

Package Leaflet: Information for the user

Bronchitol 40 mg inhalation powder, hard capsules Mannitol

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Bronchitol is and what it is used for
2. What you need to know before you use Bronchitol
3. How to use Bronchitol
4. Possible side effects
5. How to store Bronchitol
6. Contents of the pack and other information

1. What Bronchitol is and what it is used for

What Bronchitol is

Bronchitol contains a medicine called mannitol which is a mucolytic agent.

What Bronchitol is used for

Bronchitol is for use in adults 18 years of age and over. As well as using Bronchitol you will normally keep using the other medicines you take for cystic fibrosis.

How Bronchitol works

Bronchitol is inhaled into the lungs to help with cystic fibrosis, an inherited disease that affects the glands in the lungs, gut and pancreas that secrete fluids such as mucus and digestive juices.

Bronchitol helps 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.

2. What you need to know before you use Bronchitol

Do not use Bronchitol

- if you are allergic to mannitol
- if you are sensitive to mannitol. Before you are started on Bronchitol, your doctor will check whether your airways are too sensitive to mannitol. If you are too sensitive to mannitol, your airways will become narrower, and you may find it harder to breathe.

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

Warnings and precautions

Talk to your doctor or pharmacist before using this medicine:

- if you have asthma;

- if you have ever coughed up blood or had blood in your sputum;
- if you have severe cystic fibrosis, in particular if your lung function measured by the Forced Expiratory Volume in first second of expiration (FEV₁) is usually less than 30%.

Inhaling medicines can cause chest tightness and wheezing and this can happen immediately after taking this medicine. Your doctor will help you take your first dose of Bronchitol and check your lung function before, during and after dosing. Your doctor may ask you to use other medicines such as a bronchodilator before taking Bronchitol.

Inhaling medicines can also cause cough and this can happen with Bronchitol. Talk to your doctor if the cough won't go away or worries you.

Children and adolescents

Bronchitol should not be used by children and adolescents under the age of 18. This is because there is limited information in this group of people.

Other medicines and Bronchitol

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

You can carry on using your medicines for cystic fibrosis when you are using Bronchitol, this includes inhaled antibiotics such as tobramycin and colistimethate sodium. If you are not sure, talk to your doctor or pharmacist before using Bronchitol.

Pregnancy and breast-feeding

- If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor for advice before using this medicine. You should avoid using this medicine if you are pregnant.
- If you are breast-feeding or plan to breast-feed ask your doctor for advice before using this medicine. It is not known if this medicine passes into the breast milk.

Driving and using machines

Bronchitol is not likely to affect your ability to drive or use any tools or machines.

3. How to use Bronchitol

Always use this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Always take your bronchodilator before using Bronchitol.

How much to use

Adults 18 years of age and over

Initiation dose

Before you are prescribed Bronchitol your doctor will help you take your first dose of Bronchitol and test your lung function at each step to make sure you aren't sensitive to mannitol. The first dose is taken in 4 steps:-

- Step 1 – 1 capsule (40 mg)
- Step 2 – 2 capsules (80 mg)
- Step 3 – 3 capsules (120 mg)
- Step 4 – 4 capsules (160 mg)

At the end of the initiation dose you will have taken 10 capsules (400 mg) which is the same as the usual dose.

Treatment dose (2-week packs)

- You must use Bronchitol every day.
- The usual dose is 10 capsules (400 mg) inhaled in the morning, and 10 capsules inhaled in the evening.
- Have the evening dose at least 2 to 3 hours before you go to bed.
- For the best results, inhale each capsule one after another, so there is as little delay as possible between capsules.

Order of using this medicine

Use Bronchitol as part of your normal daily treatment routine. The suggested order is as follows, unless otherwise advised by your doctor:

1. Use your bronchodilator;
2. Wait 5 to 15 minutes;
3. Use your Bronchitol before physiotherapy if this is part of your treatment routine.
4. Dornase alfa (Pulmozyme) if this is part of your treatment routine
5. Inhaled antibiotics if this is part of your treatment routine

How to use your medicine

- Bronchitol is breathed in (inhaled) as a powder from the capsule using the inhaler supplied in the pack. It is for inhalation use only and must not be administered by any other route. The capsules must not be swallowed.
- The powder in the capsules must only be inhaled using the inhaler included in the pack.
- Use a new inhaler each week.
- Each of the ten capsules is put into the inhaler one at a time.
- Inhale the contents of the capsule using the inhaler, with one or two breaths in.

For instructions on how to use the inhaler, see the end of the leaflet.

If you use more Bronchitol than you should

If you think you have used too much medicine, tell your doctor or pharmacist straight away. You may:

- feel that you cannot breathe;
- become wheezy;
- cough a lot.

The doctor may give you oxygen and medicines to help you breathe.

If you forget to use Bronchitol

- If you forget a dose, use it as soon as you remember it and carry on as usual. However, if it is nearly time for the next dose, skip the missed dose.
- Do not use a double dose to make up for a forgotten dose.

If you stop using Bronchitol

If you stop using Bronchitol your symptoms may get worse. Do not stop using your Bronchitol without talking to your doctor first, even if you feel better. Your doctor will tell you how long to use this medicine for.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Stop using Bronchitol and see a doctor straight away if you notice the following serious side effects:

- Difficulty breathing, which may be due to narrowing of the airways, worsening of asthma symptoms or wheezing. This happens commonly, which may affect up to 1 in 10 people.
- Coughing up blood or blood in your sputum. This happens commonly.

Tell your doctor straight away if you notice any of the following side effects:

- Severe cough. This happens commonly.
- Worsening of symptoms. This happens commonly.

Other side effects include:

Common (May affect up to 1 in 10 people)

- Cough
- Chest discomfort
- Headache
- Pain in the back of your mouth and throat and discomfort when swallowing
- Vomiting, vomiting after coughing

Uncommon (may affect up to 1 in 100 people)

- Burning or painful sensation on the tongue
- CF related diabetes
- Chest and abdominal pain
- Change in voice
- Cold sweat
- Congestion
- Dehydration
- Decreased appetite
- Diarrhoea
- Ear pain
- Feeling tired
- Feeling dizzy
- Feeling sick (nausea)
- Feeling unwell
- Flu and fever
- Wind
- Heartburn
- Hernia pain
- Hyperventilation
- Itching, rash, acne
- Joint stiffness and pain
- Morbid thoughts
- Mouth ulcers
- Respiratory tract infection
- Runny nose
- Sputum infection
- Throat irritation
- Trouble sleeping
- Yeast infection of the mouth (thrush)
- Unintentional loss of urine

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme in the UK, Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. In Ireland to HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517; Website: www.hpra.ie; e-mail: medsafety@hpra.ie
By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Bronchitol

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and blister after EXP. The expiry date refers to the last day of that month.

Store below 30°C.

Store in the original package in order to protect from moisture.

Once removed from the blister a capsule should be used immediately.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Bronchitol contains:

The active substance is mannitol. Each capsule contains 40 milligrams mannitol. Average inhaled dose per capsule is 32.2 milligrams mannitol.

What Bronchitol looks like and contents of the pack:

Bronchitol is a powder for inhalation that is filled into hard capsules. Bronchitol 40 mg inhalation powder, hard capsules contain a white or almost white powder filled into clear, colourless, hard, capsules with "PXS 40 mg" imprinted on them. The powder is inhaled into the lungs using the inhaler provided in the pack.

One initiation dose pack of Bronchitol contains 1 blister with 10 capsules and 1 inhaler. The initiation dose pack is used during the initiation dose assessment with your doctor.

One 2-week treatment pack of Bronchitol contains 28 blisters with 10 capsules each (280 capsules in total) and 2 inhalers. The 2-week treatment pack is for treatment use.

Marketing Authorisation Holder

Pharmaxis Europe Limited, 108 Q House, Furze Road, Sandyford, Dublin 18, D18AY29, Ireland.

Manufacturer

Mawdsleys Clinical Services, Unit 22, Quest Park, Wheatley Hall Road, Doncaster, DN2 4LT, United Kingdom.

Arvato distribution GmbH, Gottlieb-Daimler Straße 1, 33428 Harsewinkel, North Rhine-Westphalia

Germany

For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder:

België/Belgique/Belgien
Pharmaxis Europe Limited
Tél/Tel: + 353 (0) 1431 9816

България
Pharmaxis Europe Limited
Тел.: + 353 (0) 1431 9816

Česká republika
4 Life Pharma CZ, s.r.o.
Tel: +420 244 403 003

Danmark
Chiesi Pharma AB
Tlf: + 46 8 753 35 20

Deutschland
Chiesi GmbH
Tel: +49 (0) 40 897 240

Eesti
PharmaSwiss Eesti OÜ
Tel: + 372 6827400

Ελλάδα
Chiesi Hellas A.E.B.E.
Τηλ: + 30.210.617.97.63

España
Medicare Pharma S.L.C
Tel: +34 91 848 9534

France
Pharmaxis Europe Limited
Tél: + 353 (0) 1431 9816

Hrvatska
PharmaSwiss d.o.o
Tel: + 385(1)6311-833

Ireland
Chiesi Limited
Tel: + 44 (0)161 488 5555

Ísland

Lietuva
AB "PharmaSwiss
Tel: + 370 5 279 07 62

Luxembourg/Luxemburg
Pharmaxis Europe Limited
Tél/Tel: + 353 (0) 1431 9816

Magyarország
Pharmaxis Europe Limited
Tel.: + 353 (0) 1431 9816

Malta
Pharmaxis Europe Limited
Tel: + 353 (0) 1431 9816

Nederland
Pharmaxis Europe Limited
Tel: + 353 (0) 1431 9816

Norge
Chiesi Pharma AB
Tlf: + 46 8 753 35 20

Österreich
Pharmaxis Europe Limited
Tel: + 353 (0) 1431 9816

Polska
IMED Poland Sp. z o. o.
Tel: +48 22 663 43 10

Portugal
Pharmaxis Europe Limited
Tel: + 353 (0) 1431 9816

România
Pharmaxis Europe Limited
Tel: + 353 (0) 1431 9816

Slovenija
PharmaSwiss d.o.o
Tel: + 386 (0) 1 2364 700

Slovenská republika

Pharmaxis Europe Limited
Sími: + 353 (0) 1431 9816

4 Life Pharma SK, s.r.o.
Tel: + 420 244 403 003

Italia

Chiesi Farmaceutici S.p.A
Tel: +39 0521 2791

Suomi/Finland

Chiesi Pharma AB
Puh/Tel: + 46 8 753 35 20

Κύπρος

Chiesi Hellas A.E.B.E.
Τηλ: + 30.210.617.97.63

Sverige

Chiesi Pharma AB
Tel: + 46 8 753 35 20

Latvija

UAB PharmaSwiss
Tel: + 371 67502185

United Kingdom

Chiesi Limited
Tel: + 44 (0)161 488 5555

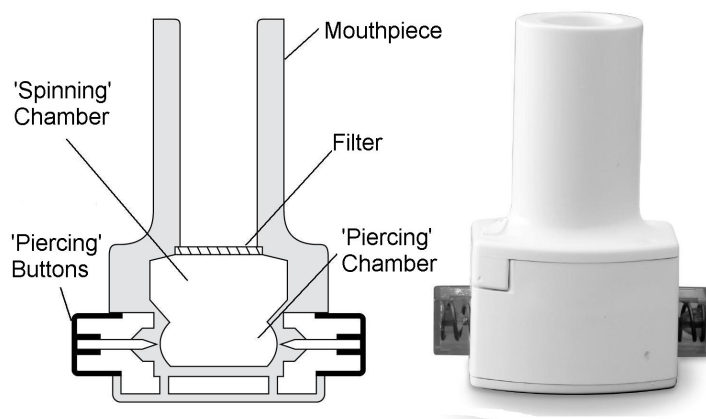
This leaflet was last revised in 01/2020.

Other sources of information

Detailed information on this medicine is available on the European Medicines Agency web site: <http://www.ema.europa.eu/>. There are also links to other websites about rare diseases and treatments.

How to use the inhaler

Below is a diagram that shows what the inhaler looks like. Bronchitol capsules can only be used with the inhaler provided in the pack.



Inhaler device

The following steps explain how to use the inhaler. For more advice on how to look after your inhaler, please see the end of the instructions.

1. Take off the cap

- Using both hands, hold the inhaler upright and take off the cap.



2. Open the inhaler

- Hold the bottom of the inhaler firmly with one hand.
- You should hold the inhaler along the bottom to make sure you don't press the piercing buttons.
- Then open it by turning the mouth-piece in the direction of the arrow on the inhaler.



3. Put in the capsule

- First make sure your hands are dry.
- Then take out a capsule from the blister (only remove the capsule just before use).
- Put the capsule into the capsule-shaped space in the bottom of the inhaler.



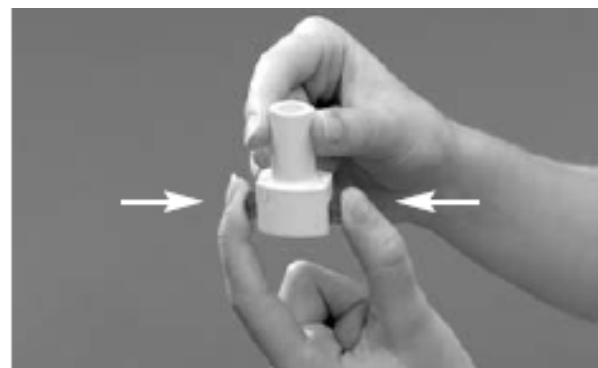
4. Close the inhaler

- Keep the inhaler in an upright position.
- Then twist the mouth-piece into the closed position - when it is closed you will hear a 'click'.



5. Make a hole in the capsule

- This lets the powder in the capsule be released when you breathe in. In this leaflet we call making the hole 'piercing'.
- Hold the inhaler upright and fully press in both 'Piercing' buttons on the sides of the inhaler at the same time, then release them. Only do this once. This is because piercing the capsule more than once may make it split or break-up.



6. Prepare for inhalation

- Tilt the inhaler so that the mouth-piece faces slightly downward.
- This allows the capsule to drop forward into the spinning chamber.
- Keep the inhaler tilted in this way and breathe out completely (away from the inhaler).



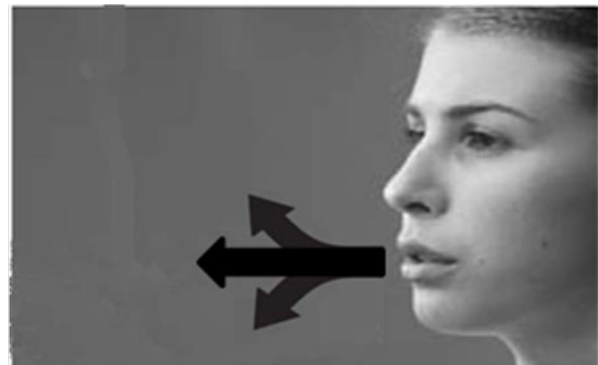
7. Inhale

- Tilt your head back slightly.
- Keeping the inhaler tilted downward, put the inhaler to your mouth and make sure you close your lips tightly around the mouth-piece.
- Take a steady deep breath in, to fill your lungs - then hold your breath for 5 seconds. When you breathe in you should hear a 'rattling' sound as the capsule spins in the inhaler. If this does not happen, the capsule may be stuck.
- If you do not hear the rattling, hold the inhaler with the mouth-piece facing downwards, and tap the bottom firmly. Do not try to loosen the capsule by pressing the piercing buttons again. Repeat the inhalation to get your dose.



8. Breathe out

- Take the inhaler away from your mouth.
- Breathe out, and then breathe normally again.



9. Check the capsule

- Look to see if the capsule is empty - the capsule must spin in the inhaler in order to empty. If the capsule has not emptied you may need to repeat steps 6 to 8.



10. Take out the used capsule

- Turn the inhaler upside down, tap the bottom and throw the empty capsule away.

11. Repeat steps 3 to 10 for each capsule

- Perform these steps for each of the ten capsules.
- To get the best results from Bronchitol, inhale each capsule one after another.

Extra information on how to look after your inhaler

- Keep your inhaler dry and always make sure your hands are dry before using it.
- Never breathe or cough into your inhaler.
- Never take your inhaler apart.
- Never place a capsule directly into the mouth-piece of your inhaler.
- Never leave a used capsule in your inhaler chamber.
- Use a new inhaler each week.
- If your inhaler breaks, use your second inhaler and talk to your doctor.

Cleaning the inhaler - Usually your inhaler will give you the correct dose of medicine for 7 days without needing cleaning. However, if your inhaler does need cleaning, the steps to follow are:

1. Ensure your inhaler is empty.
2. Wash your inhaler in warm water with the mouth-piece open.
3. Shake it until there are no large water droplets left in the inhaler.
4. Leave it to dry in the air - lay it on its side with the mouth-piece open.
5. You must let it fully dry, this can take up to 24 hours. While it is drying, use your other inhaler.