

Consumer Medicine Information (CMI)

This leaflet provides important information about using Bisolvon Chesty Forte Tablets. 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 Forte Tablets.

Where to find information in this leaflet:

- 1. Why am I using Bisolvon Chesty Forte Tablets?
- 2. What should I know before I use Bisolvon Chesty Forte <u>Tablets?</u>
- 3. What if I am taking other medicines?
- 4. How do I use Bisolvon Chesty Forte Tablets?
- 5. What should I know while using Bisolvon Chesty Forte Tablets?
- 6. Are there any side effects?
- 7. Product details

1. Why am I using Bisolvon Chesty Forte Tablets?

Bisolvon Chesty Forte Tablets contain the active ingredient bromhexine hydrochloride. Bromhexine hydrochloride thins and loosens mucus to help clear stubborn chest congestion.

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

Bisolvon Chesty Forte Tablets are 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 Forte Tablets?

Warnings

Do not use Bisolvon Chesty Forte Tablets if:

- You are allergic to Bromhexine hydrochloride, or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.
- Do not take Bisolvon Chesty Forte Tablets if you have galactose intolerance.
- If you are not sure if you have these allergies or this condition, you should raise those concerns with your doctor or pharmacist.
- The maximum recommended adult daily dose of Bisolvon Chesty Forte Tablets contains 444mg of lactose.
- Do not use Bisolvon Chesty products in children under 6 years of age (see Children).
- Do not take Bisolvon Chesty Forte Tablets after the EXPIRY DATE on the carton or container.

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

 Do not take Bisolvon Chesty Forte Tablets if the packaging is torn or shows signs of tampering.

Check with your doctor or pharmacist before taking Bisolvon Chesty Forte Tablets if:

- you have a persistent or chronic cough such as coughs occurring with smoking, asthma, chronic bronchitis, emphysema or cough accompanied by excess phlegm.
- you have, or have had any of the following conditions:
 - o liver problems
 - o 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 Forte 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.

Bisolvon Chesty Forte Tablets 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</u>. Are there any side effects?

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant during your course of medication.

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

The use of Bisolvon Chesty Forte Tablets during the first trimester is not recommended.

Check with your doctor if you are breastfeeding or intend to breastfeed during your course of medication.

Bisolvon Chesty Forte Tablets are expected to enter the breast milk.

It is not recommended that Bisolvon Chesty Forte Tablets be taken by women who are breastfeeding.

Children

- Do not use Bisolvon Chesty Forte Tablets in children under 6 years of age. Use in children 6 – 11 years only on the advice of a doctor, pharmacist or nurse practitioner.
- Bisolvon Chesty Oral Liquid, Bisolvon Chesty Kids Oral Liquid, Bisolvon Chesty Forte Oral Liquid and Bisolvon Chesty Forte Tablets are available for children between 6 and 11 years of age.
- Do not use Bisolvon Chesty Oral Liquid, Bisolvon Chesty Kids Oral Liquid, Bisolvon Chesty Forte Oral Liquid or Bisolvon Chesty Forte Tablets in children under 6 years.

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 Forte Tablets.

4. How do I use Bisolvon Chesty Forte Tablets?

How much to take

The recommended doses for Bisolvon Chesty Forte Tablets in adults and children are stated below:

Adults and children over 12 years:

- 1 tablet three times a day when necessary.
- This dose can be increased to 2 tablets three times a day for the first 7 days.

Children 6 - 11 years:

1 tablet 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 many Bisolvon Chesty Forte Tablets

If you think that you have used too many Bisolvon Chesty Forte Tablets, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26) in Australia, or
- the National Poisons Centre on 0800 POISON (0800 764766) in New Zealand, or
- contact your doctor, 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 Forte Tablets?

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

Things you should do

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

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

Stop taking Bisolvon Chesty Forte Tablets 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 Forte Tablets.

Driving or using machines

When used as recommended, and when there are no side effects, Bisolvon Chesty Forte Tablets are 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 Forte Tablets 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 Bisolvon Chesty Forte Tablets where 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 Forte Tablets.

Less serious side effects

| Less serious side effects | What to do |
|---|---|
| Gastrointestinal related nausea diarrhoea vomiting stomach pain other mild stomach problems Head and neurology related | Speak to your doctor if you have any of these less serious side effects and they worry you. |
| headachedizzinesssweatingLiver related | |
| temporary rise in some liver enzyme levels | |

Serious side effects

| Serious side effects | What to do |
|---|--|
| Serious allergic reactions have occurred with the use of Bisolvon Chesty Forte Tablets. Symptoms of allergic reactions are listed here: • skin rashes, including pinkish, itchy swellings (also called hives) • difficulty in breathing • swelling of the face, lips, mouth, tongue or throat which may cause difficulty swallowing or 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. |

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

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> in Australia and <u>https://nzphvc.otago.ac.nz/reporting/</u> in New Zealand.

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 Forte Tablets contains

| Active ingredient (main ingredient) | Each Bisolvon Chesty Forte Tablet contains bromhexine hydrochloride 8 mg. |
|--|---|
| Other ingredients (inactive ingredients) | Lactose monohydratemagnesium stearatemaize starch |

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

What Bisolvon Chesty Forte Tablets look like

Bisolvon Chesty is the brand name of your medicine. The tablets are round, white and bevel-edged. One side is scored and impressed with '51B' on both sides of the score.

Bisolvon Chesty Forte Tablets are available in Australia in blister packs of 10s, 20s, 30s, 50s and 100s*.

*Not all pack sizes may be marketed.

Bisolvon Chesty Forte Tablets are available in New Zealand in blister packs of 30s and 50s.

Each carton is labelled with the Australian Registration Number AUST R 125375.

Who distributes Bisolvon Chesty Forte Tablets

Bisolvon Chesty Forte Tablets are made in France.

Bisolvon Chesty Forte Tablets are supplied in Australia by:

Sanofi Consumer Healthcare,

87 Yarraman Place, Virginia,

Qld 4014 Australia.

Toll-free: 1800 818 806

Bisolvon Chesty Forte Tablets are supplied in New Zealand

by:

Sanofi-Aventis New Zealand Limited,

Auckland, New Zealand. Toll-free: 0800 283 684

Registration No AUST R 125375

Registration No TT50-0645 in New Zealand.

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