

Package leaflet: information for the user

Bricanyl 250 Turbuhaler , inhalation powder 250 micrograms/dose
Bricanyl 500 Turbuhaler inhalation powder 500 micrograms/dose
Terbutaline sulfate

Read the entire 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.
- Do you have any questions? Contact your doctor or pharmacist.
- Do not pass this medicine on to others, as it has been prescribed for you only. It may harm them, even if their symptoms are the same as yours.
- Do you experience any of the side effects listed in section 4? Or do you experience a side effect not mentioned in this leaflet? Then contact your doctor or pharmacist.

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1. What is Bricanyl Turbuhaler and what is it used for?

Bricanyl Turbuhaler is used in the treatment of shortness of breath caused by asthma, chronic bronchitis, emphysema (expansion of the alveoli), or other diseases where the airways are narrowed due to contraction of muscles around the bronchi.

The airways can be narrowed for various reasons. For example, in asthma patients, this can happen due to hypersensitivity to house dust mites and cold, or due to exertion. Bricanyl relieves this narrowing. This occurs because Bricanyl reduces the spasm of the muscles in the airways. After inhaling a dose, the maximum effect is reached within a few minutes. The duration of action after inhalation is approximately 5-6 hours.

2. When should you not use this medicine or be extra careful with it?

When should you not use this medicine?

- You are allergic to any of the ingredients in this medicine. You can find these ingredients in section 6.
- You have a heart muscle disease that causes your heart to be enlarged.

When should you be extra careful with this medicine?

Contact your doctor or pharmacist before using this medicine.

- if you regularly (more than 3 times a week) have recurring shortness of breath symptoms. Contact your doctor. It may be necessary to establish or adjust a maintenance treatment with, for example, anti-inflammatory drugs; maintenance treatment with, for example, anti-inflammatory drugs;
- if you have a heart condition where an increased heart rate is unfavorable. Your doctor will carefully determine the dosage of Bricanyl Turbuhaler;

- Tell your doctor before starting this medicine if you have or have had a heart condition, an irregular heartbeat, or chest tightness;
- if you have diabetes, it is wise to monitor blood sugar levels more closely after starting treatment with Bricanyl Turbuhaler. Bricanyl Turbuhaler can (but does not have to) affect blood sugar levels;
- if difficulties with urination occur;
- if you have an increase in thyroid function (hyperthyroidism) that is not treated with medication. The doctor will carefully determine the dosage of Bricanyl.

With each inhalation, part of the delivered dose may remain in the oral cavity. Towards the end of the inhaler's usage period, there is also a chance of increasing accumulation of dry powder in the mouthpiece of Bricanyl Turbuhaler that can be released when it falls (for example, from a table). To minimize unnecessary side effects, it is recommended to rinse your mouth after each use whenever possible.

Are you using any other medicines?

Are you using any other medicines besides Bricanyl Turbuhaler, or have you done so recently, or is there a possibility that you will use other medicines in the near future? Then tell your doctor or pharmacist. This also applies to medicines that you can obtain without a prescription. This also applies to medicines that you can obtain without a prescription.

Let people around you know which medicines you are using!

If you are using a theophylline preparation (medicine for shortness of breath), a thiazide preparation (diuretic), or a corticosteroid preparation (adrenal cortex hormone, with anti-inflammatory effects, among others) in addition to Bricanyl Turbuhaler, you should tell your doctor so that the dosage can be adjusted if necessary.

When using Bricanyl Turbuhaler simultaneously with a beta-blocker (medicine for high blood pressure, chest pain (angina pectoris), or heart rhythm disorders), the effect of Bricanyl Turbuhaler may be reduced or even nullified.

If you are undergoing a procedure that requires general anesthesia with halothane (anesthetic), inform your (dental) doctor that you are using Bricanyl Turbuhaler.

What should you pay attention to with food and drink?

You can use Bricanyl Turbuhaler before, during, or after meals.

Pregnancy and breastfeeding

Are you pregnant, do you think you might be pregnant, do you want to become pregnant, or are you breastfeeding? Then contact your doctor or pharmacist before using this medicine.

You may use Bricanyl Turbuhaler during pregnancy only in consultation with your doctor. During the period you are breastfeeding, Bricanyl Turbuhaler can be used.

Driving ability and the use of machines

One of the possible side effects of using Bricanyl Turbuhaler is muscle cramps or muscle twitching. If you experience this, you should not drive vehicles or operate machines.

Bricanyl Turbuhaler contains lactose

This medicine contains lactose, which is a type of sugar. If your doctor has told you that you cannot tolerate certain sugars, contact your doctor before taking this medicine. The amount of lactose in this medicine usually does not cause problems in people with lactose intolerance.

Lactose may contain a small amount of milk proteins. In patients with hypersensitivity to milk proteins, these small amounts can cause allergic reactions.

3. How to use this medicine?

Bricanyl Turbuhaler is a specially designed white plastic powder inhaler with a blue twist grip, which allows the medication terbutaline to be inhaled quickly and effectively. You inhale the medication which goes directly into the lungs, the place where it needs to be to reduce breathlessness symptoms.

On the white, non-rotatable part, it indicates:

- the number of maximum available inhalations
- the expiration date: EXP (month/year)
- the batch number of Bricanyl Turbuhaler: LOT

Always use this medicine exactly as your doctor or pharmacist has told you. Are you unsure about the correct use? Then contact your doctor or pharmacist.

The recommended dosage is 1-2 inhalations from Bricanyl 250 Turbuhaler or 1 inhalation from Bricanyl 500 Turbuhaler as needed.

The maximum dosage is 4000 micrograms per day. This is 16 inhalations from Bricanyl 250 Turbuhaler or 8 inhalations from Bricanyl 500 Turbuhaler.

Use Bricanyl Turbuhaler as needed rather than regularly.

Seek medical help immediately if your asthma symptoms (coughing, shortness of breath, wheezing, or chest tightness) worsen or if you are too short of breath to speak, eat, or sleep.

You should contact your doctor as soon as possible if you need higher doses of Bricanyl than usual to reduce your breathing problems. You may need additional medication to keep your asthma under control.

If you use Bricanyl more than twice a week to treat your asthma symptoms, this indicates that the asthma is not well controlled. This can increase the risk of severe asthma attacks (worsening of asthma). These attacks can have serious consequences and be life-threatening or even fatal. You should contact your doctor as soon as possible to review your asthma treatment.

If you use a medication daily for inflammation of your lungs, for example, "inhaled corticosteroid," it is important to continue using this medication regularly, even if you feel better.

Duration of treatment

Since Bricanyl Turbuhaler is prescribed for respiratory conditions, such as asthma, its use is generally very long-term, up to several years. Always follow the instructions of your treating physician. Never increase, decrease, or interrupt the dosage (temporarily) on your own.

Have you used too much of this medicine?

Contact a doctor immediately. Try to find out how much Bricanyl Turbuhaler has been used. Keep the packaging of Bricanyl Turbuhaler at hand. Hospitalization may sometimes be necessary.

If much more Bricanyl Turbuhaler is inhaled than the maximum allowed dosage, the following symptoms may occur:

- rapid heartbeat, palpitations
- warm red face
- headache, nausea, vomiting
- restlessness, anxiety, increased sweating
- in severe cases: chest tightness, low blood pressure

Have you forgotten to use this medicine?

It is not a problem if you forget to inhale once. You use Bricanyl Turbuhaler only when you are short of breath. It works within a few minutes. Do not take a double dose to make up for a forgotten dose.

If you stop using this medicine

Your shortness of breath symptoms may return. We advise you to discontinue the treatment only in consultation with your doctor.

Do you have any other questions about the use of this medicine? Then contact your doctor or pharmacist.

Instructions for use

Activating a new Bricanyl Turbuhaler

Before you can use your new Bricanyl Turbuhaler for the first time, you must activate the inhaler once as follows:

- Unscrew the white protective cap and remove it. You might hear a rattling sound.
- Hold your Bricanyl Turbuhaler upright with the blue grip at the bottom.
- Turn the blue grip as far as possible in one direction and then turn the grip back as far as possible in the other direction (it doesn't matter which direction you turn first).
- You should then hear a click.
- Turn the blue grip again in both directions.
- Your Bricanyl Turbuhaler is now ready for use.

How to inhale Bricanyl using the Turbuhaler?:

Each time you take an inhalation, follow the instructions listed below.

1. Unscrew the white protective cap and remove it. You might hear a rattling sound.
2. Hold your Turbuhaler upright with the blue grip at the bottom.
3. Do not hold the Turbuhaler by the mouthpiece when loading. To load your Turbuhaler with a dose, turn the blue grip as far as possible in one direction. Then turn the grip

back as far as possible in the other direction (it doesn't matter which direction you turn first). You should then hear a click. Your Turbuhaler is now loaded and ready for use. Only load your Turbuhaler when you need to use it.

4. Do not hold the Turbuhaler too close to your mouth. Now breathe out calmly and as long as possible. Do not exhale through the mouthpiece.
5. Gently place the mouthpiece between your teeth. Close your lips. Inhale as forcefully and as deeply as possible through your mouth. Do not chew or bite on the mouthpiece.
6. Remove the Turbuhaler from your mouth. Breathe out calmly. The amount of this medicine you inhale is very small. This means that you will normally taste almost nothing after inhalation. When you have followed the above instructions, you can be confident that you have inhaled the dose and that the medicine has reached your lungs.
7. If you need to take another inhalation, repeat steps 2 to 6.
8. After inhalation, screw the white protective cap back onto the Turbuhaler.
9. If possible, rinse your mouth with water after each inhalation of your dose to wash away any remaining medicine in the oral cavity.

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

Do not try to remove the mouthpiece, it is attached to the Turbuhaler and should not be taken off. The mouthpiece can rotate, but do not turn it unnecessarily. Do not use your Turbuhaler if it is damaged or if the mouthpiece is off your Turbuhaler.

Have your inhalation technique regularly checked by your doctor or pharmacist. Then you can be sure that you are inhaling correctly.

Cleaning the Turbuhaler

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

One dose at a time!

It is pointless to click multiple times in a row, as only one measured dose can be inhaled per inhalation! If you do click a few times in a row, the counter mechanism counts this as a used dose. A red line will now appear in the window sooner. This indicates that the Turbuhaler is empty (see also the section "When is the Turbuhaler empty?").

When is the Turbuhaler empty?

The counter indicates how many doses (inhalations) are left in your Turbuhaler, starting with 120 doses.

- The counter indicates per 10 doses. Therefore, the counter does not show every dose. When you see the red area appear at the top edge of the counter, there are approximately 20 doses left. In the last 10 doses, the background of the counter is red.

When the 'O' on the red background is in the middle of the window, you should start with a new Turbuhaler.

Note:

- You can keep turning the grip and hear a clicking sound, even after the Turbuhaler is empty.
- If you shake the Turbuhaler, you hear a sound made by the drying agent in your Turbuhaler and not by the medication. That sound does not indicate how much medication is left in your Turbuhaler.
- If you accidentally load your Bricanyl Turbuhaler too many times, you will still only inhale 1 dose. However, the counter does register all loaded doses.

4. Possible side effects

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

The numbers mentioned below have the following meanings:

Very common: in more than 1 in 10 people.

Common: between 1 in 10 and 1 in 100 people.

Sometimes: between 1 in 100 and 1 in 1000 people.

Rare: between 1 in the 1000 and 1 in 10,000 people.

Very rare: in less than 1 in 10,000 people.

Reported are:

Very common:

Trembling hands; headache

Common:

Low potassium in the blood, in severe form recognizable by muscle cramps or muscle weakness and fatigue (hypokalemia); accelerated heartbeat (tachycardia); palpitations; muscle cramps.

Rare:

Anxiety and perceiving things that are not there (hallucinations); sleep disorders, changes in behavior (such as agitation, hyperactivity, and restlessness); heart rhythm disorders; shortness of breath due to spasm of the muscles of the airways (bronchospasm); nausea and vomiting; skin rash (exanthema), possibly with severe itching and formation of welts (hives or urticaria).

Very rare:

Hypersensitivity reactions; dilation of the blood vessels (vasodilation); flushing; decreased or increased blood pressure; tightness in the chest; sudden fluid accumulation in the skin and mucous membranes (for example, throat or tongue), breathing difficulties and/or itching and skin rash, often as an allergic reaction (angioedema). In the latter case, you should consult a doctor immediately.

Not known:

Although it is not exactly known how often it occurs, some people may occasionally feel chest pain (as a result of heart problems, such as a tight feeling in the chest). Tell your doctor

or midwife if these symptoms occur while using Bricanyl Turbuhaler. But do not stop the medication without consulting first.

Reporting side effects

If you experience side effects, contact your doctor or pharmacist. This also applies to possible side effects not listed in this leaflet. You can also report side effects directly via the Netherlands Pharmacovigilance Centre Lareb (www.lareb.nl). By reporting side effects, you can help us obtain more information about the safety of this medicine.

5. How to store this medicine?

Store below 25°C. Keep the inhaler tightly closed. Do not store in the refrigerator or freezer.

Keep out of the sight and reach of children.

Do not use this medicine after the expiry date. It can be found on the packaging and on the Turbuhaler (after EXP... month/year). The last day of that month is the expiry date.

Always ensure that you dispose of your used Turbuhaler responsibly, as the medicine remains partially inside. Do not flush medicines down the sink or toilet and do not throw them in the trash. Ask your pharmacist what to do with medicines you no longer use. They will then be destroyed responsibly and will not enter the environment.

6. Contents of the packaging and other information

What substances are in this medicine?

Each dose (inhalation) contains:

- The active substance in this medicine is: 0.25 mg or 0.5 mg terbutaline sulfate.
- The other substance in this medicine is lactose.

What does Bricanyl Turbuhaler look like and how much is in a package?

Each Bricanyl Turbuhaler is packed in a box.

Bricanyl 250 Turbuhaler: each inhaler contains 120 inhalations.

Bricanyl 500 Turbuhaler: each inhaler contains 120 inhalations.

Not all packaging forms are marketed as standard.

Marketing authorization holder and manufacturer

Marketing authorization holder	Manufacturer
AstraZeneca BV	AstraZeneca AB
Prinses Beatrixlaan 582	Forskargatan 18
2595 BM The Hague	SE-151 36 Södertälje
Netherlands	Sweden
Tel.: 085 8089900	

Bricanyl Turbuhaler is registered under
RVG 15959 (Bricanyl 250 Turbuhaler) and
RVG 12480 (Bricanyl 500 Turbuhaler).

This leaflet was last approved in August 2023.

Transtoyou