

Package leaflet: Information for the user

Bricanyl® Turbohaler® 500 micrograms per metered dose, inhalation powder terbutaline sulfate

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

1. What Bricanyl Turbohaler is and what it is used for

Bricanyl Turbohaler is an inhaler. It contains a medicine called terbutaline. This belongs to a group of medicines called 'beta-agonists'. These work by relaxing certain muscles and opening up the airways in the lungs.

Bricanyl Turbohaler is used for asthma and other breathing problems where you have a tight chest and difficulty breathing.

2. What you need to know before you use Bricanyl Turbohaler

Do not use Bricanyl Turbohaler:

- If you are allergic to terbutaline.

Warnings and precautions

Talk to your doctor or pharmacist before using Bricanyl Turbohaler if:

- You have diabetes. If so, you may need some extra blood sugar tests when you start using Bricanyl Turbohaler.
- You have a heart problem.
- You have an overactive thyroid gland.

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before using Bricanyl Turbohaler.

Other medicines and Bricanyl Turbohaler

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes medicines that you buy without a prescription and herbal medicines. Bricanyl can affect the way that some medicines work and some medicines can have an effect on Bricanyl.

In particular, tell your doctor or pharmacist if you are taking any of the following medicines:

- Steroid medicines (such as prednisolone).
- Medicines called ‘xanthines’ (such as theophylline).
- Medicines called ‘beta-blockers’ (such as atenolol or propranolol) including eye drops (such as timolol).
- Water tablets (diuretics) such as furosemide (also known as frusemide).
- Monoamine oxidase inhibitors (such as moclobemide).
- Tricyclic antidepressants (such as imipramine or amitriptyline).

If you are to undergo surgery with general anaesthetics it is important that you inform your doctor about all medicines you use, including Bricanyl to protect you from adverse effects (e.g. irregular heart beat).

Pregnancy, breast-feeding and fertility

- If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before using this medicine.
- If you become pregnant while you are using Bricanyl Turbohaler, talk to your doctor straight away.

Driving and using machines

Bricanyl is not likely to affect you being able to drive or use any machines.

Bricanyl Turbohaler contains lactose

Bricanyl Turbohaler contains lactose, which is a type of sugar. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product. The amount of lactose in this medicine does not normally cause problems in people who are lactose intolerant.

The lactose may contain small amounts of milk protein residues. In patients with hypersensitivity to milk proteins, these small amounts may cause allergic reactions.

3. How to use Bricanyl Turbohaler

Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure. If Bricanyl Turbohaler is to be used by a child, make sure that they use it correctly.

Bricanyl Turbohaler should be used as required rather than regularly.

Seek medical attention right away if your asthma symptoms (cough, breathlessness, wheezing or tight chest) are getting worse or if you are too breathless to speak, eat or sleep.

You must contact your doctor as soon as possible if you need higher doses of Bricanyl Turbohaler than usual to relieve your breathing problems. Your doctor may want to change your asthma medicine to improve your breathing.

If you use Bricanyl Turbohaler more than twice a week to treat your asthma symptoms, this indicates poorly controlled asthma and may increase the risk of severe asthma attacks (worsening of asthma) that can have serious complications and may be life-threatening or even fatal. You should contact your doctor as soon as possible to review your asthma treatment.

If you use a medicine against inflammation of your lungs daily, e.g., “inhaled corticosteroid”, it is important to continue using it regularly, even if you feel better.

How much to take

- The recommended dose is one inhalation as required.
- Do not take more than four inhalations in any 24 hour period.
- One inhalation from your Bricanyl Turbohaler should last for up to six hours.

Talk to your doctor straight away if:

- **Your breathing is getting worse.**
- **You often wake at night with asthma.**
- **You start getting a tight chest.**
- **You are not getting relief from your current dose.**

These are signs that your asthma is not being controlled. You may need a different or additional treatment straight away.

Preparing your new Bricanyl Turbohaler Inhaler

Before using your **new** Bricanyl Turbohaler **for the first time**, you need to prepare it for use as follows:

- Unscrew the cover and lift it off. You may hear a rattling sound.
- Hold your Bricanyl Turbohaler Inhaler upright with the blue grip at the bottom.
- Turn the blue grip as far as it will go in one direction. Then turn it as far as it will go in the other direction (it does not matter which way you turn it first).
- You should hear a **click** sound.
- Do this again, turning the blue grip in both directions.
- Your Bricanyl Turbohaler Inhaler is now ready for use.

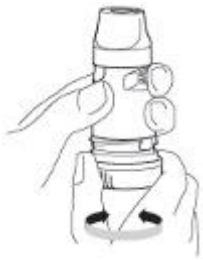
How to take an inhalation

Every time you need to take an inhalation, follow the instructions below.



1. Unscrew the cover and lift it off. You may hear a rattling sound.
2. Hold your Turbohaler upright with the blue grip at the bottom.
3. Do not hold the mouthpiece when you load your Turbohaler. To load your Turbohaler with a dose, turn the blue grip as far as it will go in one direction. Then turn it as far as it will go in the other direction (it does not matter which way you turn it first). You should hear a **click** sound.

Your Turbohaler is now loaded and ready to use. Only load your Turbohaler when you need to use it.



4. Hold your Turbohaler away from your mouth. Breathe out gently (as far as is comfortable). Do not breathe out through your Turbohaler.
5. Place the mouthpiece gently between your teeth. Close your lips. Breathe in as deeply and as hard as you can through your mouth. Do not chew or bite on the mouthpiece.



6. Remove your Turbohaler from your mouth. Then breathe out gently. The amount of medicine that is inhaled is very small. This means you may not be able to taste it after inhalation. If you have followed the instructions, you can be confident that you have inhaled the dose and the medicine is now in your lungs.
7. If you are to take a second inhalation, repeat steps 2 to 6.
8. Replace the cover tightly after use.
9. Rinse your mouth out with water each time after taking your dose, if possible, to remove any medicine that remains in your mouth.

As with all inhalers, caregivers should ensure that children prescribed Bricanyl Turbohaler use correct inhalation technique, as described above.

Do not try to remove the mouthpiece since it is fixed to your Turbohaler and must not be taken off. The mouthpiece can be rotated but do not twist it unnecessarily. Do not use your Turbohaler if it has been damaged or if the mouthpiece has come apart from your Turbohaler.

Cleaning your Turbohaler

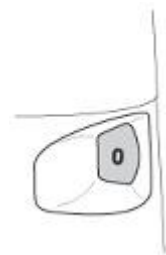
Wipe the outside of the mouthpiece once a week with a dry tissue. Do not use water or liquids.

When to start using a new Turbohaler

The dose indicator tells you how many doses are left in the Turbohaler, starting with 120 doses when it is full.



- The dose indicator is marked in intervals of 10 doses. Therefore, it does not show every dose. When you first see a red mark at the edge of the indicator window, there are approximately 20 doses left. For the last 10 doses, the background of the dose indicator is red. When the '0' on the red background has reached the middle of the window, you must start using your new Turbohaler.



Note:

- The grip will still twist and **'click'** even when your Turbohaler is empty.
- The sound that you hear as you shake your Turbohaler is produced by a drying agent and not the medicine. Therefore, the sound does not tell you how much medicine is left in your Turbohaler.
- If you load your Bricanyl Turbohaler more than once by mistake before taking your dose, you will still only receive one dose. However, the dose indicator will register all the loaded doses.

If you use more Bricanyl Turbohaler than you should

If you use more Bricanyl Turbohaler than you should, contact your doctor or pharmacist for advice.

If you forget to use Bricanyl Turbohaler

- If you forget to take a dose, take it as soon as you remember. However, if it is nearly time for your next dose, skip the missed dose.
- Do **not** take a double dose to make up for a forgotten dose.

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.

Important side effects to look out for:

- Allergic reactions. The signs may include a swollen face, skin rash, breathing problems, low blood pressure (feeling faint) and collapse. It is not known how often this happens. **If this happens to you, stop using Bricanyl Turbohaler and see a doctor straight away.**
- Sudden wheezing soon after inhaling your dose of Bricanyl Turbohaler. It is not known how often this happens. **If this happens to you, stop using Bricanyl Turbohaler and see a doctor straight away.**

Other side effects include:

Very Common (may affect more than 1 in 10 people)

- Trembling or shaking.
- Headache.

Common (may affect up to 1 in 10 people)

- Pounding or rapid heart beat (palpitations).
- Cramp or feeling tense.
- Low levels of potassium in your blood which may cause muscle weakness, thirst, or 'pins and needles'.

Not known (frequency cannot be estimated from the available data)

- Although it is not known exactly how often it happens, some people may occasionally experience chest pain (due to heart problems such as angina). Seek advice from your doctor if you develop these symptoms whilst taking Bricanyl Turbohaler.
- Irregular heartbeats
- Feeling sick (nausea).
- Changes in sleeping patterns and changes in behaviour, such as feeling agitated, restless or hyperactive.

Do not be concerned by this list of possible side effects. You may not get any of them.

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 (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

Ireland

HPRA Pharmacovigilance

Website: www.hpra.ie

Malta

ADR Reporting Website:

www.medicinesauthority.gov.mt/adrportal

5. How to store Bricanyl Turbohaler

- 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 on the inhaler after EXP. The expiry date refers to the last day of that month.
- Do not store above 30°C.
- When not in use, Bricanyl Turbohaler should be stored with the cover tightened.
- 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 Bricanyl Turbohaler contains

The active substance is terbutaline sulfate.

One dose (inhalation) contains:

- The active substance is terbutaline sulfate 0.5 mg.
- The excipient is lactose.

What Bricanyl Turbohaler looks like and contents of the pack

Bricanyl Turbohaler is a multi-dose, dry powder inhaler. Each inhaler contains 120 doses.

Marketing Authorisation Holder and Manufacturer

The Marketing Authorisation for Bricanyl Turbohaler is held by AstraZeneca AB, SE-151 85 Södertälje, Sweden.

Bricanyl Turbohaler is manufactured by AstraZeneca AB, Forskargatan 18, SE-151 36 Södertälje, Sweden.

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