

Bisolvon® Chesty Kids Oral Liquid

Bromhexine hydrochloride

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Bisolvon Chesty Kids Oral Liquid.

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 Kids Oral Liquid.

You may need to read it again later.

To find out more about Bisolvon Chesty Kids Oral Liquid:

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

What Bisolvon Chesty Kids Oral Liquid is used for

Bisolvon Chesty Kids 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.

Bisolvon Chesty Kids Oral Liquid contains bromhexine hydrochloride, which thins and loosens mucus to help clear chest congestion. Relieves chesty coughs and breathing difficulties due to excess mucus in cold, flu and respiratory tract infections.

Before you take Bisolvon Chesty Kids Oral Liquid

When you must not take Bisolvon Chesty Kids Oral Liquid

Do not take Bisolvon Chesty Kids Oral Liquid if you are allergic to bromhexine or to any of the other ingredients in Bisolvon Chesty Kids Oral Liquid.

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

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

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 Kids 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 Kids Oral Liquid if the cap seal is broken or the packaging is torn or shows signs of tampering.

Before you start to take Bisolvon Chesty Kids Oral Liquid

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 Kids Oral Liquid.

Before taking Bisolvon Chesty Kids Oral Liquid, 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 Kids 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 Kids Oral Liquid 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 Kids Oral Liquid must be assessed against any risks. Your doctor will discuss the risks and benefits of using Bisolvon Chesty Kids Oral Liquid while you are pregnant.

The use of Bisolvon Chesty Kids Oral Liquid 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 Kids Oral Liquid is expected to enter the breast milk.

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

Children

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

Taking Bisolvon Chesty Kids Oral Liquid

Recommended dose

Use the enclosed measuring cup to measure the doses correctly.

The recommended doses for Bisolvon Chesty Kids Oral Liquid in adults and children are stated below:

Children 6 - 11 years:

10 mL three times a day when necessary.

Adults and children over 12 years:

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.

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

If you have taken too much Bisolvon Chesty Kids Oral Liquid

Immediately telephone your doctor, pharmacist or the Poisons Information Centre (telephone 13 11 26 in Australia) if you think you or anyone else may have taken too much Bisolvon Chesty Kids Oral Liquid.

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

While you are taking Bisolvon Chesty Kids Oral Liquid

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

The maximum recommended daily dose of Bisolvon Chesty Kids 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 Kids 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 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 Kids Oral Liquid or if a new treatment plan is needed.

Stop taking Bisolvon Chesty Kids 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.

Effects on ability to drive or operate machinery

When used as recommended, and when there are no side effects, Bisolvon Chesty Kids Oral Liquid is 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 Kids Oral Liquid.

Side effects from Bisolvon Chesty Kids Oral Liquid 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 Kids Oral Liquid. 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 Kids Oral Liquid, 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 Kids Oral Liquid.

After taking Bisolvon Chesty Kids Oral Liquid

Storage

Bisolvon Chesty Kids Oral Liquid 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 Kids Oral Liquid where children cannot reach it.

Product Description

What is Bisolvon Chesty Kids Oral Liquid

Bisolvon Chesty Kids 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 a fruity aromatic odour of strawberry.

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

Each carton is labelled with the Australian Registration Number AUST R 182576.

Ingredients

Each 5 mL of Bisolvon Chesty Kids Oral Liquid contains bromhexine hydrochloride 4 mg.

The other ingredients contained in Bisolvon Chesty Kids Oral Liquid are:

- maltitol solution
- sucralose
- benzoic acid
- hydroxyethylcellulose
- strawberry flavour -1200M
- cherry flavour 96323-33
- purified water.

Manufacturer

Bisolvon Chesty Kids Oral Liquid is made in France.

Bisolvon Chesty Kids Oral Liquid is supplied in Australia by:

BOEHRINGER INGELHEIM PTY LIMITED

ABN 52 000 452 308

78 Waterloo Road

North Ryde NSW 2113



Date of first inclusion in the Australian Register of Therapeutic Goods: 24 April 2011.

This leaflet was amended December 2012.

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