

Bricanyl® Turbohaler® (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 history of heart disease, irregular heart rhythm or angina.
- You have an overactive thyroid gland.

If you are not sure if any of the above applies 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).

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 or pharmacist 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, talk to the doctor before using this medicine. 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.

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.

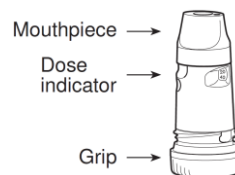
Preparing your new Bricanyl Turbohaler Inhaler

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.



- 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.
- If you are to take a second inhalation, repeat steps 2 to 6.
- Replace the cover tightly after use.
- 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 exactly 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 exactly how often this happens. **If this happens to you, stop using Bricanyl Turbohaler and see a doctor straight away.**

Other possible side effects:

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)

- Unusual or irregular heart beats.
- Chest pain (due to heart problems such as angina). Tell your doctor if you develop this symptom whilst receiving treatment with Bricanyl Turbohaler, but do not stop using this medicine unless told to.
- Feeling sick (nausea).
- Mouth and throat irritation.
- Changes in sleeping patterns and changes in behaviour, such as feeling agitated, restless or hyperactive.

Do not be concerned by this list of 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 via the Yellow Card Scheme at:

www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the **Google Play** or **Apple App Store**.

By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Bricanyl Turbohaler

- Keep out of the sight and reach of children.
- Do not store above 30°C.
- Replace the cover properly after use.
- Do not use Bricanyl Turbohaler after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.
- If your medicine becomes discoloured or shows any signs of deterioration, return it to your pharmacist.
- Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. This will help to protect the environment.

6. Contents of the pack and other information

What Bricanyl Turbohaler contains

The active substance is terbutaline sulfate.

Each actuation delivers 500 micrograms of terbutaline sulfate.

Also contains lactose.

What Bricanyl Turbohaler looks like and the contents of the pack

Bricanyl Turbohaler is a metered dose inhaler, with a white mouth-piece and cover and a blue turn grip. A Braille code for identification of Bricanyl Turbohaler is embossed at the bottom of the turning grip. The inhaler contains white to off-white spherical particles which break into a fine powder on inhalation.

Bricanyl Turbohaler comes in a pack of 1 x 120 actuations.

The device is contained within a printed carton.

Manufactured by

AstraZeneca AB, SE-151 85 Södertälje, Sweden.

Procured from within the EU by the Product Licence holder:

MPT Pharma Ltd, Westgate Business Park, Unit 5-7 Tintagel Way, Aldridge, Walsall, WS9 8ER.

Repackaged by MPT Pharma Ltd.

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Terbutaline sulfate 0.5mg/dose Turbohaler®

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.
- The name of this medicine is Terbutaline sulfate 0.5mg/dose Turbohaler but it will be referred to as Terbutaline sulfate throughout the remainder of the leaflet.

What is in this leaflet

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

1. What Terbutaline sulfate is and what it is used for

Terbutaline sulfate 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.

Terbutaline sulfate 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 Terbutaline sulfate

Do not use Terbutaline sulfate:

- If you are allergic to terbutaline.

Warnings and precautions

Talk to your doctor or pharmacist before using Terbutaline sulfate if:

- You have diabetes. If so, you may need some extra blood sugar tests when you start using Terbutaline sulfate.
- You have a history of heart disease, irregular heart rhythm or angina.
- You have an overactive thyroid gland.

If you are not sure if any of the above applies to you, talk to your doctor or pharmacist before using Terbutaline sulfate.

Other medicines and Terbutaline sulfate

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. Terbutaline sulfate can affect the way that some medicines work and some medicines can have an effect on Terbutaline sulfate.

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).

If you are to undergo surgery with general anaesthetics it is important that you inform your doctor about all medicines you use, including Terbutaline sulfate 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 or pharmacist for advice before using this medicine.
- If you become pregnant while you are using Terbutaline sulfate, talk to your doctor straight away.

Driving and using machines

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

Terbutaline sulfate contains lactose

Terbutaline sulfate contains lactose, which is a type of sugar. If you have been told by your doctor that you have an intolerance to some sugars, talk to the doctor before using this medicine. 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 Terbutaline sulfate

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 Terbutaline sulfate is to be used by a child, make sure that they use it correctly.

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 Terbutaline sulfate 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 Terbutaline sulfate Inhaler

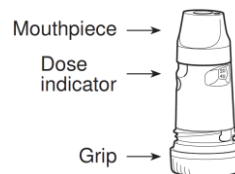
Before using your **new** Terbutaline sulfate inhaler **for the first time**, you need

to prepare it for use as follows:

- Unscrew the cover and lift it off. You may hear a rattling sound.
- Hold your Terbutaline sulfate 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 Terbutaline sulfate 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 Terbutaline sulfate inhaler upright with the blue grip at the bottom.
3. Do not hold the mouthpiece when you load your Terbutaline sulfate inhaler. To load your Terbutaline sulfate inhaler 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 Terbutaline sulfate inhaler is now loaded and ready to use. Only load your Terbutaline sulfate inhaler when you need to use it.



4. Hold your Terbutaline sulfate inhaler away from your mouth. Breathe out gently (as far as is comfortable). Do not breathe out through your Terbutaline sulfate inhaler.
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 Terbutaline sulfate inhaler 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 Terbutaline sulfate use correct inhalation technique, as described above.

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

Cleaning your Terbutaline sulfate inhaler

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 Terbutaline sulfate inhaler

The dose indicator tells you how many doses are left in the Terbutaline sulfate inhaler, 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 Terbutaline sulfate inhaler.



Note:

- The grip will still twist and 'click' even when your Terbutaline sulfate inhaler is empty.
- The sound that you hear as you shake your Terbutaline sulfate inhaler is produced by a drying agent and not the medicine. Therefore, the sound does not tell you how much medicine is left in your Terbutaline sulfate inhaler.
- If you load your Terbutaline sulfate 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 Terbutaline sulfate than you should

If you use more Terbutaline sulfate than you should, contact your doctor or pharmacist for advice.

If you forget to use Terbutaline sulfate

- 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 exactly how often this happens. **If this happens to you, stop using Terbutaline sulfate and see a doctor straight away.**
- Sudden wheezing soon after inhaling your dose of Terbutaline sulfate. It is not known exactly how often this happens. **If this happens to you, stop using Terbutaline sulfate and see a doctor straight away.**

Other possible side effects:

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)

- Unusual or irregular heart beats.
- Chest pain (due to heart problems such as angina). Tell your doctor if you develop this symptom whilst receiving treatment with Terbutaline sulfate, but do not stop using this medicine unless told to.
- Feeling sick (nausea).
- Mouth and throat irritation.
- Changes in sleeping patterns and changes in behaviour, such as feeling agitated, restless or hyperactive.

Do not be concerned by this list of 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 via the Yellow Card Scheme at:

www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the **Google Play** or **Apple App Store**.

By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Terbutaline sulfate

- Keep out of the sight and reach of children.
- Do not store above 30°C.
- Replace the cover properly after use.
- Do not use Terbutaline sulfate after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.
- If your medicine becomes discoloured or shows any signs of deterioration, return it to your pharmacist.
- Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. This will help to protect the environment.

6. Contents of the pack and other information

What Terbutaline sulfate contains

The active substance is terbutaline sulfate. Each actuation delivers 500 micrograms of terbutaline sulfate. Also contains lactose.

What Terbutaline sulfate looks like and the contents of the pack

Terbutaline sulfate is a metered dose inhaler, with a white mouth-piece and cover and a blue turn grip. A Braille code for identification of Terbutaline sulfate is embossed at the bottom of the turning grip. The inhaler contains white to off-white spherical particles which break into a fine powder on inhalation.

Terbutaline sulfate comes in a pack of 1 x 120 actuations. The device is contained within a printed carton.

Manufactured by AstraZeneca AB, SE-151 85 Södertälje, Sweden.

Procured from within the EU by the Product Licence holder: MPT Pharma Ltd, Westgate Business Park, Unit 5-7 Tintagel Way, Aldridge, Walsall, WS9 8ER.

Repackaged by MPT Pharma Ltd.

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