

Bisolvon® Dry Pastilles

Active ingredient: Dextromethorphan hydrobromide monohydrate

Consumer Medicine Information (CMI)

This leaflet provides important information about using Bisolvon Dry Pastilles. **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 Dry Pastilles.**

Where to find information in this leaflet:

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1. Why am I using Bisolvon Dry Pastilles?

Bisolvon Dry Pastilles contains the active ingredient dextromethorphan hydrobromide monohydrate.

Bisolvon Dry Pastilles are a cough suppressant that acts on the cough centre in the brain to suppress a dry cough.

Bisolvon Dry Pastilles are used for the treatment of dry, irritating coughs.

Bisolvon Dry Pastilles also helps soothe sore throats.

Bisolvon Dry Pastilles does not have any pain-relieving (analgesic) properties.

2. What should I know before I use Bisolvon Dry Pastilles?

Warnings

This medicine can lead to dependence. Therefore, the treatment should be of short duration.

Do not use Bisolvon Dry Pastilles if:

- You are allergic to dextromethorphan hydrobromide monohydrate (active ingredient), or any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin
- you have the following medical conditions:
 - asthma

- a lung condition called chronic obstructive airways disease (COAD or COPD)
- respiratory failure
- pneumonia
- shallow breathing (respiratory depression)
- fructose intolerance
- mastocytosis

- you are taking, or have taken in the previous 14 days an antidepressant such as a monoamine oxidase inhibitor (MAOI) used to treat depression and Parkinson's disease.

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, talk to your doctor or pharmacist.

Before you start to take it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Your doctor can discuss with you the risks and benefits involved.

Tell your doctor or pharmacist if you have developed a chesty, mucus-producing (productive) cough.

Tell your doctor if your irritant, dry cough has lasted for more than 5 days.

This could be a symptom of a condition that requires treatment by your doctor.

Tell your doctor or pharmacist if you have impaired liver or kidney function.

Bisolvon Dry Pastilles should also be used with caution in patients with impaired liver or kidney function.

If you have not told your doctor or pharmacist about any of the above, tell him/her before you start taking Bisolvon Dry Pastilles.

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 [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Tell your doctor if you are pregnant or plan to become pregnant.

Your doctor can discuss with you the risks and benefits involved.

Do not take this medicine if you are breastfeeding, or intend to breastfeed.

The active ingredient in Bisolvon Dry Pastilles may pass into breast milk and there is a possibility that your baby may be affected.

Use in children

Do not use Bisolvon Dry Pastilles 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.

Some medicines and Bisolvon Dry Pastilles may interfere with each other. These include:

- monoamine oxidase inhibitors (MAOIs), medicines used to treat depression
- medicines used to treat mental disorders, such as haloperidol
- medicines used to treat depression such as SSRI (selective serotonin reuptake inhibitors) used to treat depression and anxiety e.g. fluoxetine or paroxetine or tricyclic antidepressants e.g. clomipramine and imipramine
- medicines with a sedative or suppressant effect on the body
- medicines containing alcohol
- antiarrhythmics, medicines used to treat irregular heartbeats e.g. quinidine, amiodarone, flecainide
- berberine, an antioxidant medicine
- bupropion, a medicine used for smoking cessation
- cinacalcet, a medicine used to treat an over active thyroid
- terbinafine, a medicine used to treat fungal infections
- cimetidine, a medicine used to treat reflux and ulcers
- ritonavir, a medicine used to treat HIV infections

These medicines may be affected by Bisolvon Dry Pastilles or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

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 Dry Pastilles.

4. How do I use Bisolvon Dry Pastilles?

- Follow the instructions provided with the medicine.
- **Do not exceed the recommended dosage.**
- While rare cases of dextromethorphan abuse and dependency have been reported, including cases in children and adolescents.

How much and when to take

The recommended doses for Bisolvon Dry Pastilles in adults and children are stated below:

Children 6 – 11 years:

- Slowly suck 1 pastille every 4 to 6 hours when necessary.
- **Do not exceed 6 pastilles in a 24 hour period.**

Adults and children 12 years and over:

- Slowly suck 1 - 3 pastilles every 4 to 6 hours when necessary.

Do not exceed 12 pastilles in a 24 hour period.

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

Bisolvon Dry Pastilles starts to act within an hour after being taken and is effective for approximately 3-6 hours.

Serious adverse events, including neurological disorders, may occur in children in case of overdose.

Caregivers should not exceed the recommended dose.

How long to take it

- If the cough persists for more than 5 days, seek medical advice before continuing to take this medicine. The active ingredient dextromethorphan has minor addictive potential.

If you forget to take it

If it is almost time for your next dose and you think you need it, skip the dose you missed and take your next dose.

Do not take a double dose to make up for the dose that you missed.

This may increase the chance of you getting an unwanted side effect. Your next dose should be taken in 4 to 6 hours if you think you need it.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering when to take your medicine, ask your pharmacist for some hints.

If you use too many Bisolvon Dry Pastilles

If you think that you have used too many Bisolvon Dry Pastilles, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26 in Australia
- by calling 0800 764 766 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.

Signs of an overdose with Bisolvon Dry Pastilles include:

- nausea
- vomiting

- impaired vision
- lack of muscle coordination
- dizziness/sleepiness
- inability to pass urine
- fast heart beat
- impaired consciousness
- shallow breathing
- agitation
- hyperexcitability
- hallucinations
- disorientation
- delusions
- confused/paranoid state
- clumsiness and lack of coordination
- uncontrollable muscle spasms affecting the eyes, head, neck and body
- convulsions

Other symptoms of massive overdose may include:

- coma
- convulsions
- severe breathing problems

5. What should I know while using Bisolvon Dry Pastilles?

Things you should do

Remind any doctor, dentist or pharmacist you visit that you are using Bisolvon Dry Pastilles.

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 Dry Pastilles or if a new treatment plan is needed.

Driving or using machines

Be careful driving or operating machinery until you know how Bisolvon Dry Pastilles affects you.

This medicine may cause dizziness or drowsiness in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

Drinking alcohol

Tell your doctor if you drink alcohol.

Avoid drinking alcohol while you are taking this medicine.

If you drink alcohol, dizziness or drowsiness may be worse.

Looking after your medicine

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

- Keep Bisolvon Dry Pastilles 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

Heat and dampness can destroy some medicines.

Keep Bisolvon Dry Pastilles where children cannot reach it.

A locked cupboard at least one-and-one-half metres above the ground is a good place to store medicines.

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?

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Bisolvon Dry Pastilles.

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.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

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 Dry Pastilles.

In general, side effects from Bisolvon Dry Pastilles are rare. The most common side effects include:

Side effects	What to do
Gastrointestinal related • nausea • vomiting • constipation • reduced appetite • gastrointestinal disorders Head and neurology related • confusion • drowsiness • dizziness General • fatigue • allergic reactions	Speak to your doctor if you have any of these side effects and they worry you.

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell, during or after taking Bisolvon Dry Pastilles.

Other side effects not listed above may also occur in some people.

Bisolvon Dry Pastilles contain 10.2 g of maltitol and 0.8 g of sorbitol per maximum adult daily dose of 12 pastilles. Products containing maltitol and sorbitol may have a laxative effect or cause diarrhoea.

This is more likely if several products containing maltitol, sorbitol or other related substances are consumed at the same time.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects as follows:

For Australia: Therapeutic Goods Administration online at:
www.tga.gov.au/reporting-problems.

New Zealand: Medsafe online at:
<https://www.medsafe.govt.nz/safety/report-a-problem.asp>

By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

58 Richard Pearse Drive

Airport Oaks

Auckland

New Zealand

Phone: (09) 918 5100

Registration No AUST R 191459

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7. Product details

Bisolvon Dry Pastilles is the brand name of your medicine.

What Bisolvon Dry Pastilles contains

Active ingredient (main ingredient)	Each Bisolvon Dry Pastille contains dextromethorphan hydrobromide monohydrate 10 mg
Other ingredients (inactive ingredients)	• betadex • acacia • sodium cyclamate • saccharin sodium • quinoline yellow C147005 • limette flavour 18635/02 • honey flavour 8366/001 • menthol • citric acid • maltitol solution • paraffin light liquid • beeswax white • purified water

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

What Bisolvon Dry Pastilles look like

Bisolvon Dry Pastilles is a yellow, round pastille with a honey lime flavour. It is available in blisters containing 20 pastilles enclosed in a carton.

Bisolvon Dry Pastilles are available from your local pharmacy without a prescription.

Who distributes Bisolvon Dry Pastilles

Bisolvon Dry Pastilles are supplied in Australia by:

Sanofi Consumer Healthcare

87 Yarraman Place, Virginia

Qld 4014 Australia

Toll-free: 1800 818 806

Bisolvon Dry Pastilles are supplied in New Zealand by:

Healthcare Logistics