

# BRALTUS®

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## Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

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### 1. Why am I using BRALTUS?

BRALTUS contains the active ingredient tiotropium (as bromide). BRALTUS is used to make breathing easier for people with chronic obstructive pulmonary disease (COPD)

For more information, see Section [1. Why am I using BRALTUS?](#) in the full CMI.

### 2. What should I know before I use BRALTUS?

Do not use if you have ever had an allergic reaction to tiotropium, atropine, medicines like atropine (e.g. ipratropium or oxitropium) or any of the ingredients listed at the end of the CMI.

**Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.**

For more information, see Section [2. What should I know before I use BRALTUS?](#) in the full CMI.

### **3. What if I am taking other medicines?**

Some medicines may interfere with BRALTUS and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

### **4. How do I use BRALTUS?**

- The recommended dose for adults is 1 capsule to be inhaled, once a day
- Inhale the powder in the capsules only using the Zonda<sup>®</sup> device. Do not swallow the capsules. Do not place a capsule directly into the mouthpiece. Do not open the capsules.

More instructions can be found in Section [4. How do I use BRALTUS?](#) in the full CMI.

## 5. What should I know while using BRALTUS?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>• Remind any doctor, dentist or pharmacist you visit that you are using BRALTUS.</li><li>• Tell your doctor immediately if your breathing becomes more difficult while you are taking BRALTUS.</li></ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"><li>• Do not use BRALTUS more frequently than once daily.</li></ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"><li>• Be careful driving or operating machinery until you know how BRALTUS affects you.</li><li>• BRALTUS may cause dizziness or blurred vision in some people.</li></ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"><li>• Keep your capsules in the bottle until it is time to use them.</li><li>• Keep your capsules in a cool, dry place where the temperature stays below 25°C</li></ul>

- Do not store your capsules in the refrigerator or freezer. Use the capsules within 60 days of opening the bottle

For more information, see Section [5. What should I know while using BRALTUS?](#) in the full CMI.

## **6. Are there any side effects?**

All medicines can have side effects. If they do occur, they are usually minor and temporary. Do not be alarmed by this list. You may not experience any of them.

A common side effect is dry mouth, which is usually mild.

Side effects that require urgent medical attention include allergic reaction, changes in heart rate or palpitations and severe pain in the stomach with bloating, gut cramps and vomiting.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

# BRALTUS®

Powder for Inhalation (in capsule)

**Active ingredient(s):** *Tiotropium (as bromide)*

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## Consumer Medicine Information (CMI)

This leaflet provides important information about using BRALTUS. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using BRALTUS.**

**Where to find information in this leaflet:**

- [1. Why am I using BRALTUS?](#)
- [2. What should I know before I use BRALTUS?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use BRALTUS?](#)
- [5. What should I know while using BRALTUS?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

## 1. Why am I using BRALTUS?

**BRALTUS contains the active ingredient tiotropium (as bromide).** BRALTUS belongs to a group of medicines called anticholinergics.

**BRALTUS is used to make breathing easier for people with chronic obstructive pulmonary disease (COPD).**

This helps to improve your condition and to prevent exacerbations (periodic worsening of symptoms) from occurring.

BRALTUS improves breathing by relaxing the air passages that carry air to and from the lungs. It begins to act within 30 minutes after use and the effect should last a full day.

## **2. What should I know before I use BRALTUS?**

### **Warnings**

**Do not use BRALTUS to treat a sudden attack of breathlessness, wheezing or coughing.** You will need a different type of medicine.

### **Do not use BRALTUS if:**

- you are allergic to tiotropium bromide, or any of the ingredients listed at the end of this leaflet.
- you are allergic to any medicine containing atropine or its derivatives, e.g. ipratropium or oxitropium.
- you are allergic to any other anticholinergic medicines.
- you have been told by your doctor that you have an intolerance to some sugars, or an allergy to milk

proteins (which may be contained in small amounts in the ingredient lactose monohydrate).

- always check the ingredients to make sure you can use this medicine.

### **Check with your doctor if you:**

- Have or have had any of the following medical conditions:
- High pressure in the eye (glaucoma)
- Kidney or liver problems
- Problems with your prostate gland
- Problems with passing urine
- You have suffered from a heart attack during the last 6 months or from any unstable or life threatening irregular heart beat or severe heart failure within the past year.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

### **Pregnancy and breastfeeding**

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

Your doctor can discuss with you the risks and benefits involved. BRALTUS is not generally recommended for use in pregnant women.

## **Children and adolescents**

Do not give this medicine to children or adolescents (below the age of 18 years).

## **Eyes**

**Do not allow the powder to enter into the eyes. Should this occur, immediately flush your eyes with cold tap water for several minutes and immediately consult your doctor for further advice.**

If the powder enters the eye, it may result in eye pain or discomfort, blurred vision, seeing halos around lights or coloured images in association with red eyes (i.e. narrow angle glaucoma).

## **3. What if I am taking other medicines?**

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

**Some medicines may interfere with BRALTUS and affect how it works.**

These include other anticholinergic medicines used to treat COPD such as glycopyrronium, aclidinium, umeclidinium or ipratropium.

You may need different amounts of your medicines, or you may need to take different medicines.

**Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect BRALTUS.**

## **4. How do I use BRALTUS?**

### **How much to use**

- The recommended dose for adults is 1 capsule to be inhaled, once a day.
- One capsule provides the required daily dose of tiotropium (a delivered dose of 10 micrograms of tiotropium); do not take more than the recommended dose.
- Follow the instructions provided and use BRALTUS until your doctor tells you to stop.

### **When to use BRALTUS**

- BRALTUS should be used about the same time each day.

### **How to use BRALTUS**

- Inhale the powder in the capsules only using the Zonda device.
- Do not swallow the capsules.
- Do not place a capsule directly into the mouthpiece.

- Do not open the capsules. If you open the capsules, the small amount of powder inside may be lost, or you may accidentally get the powder in your eyes.
- Use the capsules within 60 days of opening the bottle.
- Read the Directions for Use at the end of this CMI for instructions on how to use BRALTUS capsules with the Zonda device.
- Follow the Directions for Use carefully. Pierce the capsule only once using the Zonda device.
- Do not allow the powder to enter into the eyes. Should this occur, immediately flush your eyes with cold tap water for several minutes.
- If you have any problems inhaling BRALTUS capsules using the Zonda device ask your doctor or pharmacist for advice.

## **If you forget to use BRALTUS**

BRALTUS should be used regularly at the same time each day.

**If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.**

**Do not take a double dose to make up for the dose you missed.**

**Otherwise, take it as soon as you remember, and then go back to taking your medicine as you would normally.**

If you are not sure what to do, ask your doctor or pharmacist.

## **If you use too much BRALTUS**

If you think that you have used too much BRALTUS, you may need urgent medical attention.

### **You should immediately:**

- phone the Poisons Information Centre (In Australia by calling **13 11 26** or in New Zealand by calling **0800 POISON (0800 764 766)**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

**You should do this even if there are no signs of discomfort or poisoning.**

Symptoms of an overdose may include fast or irregular heart beat, blurred vision, nausea, stomach pain, dry mouth, constipation and difficulty passing urine.

## **5. What should I know while using BRALTUS?**

### **Things you should do**

- Remind any doctor, dentist or pharmacist you visit that you are using BRALTUS, especially if you are about to start any new medicine or if you are going to have surgery.

- Keep all of your doctor's appointments so that your progress can be checked. Your doctor may do some tests from time to time to make sure the medicine is working and to prevent unwanted side effects.
- Follow the Directions for Use carefully.
- If you are a smoker, your doctor or pharmacist can advise you on the steps to take to quit smoking.

### **Call your doctor straight away if you:**

- become pregnant while taking this medicine
- your breathing becomes more difficult while you are taking this medicine.

### **Things you should not do**

- Do not take BRALTUS to treat any other complaints unless your doctor tells you to.
- Do not give your medicine to anyone else, even if they have the same condition as you.
- Do not take BRALTUS more frequently than once daily.

### **Driving or using machines**

**Be careful before you drive or use any machines or tools until you know how BRALTUS affects you.**

BRALTUS may cause dizziness or blurred vision in some people. If you have any of these symptoms, do not drive, operate machinery, or do anything else that could be dangerous.

## Looking after your medicine

- If necessary, you may wipe the mouthpiece of your Zonda inhaler after use with a dry cloth or tissue.
- The Zonda inhaler should not be rinsed with water.
- Keep your capsules in the bottle until it is time to use them. If you take the capsules out of the bottle they may not keep well.
- Keep your capsules in a cool, dry place where the temperature stays below 25°C
- Keep the bottle tightly closed. Store in the original package to protect from moisture.
- Do not store your capsules in the refrigerator or freezer. Use the capsules within 60 days of opening the bottle.

Follow the instructions in this leaflet on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

**Keep it where young children cannot reach it.**

## When to discard your medicine

Discard the Zonda device after 30 uses. Do not reuse the inhaler for another bottle of capsules. There is a new inhaler provided with each pack of BRALTUS.

## Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

## 6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

### Less serious side effects

Less serious side effects	What to do
<p><b>Brain and nerves:</b></p> <ul style="list-style-type: none"><li>• dizziness</li><li>• trouble sleeping</li></ul> <p><b>Nose and sinus:</b></p> <ul style="list-style-type: none"><li>• nose bleeds</li><li>• sinusitis, a feeling of tension or fullness in the nose, cheeks and behind your eyes, sometimes with a</li></ul>	<p><b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b></p>

<b>Less serious side effects</b>	<b>What to do</b>
<p>throbbing ache, fever, stuffy nose and loss of the sense of smell.</p> <p><b>Mouth, throat and airways:</b></p> <ul style="list-style-type: none"> <li>• dry mouth (usually mild)</li> <li>• sore mouth, gums or throat</li> <li>• swollen, red, sore tongue</li> <li>• oral thrush</li> <li>• hoarse voice</li> <li>• cough</li> </ul> <p><b>Gut and digestion:</b></p> <ul style="list-style-type: none"> <li>• constipation</li> </ul>	

## **Serious side effects**

<b>Serious side effects</b>	<b>What to do</b>
<p><b>Eyes:</b></p> <ul style="list-style-type: none"> <li>• blurred vision</li> <li>• seeing halos around lights or coloured images in association with red eyes;</li> </ul>	<p><b>Speak to your doctor as soon as possible if you have any of these serious side effects.</b></p>

<b>Serious side effects</b>	<b>What to do</b>
<ul style="list-style-type: none"> <li>● high pressure in the eye (glaucoma)</li> </ul> <p><b>Mouth, throat and airways:</b></p> <ul style="list-style-type: none"> <li>● difficulty in swallowing</li> <li>● a worsening of breathing problems (induced by the inhalation process). Inhaled medicines such as BRALTUS may cause tightness of the chest, coughing, wheezing or breathlessness immediately after inhalation.</li> </ul> <p><b>Gut and digestion:</b></p> <ul style="list-style-type: none"> <li>● heartburn</li> </ul> <p><b>Bladder:</b></p> <ul style="list-style-type: none"> <li>● difficulty in passing urine</li> <li>● pain while passing urine, urinary tract infection, increased need and frequency in passing urine.</li> </ul>	

Very serious side effects	What to do
<p><b>Signs of an allergic reaction:</b></p> <ul style="list-style-type: none"> <li>● shortness of breath, wheezing or difficulty breathing</li> <li>● swelling of the face, lips, tongue or other parts of the body</li> <li>● rash, itching or hives on the skin.</li> </ul> <p><b>Heart:</b></p> <ul style="list-style-type: none"> <li>● changes in heart rate (fast, slow or irregular)</li> <li>● palpitations</li> </ul> <p><b>Gut and digestion:</b></p> <ul style="list-style-type: none"> <li>● severe pain in the stomach with bloating, gut cramps and vomiting.</li> </ul>	<p><b>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</b></p>

**Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.**

Other side effects not listed here may occur in some people.

## Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems) or Medsafe at <https://www.medsafe.govt.nz/safety/report-a-problem.asp#Medicine>. By reporting side effects, you can help provide more information on the safety of this medicine.

**Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.**

## 7. Product details

This medicine is only available with a doctor's prescription.

### What BRALTUS contains

<b>Active ingredient (main ingredient)</b>	BRALTUS capsules contain 13 micrograms of tiotropium (equivalent to tiotropium bromide 15.6 micrograms) as the active ingredient.  During inhalation, 10 micrograms of tiotropium is delivered from each
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	<p>capsule from the mouthpiece of the Zonda inhaler.</p> <p>BRALTUS and Spiriva both deliver 10 micrograms of tiotropium and are equivalent.</p>
<b>Other ingredients (inactive ingredients)</b>	<p>It also contains lactose monohydrate (which contains milk protein). The outer capsule is an empty hard hypromellose capsule for inhalation size 3.</p>
<b>Potential allergens</b>	<p>lactose</p>

**Do not take this medicine if you are allergic to any of these ingredients.**

## **What BRALTUS looks like**

BRALTUS capsules are colourless and transparent. BRALTUS capsules contain a white powder. The Zonda inhaler has a green body and a cap with a white push button (Aust R 293317).

BRALTUS capsules contain only a small amount of powder, which means that the capsule is only partially filled. The amount of powder in each capsule is equivalent in size to the tip of a matchstick.

BRALTUS is available in a carton containing a bottle of 30 capsules with the Zonda device.

## **Who distributes BRALTUS**

Braltus is supplied in Australia by:

Teva Pharma Australia Pty Ltd

Level 1, 37 Epping Road

Macquarie Park NSW 2113

Braltus is supplied in New Zealand by:

Teva Pharma (New Zealand) Ltd

Auckland, New Zealand.

This leaflet was updated in May 2022

### Zonda Instructions for Use

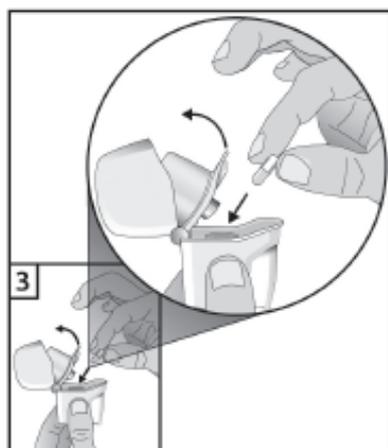
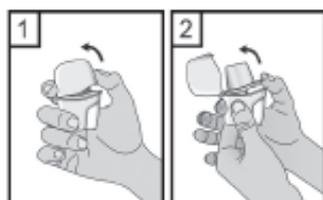
The Zonda inhaler enables you to inhale the medicine contained in the Braltus capsule that your doctor has prescribed for your breathing problems.

Remember to carefully follow your doctor's instructions for using Braltus. The Zonda inhaler is especially designed for Braltus capsules: you must not use it to take any other medication. The capsules must only be inhaled using the Zonda inhaler. Do **not** use any other inhalers to take Braltus capsules. Each capsule contains only a small amount of powder. Do **not** open the capsule or it may not work.

The Zonda inhaler should only be used with the bottle of capsules provided. Do not reuse the inhaler for another bottle of capsules. Discard the Zonda device after 30 uses.



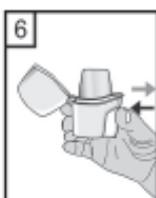
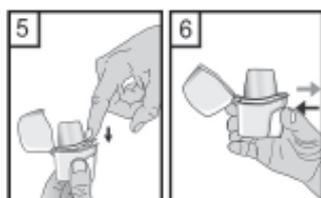
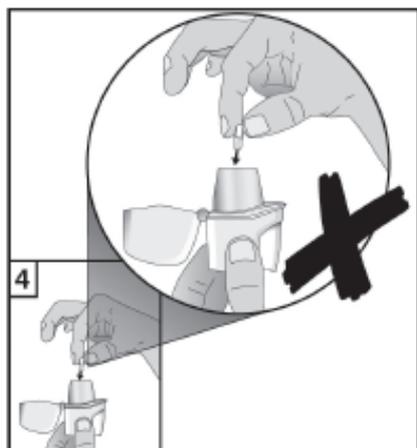
1. Dust cap
2. Mouthpiece
3. Base
4. Piercing button
5. Centre chamber



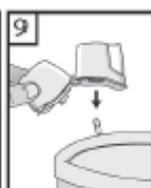
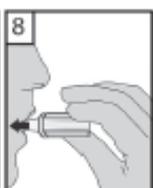
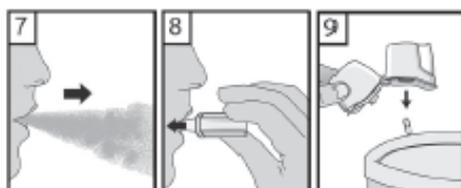
1. Pull the cap upwards
2. Hold the base of the inhaler firmly and open the mouthpiece by pulling it upwards, in the direction of the arrow.
3. Remove a Braltus capsule from the bottle immediately before use and close the bottle tightly. Place one capsule in the capsule-shaped compartment in the base of the inhaler. Do **not** store the capsule in the Zonda inhaler.



4. **Never** place a capsule directly into the mouthpiece



5. Close the mouthpiece until you hear a click, leaving the cap open.
6. Hold the inhaler with the mouthpiece upwards, and firmly press the piercing button completely in only once. Release the button. This will pierce the capsule and allows the medication to be released when you breathe in.
7. Breathe out fully. It is important to do this away from the mouthpiece. Avoid breathing into the mouthpiece at any time.



8. Place the mouthpiece in your mouth and keep your head in an upright position. Close your lips around the mouthpiece and breathe in slowly and deeply enough to hear or feel the capsule vibrating inside the compartment. Hold your breath for as long as you comfortably can whilst taking the inhaler out of your mouth. Then breathe normally. Repeat steps 7 and 8 to empty the capsule completely.
9. After use, open the mouthpiece again, and tip out the empty capsule. Close the mouthpiece and cap, and store your Zonda inhaler.

**Manufacturer:**

Plastiapi S.p.A.

Via 1 Maggio, 8, 23875 Osnago LC, Italy

