

Bisolvon® Dry Pastilles

Dextromethorphan hydrobromide monohydrate

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Bisolvon Dry Pastilles.

It does not contain all the available information.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits.

If you have any concerns about taking this medicine, ask 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 (Australia) and www.medsafe.govt.nz/Consumers/cmi/CMIForm.asp (New Zealand) and may contain important information about the medicine and its use of which you should be aware.

Keep this information with your medicine.

You may need to read it again.

What Bisolvon Dry Pastilles is used for

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

Bisolvon Dry Pastilles contains the active ingredient dextromethorphan hydrobromide, a cough suppressant that acts on the cough centre in the brain to suppress a dry cough.

Bisolvon Dry Pastilles also helps soothe sore throats.

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

Before you take Bisolvon Dry Pastilles

When you must not take it

Do not take Bisolvon Dry Pastilles if you have any allergy to:

- any medicine containing dextromethorphan hydrobromide (active ingredient)
- 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.

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.

Do not take Bisolvon Dry Pastilles if 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.

Do not take this medicine if you are taking, or have taken in the previous 14 days a monoamine oxidase inhibitor (MAOI).

Do not give this medicine to a child under the age of 6 years. Use in children 6 - 11 years only on the advice of a doctor, pharmacist or nurse practitioner.

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.

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

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.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get 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) 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.

How to take Bisolvon Dry Pastilles

How much to take

Bisolvon Dry Pastilles should be taken according to the following dosage directions:

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.

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 have taken too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (in Australia telephone 13 11 26; in New Zealand telephone 0800 764 766) for advice, or go to Emergency at the nearest hospital, if you think that you or anyone else may have taken too much Bisolvon Dry Pastilles. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

Signs of an overdose with Bisolvon Dry Pastilles include:

- nausea
- vomiting
- impaired vision
- lack of muscle coordination
- dizziness
- inability to pass urine
- fast heart beat
- impaired consciousness
- shallow breathing.

While you are taking Bisolvon Dry Pastilles

Things to be careful of

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.

Avoid drinking alcohol while you are taking this medicine.

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

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. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

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

Ask your doctor or pharmacist to answer any questions you may have.

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

- confusion
- drowsiness
- dizziness
- nausea
- vomiting
- constipation
- reduced appetite
- gastrointestinal disorders
- allergic reactions
- fatigue

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

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

Tell your doctor or pharmacist if you notice anything unusual, during or after taking Bisolvon Dry Pastilles.

Cases of dextromethorphan abuse and dependency have been reported. Your doctor can provide you with more information about this.

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.

After taking Bisolvon Dry Pastilles

Storage

Keep Bisolvon Dry Pastilles in a cool dry place, where the temperature stays below 25°C.

Do not store Bisolvon Dry Pastilles or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.

Heat and dampness can destroy some medicines.

Keep it 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.

Disposal

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

Bisolvon Dry Pastilles is the brand name of your medicine.

What it looks 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.

Ingredients

Each Bisolvon Dry Pastille contains:

- dextromethorphan hydrobromide monohydrate 10 mg

and the following ingredients:

- betadex
- acacia
- sodium cyclamate
- saccharin sodium
- quinoline yellow CI47005
- limette flavour 18635/02
- honey flavour 8366/001
- menthol
- citric acid anhydrous
- maltitol solution
- paraffin light liquid
- beeswax white
- purified water.

Supplier

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:

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

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