

Bisolvon® Chesty Forte Tablets

Bromhexine hydrochloride

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Bisolvon Chesty Forte Tablets.

It does not contain all available information, nor does it take the place of talking to your doctor or pharmacist.

This leaflet was last updated on the date at the end of this leaflet. More recent information may be available. The latest Consumer Medicine Information is available from your pharmacist, doctor, or from www.medicines.org.au and may contain important information about the medicine and its use of which you should be aware.

Keep this information with your Bisolvon Chesty Forte Tablets.

You may need to read it again later.

To find out more about Bisolvon Chesty Forte Tablets:

You should ask your doctor or pharmacist if you have any questions about Bisolvon Chesty Forte Tablets, or if you have any trouble before, during or after using Bisolvon Chesty Forte Tablets.

What Bisolvon Chesty Forte Tablets are used for

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.

Bisolvon Chesty Forte Tablets contain bromhexine hydrochloride, which thins and loosens mucus to help clear stubborn chest congestion. Relieves chesty coughs and breathing difficulties due to excess mucus in cold, flu and respiratory tract infections.

Before you take Bisolvon Chesty Forte Tablets

When you must not take Bisolvon Chesty Forte Tablets

Do not take Bisolvon Chesty Forte Tablets if you are allergic to bromhexine or to any of the other ingredients in Bisolvon Chesty Forte Tablets.

These ingredients are listed in full at the end of this leaflet (see Ingredients).

Do not take Bisolvon Chesty Forte Tablets if you have galactose intolerance.

The maximum recommended adult daily dose of Bisolvon Chesty Forte Tablets contain 444 mg of lactose.

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

Do not use Bisolvon Chesty products in children under 6 years of age (see Children).

You should not use 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 use Bisolvon Chesty Forte Tablets if the packaging is torn or shows signs of tampering.

Before you start to take 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, consult your doctor before taking Bisolvon Chesty Forte Tablets.

Before taking Bisolvon Chesty Forte Tablets, you must tell your doctor or pharmacist if you 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 using 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.

Pregnancy

Ask for your doctor's advice if you are pregnant, or likely 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.

Breastfeeding

Ask for your doctor's advice if you are breastfeeding, or likely to breastfeed during your course of medication.

Bisolvon Chesty Forte Tablets is 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 and Bisolvon Chesty Forte Oral Liquid are also available for children between 6 and 11 years of age. Do not use Bisolvon Chesty Oral Liquid or Bisolvon Chesty Forte Oral Liquid in children under 6 years.

Taking Bisolvon Chesty Forte Tablets

Recommended dose

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.

If you have taken too many Bisolvon Chesty Forte Tablets

Immediately telephone your doctor, pharmacist or the Poisons Information Centre (telephone 13 11 26 in Australia; 0800 764 766 in New Zealand) if you think you or anyone else may have taken too many Bisolvon Chesty Forte Tablets.

Do this even if there are no signs of discomfort or poisoning.

While you are taking 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 must 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

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.

Effects on ability to drive or operate machinery

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.

Side effects

You should be aware that all medicines carry some risks and that all possible risks may not be known at this stage despite thorough testing.

Ask for the advice of your doctor or pharmacist if you have any concerns about the effects of taking Bisolvon Chesty Forte Tablets.

Side effects from Bisolvon Chesty Forte Tablets include:

- nausea
- diarrhoea
- vomiting
- stomach pain
- other mild stomach problems
- headache
- dizziness
- sweating
- temporary rise in some liver enzyme levels.

Serious allergic reactions have occurred with the use of Bisolvon

Chesty Forte Tablets. Symptoms of allergic reactions may include:

- 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.

Tell your doctor or pharmacist as soon as possible if you experience any side effects during or after taking Bisolvon Chesty Forte Tablets, so that these may be properly treated.

In addition, unexpected effects, not listed above, can occur with any medicine.

You should tell your doctor or pharmacist if you notice anything unusual, during or after taking Bisolvon Chesty Forte Tablets.

After taking Bisolvon Chesty Forte Tablets

Storage

Bisolvon Chesty Forte Tablets should be kept in a cool dry place where the temperature stays below 25°C.

Do not store in direct sunlight or heat.

For example, do not leave it in the car on hot days.

Keep Bisolvon Chesty Forte Tablets where children cannot reach it.

Product Description

What is Bisolvon Chesty

Bisolvon Chesty Forte Tablets 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. The other is impressed with the company logo.

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

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.

*not currently distributed

Ingredients

Each Bisolvon Chesty Forte tablet contains bromhexine hydrochloride 8 mg.

Bisolvon Chesty Forte Tablets also contain:

- lactose
- maize starch
- magnesium stearate.

Manufacturer

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

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