

PACKAGE LEAFLET: INFORMATION FOR THE USER

Bricanyl® Turbohaler® 500micrograms per metered dose, inhalation powder (terbutaline sulphate)

Read all of this leaflet carefully before you start taking this medicine.

- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

The name of your medicine is "Bricanyl® Turbohaler® 500micrograms per metered dose, inhalation powder" but will be referred to as "Bricanyl Turbohaler" throughout this leaflet.

In this leaflet:

1. What Bricanyl Turbohaler is and what it is used for
2. Before you use Bricanyl Turbohaler
3. How to use Bricanyl Turbohaler
4. Possible side effects
5. How to store Bricanyl Turbohaler
6. Further 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. Before you use Bricanyl Turbohaler

Do not use Bricanyl Turbohaler if:

- You are allergic (hypersensitive) to terbutaline or any of the other ingredients of Bricanyl Turbohaler (listed in Section 6: Further information).

Take special care with Bricanyl Turbohaler

Check with 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.

Taking other medicines

Please tell your doctor or pharmacist if you are taking, or have recently taken, 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).

Pregnancy and breast-feeding

- Talk to your doctor before using Bricanyl Turbohaler if you are pregnant, might become pregnant or are breast-feeding.
- If you become pregnant while you are using Bricanyl Turbohaler, talk to your doctor straight away.

Driving and using tools and machines

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

3. How to use Bricanyl Turbohaler

Always use Bricanyl Turbohaler exactly as your doctor, nurse or pharmacist has told you. Ask one of them for advice if you are not sure. If Bricanyl Turbohaler is to be used by a child, make sure that they use it correctly.

How much to take

- The usual 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:

- **You 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.**

Please read the complete instructions carefully before you start to take your medication

Turbohaler is a multidose inhaler from which very small amounts of powder are administered (Figure 1). When you breathe in through Turbohaler the powder is delivered to your lungs.

It is therefore important that you **inhale forcefully and deeply** through the mouthpiece.

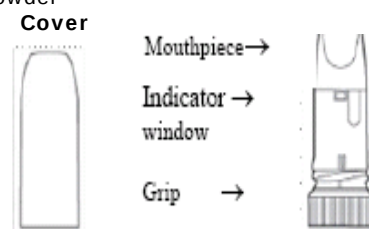


Figure 1

How to prepare a new inhaler for use

Before using Turbohaler for the first time you need to prepare the inhaler for use.

Unscrew and lift off the white cover.

Hold the inhaler upright with the blue grip downwards (Figure 2). Do not hold the mouthpiece when you turn the blue grip.

Turn the blue grip as far as it will go in one direction, and then back again in the opposite direction as far as it will go. It does not matter which way you turn first. During this procedure you will hear a click.

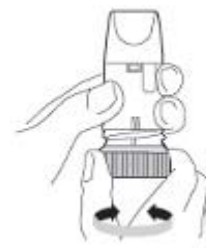


Figure 2

The inhaler is now prepared for use, and **you should not repeat the above procedure again.** To take a dose, please continue according to the instructions below.

How to take an inhalation

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

1. Unscrew the white cover and lift it off.



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.

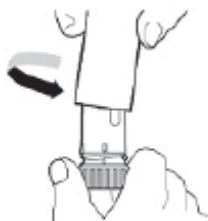
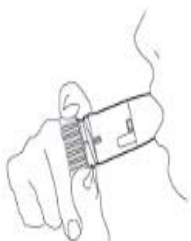
5. Place the mouthpiece gently between your teeth. Close your lips. **Breathe in as deeply and as hard as you can** through your mouth. Do not chew or bite on the mouthpiece.

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 still 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** by screwing it back on tightly.

With each inhalation some medication may stick to the inside of your mouth and throat. To reduce the risk of side effects it is advised that you, when possible, **rinse your mouth with water** after using Bricanyl Turbohaler.

Do not try to remove or twist the mouthpiece. It is fixed to your Turbohaler and must not be taken off. 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

- When a red mark first appears in the indicator window under the mouthpiece, there are about 20 doses left. You will need to see your doctor for another prescription.
- When the red mark reaches the bottom of the indicator window, your Turbohaler is empty and 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 Turbohaler more than once by mistake before taking your dose, you will still only receive one dose.

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.

4. Possible side effects

Like all medicines, Bricanyl Turbohaler 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 (affects more than 1 in 10 people)

- Trembling or shaking.
- Headache.

Common (affects less than 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'.

Unknown (it is not known exactly how often they happen):

- 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. If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. How to store Bricanyl Turbohaler

- Keep out of the reach and sight of children.
- Do not use Bricanyl Turbohaler after the expiry date printed on the outer packaging and inhaler labels. The expiry date refers to the last day of that month.
- Do not store above 30°C.
- Keep the cap screwed on your Turbohaler when you are not using it.
- Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines that are no longer required. This will help to protect the environment.

6. Further information

What Bricanyl Turbohaler contains

Each inhalation (metered dose) contains 500micrograms of the active ingredient, terbutaline sulphate. Bricanyl Turbohaler does not contain any other ingredients.

What Bricanyl Turbohaler looks like and the contents of the pack

Bricanyl Turbohaler is multi-dose breath-actuated metered dose powder inhaler containing white to off-white spherical particles which break into a fine powder on inhalation.

Each inhaler contains 100 or 200 inhalations.

Manufactured by: AstraZeneca Dunkerque Production, 224, Avenue de la Dordogne, 59640 Dunkerque, France.

Procured from within the EU and repackaged by PPA holder: B&S Healthcare, Unit 4, Bradfield Road, Ruislip, Middlesex HA4 0NU, UK.

Bricanyl Turbohaler 500mcg per metered dose, inhalation powder PPA: 1328/55/1

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FURTHER INFORMATION ABOUT ASTHMA

If you would like further information about asthma and its treatment, please contact:

Asthma Society of Ireland, 26 Mountjoy Square, Dublin 1.
Asthma Information Line: 1850 44 54 64

Leaflet date: 13.06.2013

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