

Bronchitol[®]

Mannitol

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Bronchitol.

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. Your doctor has weighed the risks of you taking Bronchitol against the benefits they expect it will have for you.

If you have any concerns about taking Bronchitol, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What Bronchitol is used for

Bronchitol is used to treat Cystic Fibrosis.

Bronchitol is inhaled into the lungs to relieve the symptoms of cystic fibrosis. It does this by helping to clear mucus from the lungs.

Bronchitol contains the active ingredient mannitol.

It works by increasing the amount of water on the surface of your airways and in your mucus. This helps your lungs to clear mucus more easily. It also helps improve the condition of your lungs and your breathing. As a result, you may get a 'productive cough', which also helps to remove mucus from your lungs.

Your doctor may have prescribed Bronchitol for another reason. Ask your doctor if you have any

questions about why Bronchitol has been prescribed for you.

There is no evidence that Bronchitol is addictive.

This medicine is available only with a doctor's prescription.

Before you take Bronchitol

Before you are started on Bronchitol, your doctor will check whether your airways are too sensitive to mannitol.

This is done by giving your first (initiation) dose of Bronchitol under strictly controlled conditions.

Your doctor will monitor you while you take your initiation dose and determine if you are sensitive to mannitol.

If you are too sensitive to mannitol, your airways will become narrower, and you may find it harder to breathe.

When you must not take it

Do not take Bronchitol if you have an allergy to Bronchitol (mannitol) or gelatin 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.

Do not take Bronchitol if:

- your doctor has not tested if you are sensitive to mannitol.
- you have previously experienced severe symptoms of difficulty breathing, wheezing or coughing after inhaling mannitol.

If any of the above apply to you (or you are not sure), talk to your doctor before using Bronchitol.

Do not give Bronchitol to a child under 6 years, unless directed to by the child's doctor.

Bronchitol is not recommended for use in children under 6 years because there have not been any studies in children of this age group.

Do not take Bronchitol after the expiry date (EXP) printed on the pack.

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

Do not take Bronchitol if the packaging is torn or shows signs of tampering.

If you are not sure whether you should start using Bronchitol, contact your doctor or pharmacist.

Tell your doctor if:

- you have allergies to any other medicines, foods, preservatives or dyes.

Your doctor may want to take special precautions if you have any of these conditions.

Take special care with Bronchitol if:

- you have ever coughed up blood or had blood in your sputum
- you have asthma

- you have severe cystic fibrosis, in particular if your lung function (FEV1) is usually less than 30%

If any of the above apply to you (or you are not sure), talk to your doctor or pharmacist before using Bronchitol.

Tell your doctor or pharmacist if you are pregnant or plan to become pregnant or are breast-feeding.

Your doctor can discuss the possible risks involved.

Taking other medicines

Tell your doctor or pharmacist if you are using any other medicines, including any that you buy without a prescription from your pharmacy, supermarket or health food shop.

You can carry on using your medicines for cystic fibrosis when you are using Bronchitol. If you are not sure, talk to your doctor or pharmacist before using Bronchitol.

How to take Bronchitol

Do not swallow the capsules.

The powder in the capsules must only be inhaled using the inhaler device included in the carton. Each pack of Bronchitol contains an instruction leaflet that tells you the correct way to use the inhaler device. Please read this carefully.

Follow all directions given to you by your doctor carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the box, ask your doctor or pharmacist for help.

If you are not sure how to use an inhaler, ask your doctor or pharmacist.

Children should only use their inhaler with the help of an adult.

How much to take

The usual dose of Bronchitol is the contents of 10 capsules (400 mg) inhaled twice a day.

How to take it

Full instructions on how to use the inhaler device are provided in a leaflet with the pack. **Follow the instructions in the leaflet carefully.**

If you have any problems inhaling Bronchitol using the inhaler device, ask your doctor or pharmacist for assistance.

When to take it

Take Bronchitol in the morning and 2-3 hours before bedtime. You should take your bronchodilator 5-15 minutes before taking Bronchitol, and physiotherapy is usually done after taking Bronchitol.

If you forget to take it

If you forget to take a dose of Bronchitol, skip the dose you missed and take your next dose when you are meant to.

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

How long to take it

Keep taking your medicine for as long as your doctor or pharmacist tells you.

Bronchitol helps treat the symptoms of cystic fibrosis but does not cure it.

Do not stop using it unless your doctor or pharmacist tells you to - even if you feel better.

If you take too much (overdose)

Telephone your doctor or pharmacist or the Poisons Information Centre (telephone Australia 13 11 26, or go to Accident and Emergency at your nearest hospital if you think that you or anyone else may have taken too much Bronchitol.

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

If you take too much Bronchitol, you may feel that you cannot breathe, become wheezy or cough. These symptoms are usually mild side effects of using Bronchitol. However, if they are severe or do not go away, it may be that you have taken too much Bronchitol. If large quantities of Bronchitol capsules are swallowed it may cause diarrhoea.

While you are using Bronchitol

Things you must do

Continue using Bronchitol for as long as your doctor tells you.

If your breathing becomes more difficult while you are taking Bronchitol, stop taking it, and tell your doctor immediately.

Visit your doctor regularly to check on your condition.

Tell any other doctors, dentists, and pharmacists who are treating you that you are using Bronchitol.

If you are about to be started on any new medicine, tell your doctor or pharmacist that you are using Bronchitol.

If you plan to have surgery, tell your doctor or dentist that you are using Bronchitol.

If you become pregnant while using Bronchitol, tell your doctor.

Things you must not do

Do not give Bronchitol to anyone else, even if they have the same condition as you.

Do not take Bronchitol to treat any other complaints unless your doctor tells you to.

Do not stop using Bronchitol, or lower the dosage, without checking with your doctor.

When taken as recommended, and when there are no side effects, Bronchitol is not known to have any effect on the ability to drive or operate machinery.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using Bronchitol.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

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

If you get any side effects, do not stop using Bronchitol without first talking to your doctor or pharmacist.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

Common (likely to affect less than 1 in 10 but more than 1 in 100 people):

- cough
- headache
- blood in your sputum
- tightening or restriction of your airway
- mouth, tongue or throat pain

- vomiting
- chest discomfort

It is important to understand that Bronchitol works by making the mucus in your lungs more fluid and thus easier to cough up. A productive cough may actually be a helpful side effect.

Other side effects not listed above may occur in some patients. Tell your doctor or pharmacist if you notice anything else that is making you feel unwell.

This is not a complete list of side effects. Other side effects not listed above may also occur in some people and there may be some side effects not yet known.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

After using Bronchitol

Cleaning

Replace the inhaler device after you have used it for 1 week. If for some reason you feel the need to clean the inhaler, wash it in warm water and allow it to thoroughly air dry for 24 hours before use.

Storage

Keep Bronchitol in a cool dry place where the temperature stays below 30°C.

Do not store Bronchitol or any other medicine in the bathroom or near a sink.

Do not leave it in the car on hot days or on window sills.

Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the

ground is a good place to store medicines.

Disposal

The inhaler device should be thrown away after 7 days of use.

If your doctor or pharmacist tells you to stop using Bronchitol or it has passed its expiry date, ask your pharmacist what to do with any that is left over.

Product Description

What it looks like

Bronchitol capsules are clear capsules containing white powder with "PXS 40 mg" imprinted on them.

The capsules are supplied in blister strips of 10 capsules.

The inhaler is off-white with blue buttons.

The Initiation Dose pack contains:

- 1 blister strip (10 capsules)
- 1 Inhaler

The 7-day pack contains:

- 14 blister strips (140 capsules)
- 1 Inhaler

The 14-day pack contains:

- 28 blister strips (280 capsules)
- 2 Inhalers

Ingredients

Active Ingredients

Bronchitol capsules contain 40 mg of the active ingredient mannitol.

Inactive Ingredients

There are no inactive ingredients in the Bronchitol powder.

The capsules containing the powder are made from gelatin. The capsules are not inhaled or swallowed.

Bronchitol does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

Supplier

Bronchitol is manufactured and supplied in Australia by:

Pharmaxis Ltd

20 Rodborough Road

Frenchs Forest NSW 2086

Tel: (02) 9454 7200

Australian Registration Number

AUST R 168002

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