

# Braltus<sup>®</sup>

## Powder for Inhalation (in Capsule)

*Tiotropium (as bromide)*

### Consumer Medicine Information

#### What is in this leaflet

This leaflet answers some common questions about Braltus. Braltus capsules are supplied with a Zonda inhaler.

It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits.

Your doctor has weighed the risks of you taking Braltus against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet.

You may need to read it again.

#### What Braltus is used

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.

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

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

#### Before you take Braltus

##### When you must not take it

Do not take Braltus if you have an allergy to:

- any medicine containing tiotropium bromide
- any of the ingredients listed at the end of this leaflet
- any medicine containing atropine or its derivatives, e.g. ipratropium or oxitropium
- any other anticholinergic medicines.

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin

Do not take this medicine to treat a sudden attack of breathlessness, wheezing or coughing.

You will need a different type of medicine.

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

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, talk to your doctor.

##### Before you start to take it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell 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

Tell your doctor if you are pregnant or plan to become pregnant or are breast-feeding.

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

If you have not told your doctor about any of the above, tell him/her before you start taking Braltus.

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).

Take this medicine only with the Zonda® device which is provided with each pack of Braltus.

### **Taking other medicines**

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

Some medicines and Braltus may interfere with each other. These include other anticholinergic

medicines used to treat COPD such as tiotropium, aclidinium, umeclidinium or ipratropium.

These medicines may be affected by Braltus or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

## **How to take Braltus**

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions provided with your medicine, ask your doctor or pharmacist for help.

### **How much to take**

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.

### **How it is given**

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 leaflet 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.

### **When to take it**

Take your medicine at about the same time each day.

Taking it at the same time each day will have the best effect. It will also help you remember when to take it.

### **How long to take it**

Continue taking your medicine for as long as your doctor tells you.

This medicine helps to control your condition, but does not cure it. It is important to keep taking your medicine even if you feel well.

### **If you forget to take it**

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

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

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

This may increase the chance of you getting an unwanted side effect.

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

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

### **If you take too much (overdose)**

Immediately telephone your doctor or the Poisons Information Centre (Australia 13 11 26) for advice, or go to Emergency at the nearest hospital, if you think that you or anyone else may have taken too much Braltus. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

Symptoms of an overdose may include fast or irregular heart beat, blurred vision, nausea, stomach

pain, dry mouth, constipation and difficulty passing urine.

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## While you are taking Braltus

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### Things you must do

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking Braltus.

Tell any other doctors, dentists, and pharmacists who treat you you are taking this medicine.

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine.

It may affect other medicines used during surgery.

If you become pregnant while taking this medicine, tell your doctor immediately.

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.

It is very important to follow the Directions for Use carefully.

If your breathing becomes more difficult while you are taking this medicine, tell your doctor immediately.

If you are a smoker, your doctor or pharmacist can advise you on the steps to take to quit smoking.

### Things you must 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.

### Things to be careful of

Be careful driving or operating machinery until you know how Braltus affects you.

This medicine 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.

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## Side effects

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Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Braltus.

This medicine helps most people with COPD, but it can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor or pharmacist if you notice any of the following and they worry you:

- dry mouth: this is usually mild
- sore mouth, gums, or throat; swollen, red, sore tongue
- oral thrush
- hoarse voice
- nose bleeds
- cough
- dizziness
- constipation
- trouble sleeping
- sinusitis, a feeling of tension or fullness in the nose, cheeks and behind your eyes, sometimes with a throbbing ache, fever, stuffy nose and loss of the sense of smell.

These are mild side effects of the medicine, and usually short-lived.

Tell your doctor as soon as possible if you notice any of the following:

- blurred vision
- seeing halos around lights or coloured images in association with red eyes; high pressure in the eye (glaucoma)
- difficulty in swallowing
- heartburn
- difficulty in passing urine
- pain while passing urine, urinary tract infection, increased need and frequency in passing urine
- 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.

The above list includes serious side effects that may require medical attention.

If any of the following happen, tell your doctor immediately or go to Emergency at your nearest hospital:

- severe pain in the stomach with bloating, gut cramps and vomiting
- changes in heart rate (fast, slow or irregular), palpitations
- allergic reaction (shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body, rash, itching or hives on the skin).

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation.

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

Other side effects not listed above may also occur in some people.

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## After taking Braltus

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### Cleaning

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.

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.

### Storage

Keep your capsules in the bottle until it is time to use them.

Do not 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.

Do not store Braltus or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.

Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

### Disposal

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

## Product description

### What it 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.

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.

### Ingredients

Braltus capsules contains 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 capsule from the mouthpiece of the Zonda inhaler.

Braltus and Spiriva both deliver 10 micrograms of tiotropium and are equivalent.

It also contains lactose monohydrate (which contains milk protein). The outer capsule is known as a -and Vcaps - The Vegetarian Alternative empty hard capsules size 3 (Ingredient ID 10127).

### Sponsor

Braltus is supplied in Australia by:

Teva Pharma Australia Pty Ltd

37 Epping Road

Macquarie Park NSW 2113

Braltus® is a registered trademark of the Teva group of companies. An Ivax International trademark.

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® = Registered Trademark

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Commented : As per Milestone 5 FileNote

Commented : As per recommendation in Milestone FileNote

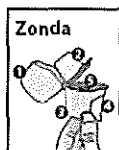
## Zonda Instructions for Use

Dear Patient,

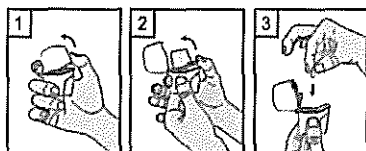
The Zonda inhaler enables you to inhale the medicine contained in the Braltus capsule that your doctor has prescribed for your breathing problems.

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 15 uses (if used with a 15 capsule bottle) or 30 uses (if used with a 30 capsule bottle).

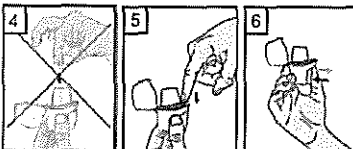


1. Dust cap
2. Mouthpiece
3. Base
4. Piercing button
5. Centre chamber

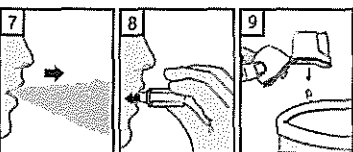


1. Pull the cap upwards.
2. Hold the base of the inhaler firmly and open the mouthpiece by pulling it upwards, in the direction of the arrow.
3. Remove a Braltus capsule from the bottle immediately before use and close the bottle tightly. Place one capsule in the capsule-shaped compartment in the base 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 breathe 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:**  
Plastiap S.p.A.  
Via 1 Maggio, 8, 23875 Osnago LC, Italy

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