Package leaflet: Information for the patient

Braltus® 10 microgram per delivered dose inhalation powder, hard capsule
(tiotropium bromide)

Your medicine is called Braltus 10 microgram per delivered dose inhalation powder, hard capsule and will be referred to as Braltus throughout the rest of this leaflet.

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, pharmacist or nurse.
- 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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

1. WHAT BRALTUS IS AND WHAT IT IS USED FOR
Braltus contains the active substance tiotropium. Tiotropium helps people who have chronic obstructive pulmonary disease (COPD) to breathe more easily. COPD is a chronic lung disease that causes shortness of breath and coughing.
The term COPD is associated with the conditions chronic bronchitis and emphysema. As COPD is a chronic disease you should use this medicine every day and not only when you have breathing problems or other symptoms of COPD.

Braltus is a long-acting bronchodilator that helps to open your airways and makes it easier to get air in and out of the lungs. Regular use of this medicine can also help you when you have on-going shortness of breath related to your disease and will help you to minimise the effects of the disease on your everyday life. It also helps you to be active longer. Daily use of this medicine will also help to prevent sudden, short-term worsening of your COPD symptoms which may last for several days. The effect of this medicine lasts for 24 hours, so you only need to use it once a day.

This medicine should not be used as a rescue therapy for the treatment of unexpected tightness of the chest, coughing or sudden attacks of breathlessness or wheezing. Please use a fast-acting 'reliever' (rescue) inhaler, such as salbutamol instead. Please keep this 'reliever' inhaler with you at all times.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE BRALTUS
Do not use Braltus:
- if you are allergic (hypersensitive) to tiotropium or any of the other ingredients of this medicine (listed in section 6)
- if you are allergic (hypersensitive) to atropine or substances related to it, e.g. ipratropium or oxitropium
- if you are allergic (hypersensitive) to lactose or any other sugars

Warnings and precautions
Talk to your doctor, pharmacist or nurse before using Braltus:
- if you are taking any other medicinal products containing ipratropium or oxitropium
- if you are suffering from narrow angle glaucoma, prostate problems or have difficulty passing urine
- if you have any kidney problems
- if you have suffered from a heart attack (myocardial infarction) during the last 6 months, or from any unstable or life-threatening irregular heart beat or severe heart failure in the past year.

Braltus is indicated for maintenance treatment of your chronic obstructive pulmonary disease; it should not be used to treat a sudden attack of breathlessness or wheezing.

Immediate allergic reactions such as rash, swelling, itching, wheezing or breathlessness may occur after administration of Braltus. If this occurs, please consult your doctor **immediately** (see section 4).

Inhaled medicines such as Braltus may cause tightness of the chest, coughing, wheezing or breathlessness (bronchospasm) immediately after inhalation. In such instances you should immediately use a fast-acting 'reliever' inhaler, such as salbutamol. If these symptoms occur stop using Braltus inhaler and please consult your doctor **immediately**.

Take care not to let the inhalation powder enter your eyes as this may result in watering eyes or it may cause narrow-angle glaucoma or may worsen this condition. Narrow-angle glaucoma is a disease of the eyes. Eye pain or discomfort, blurred vision, seeing halos around lights or coloured images in association with red eyes may be signs of an acute attack of narrow-angle glaucoma. Eye symptoms may be accompanied by headache, nausea or vomiting. You should stop using this medicine and immediately consult your doctor, preferably an eye specialist, when signs and symptoms of narrow-angle glaucoma appear.

The medicine in your inhaler may decrease the normal secretions (saliva) in your mouth and make your mouth feel dry. Long-term this may be associated with dental caries (tooth decay). Therefore, please remember to pay attention to oral hygiene, rinse your mouth out and brush your teeth regularly.

If you have suffered from a heart attack (myocardial infarction) during the last 6 months, or from any unstable or life-threatening irregular heart beat or severe heart failure in the past year, please inform your doctor. This is important so that the doctor can decide whether or not Braltus is the right treatment for you to use.

Do **not** use this medicine more than once daily (see section 3).

Children and adolescents
Braltus should not be used in children and adolescents under the age of 18 years.

Other medicines and Braltus
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including any other inhalers and medicines bought over the counter from the pharmacy.

Please tell your doctor or pharmacist if you are taking/have taken similar medicines for your lung disease, such as ipratropium or oxitropium.

No specific side effects have been reported when this medicine has been used together with other products used to treat COPD such as reliever inhalers, e.g. salbutamol, methylxanthines, e.g. theophylline and/or oral and inhaled steroids e.g. prednisolone.

Pregnancy and breast-feeding
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. You should not use this medicine unless specifically recommended by your doctor.

Driving and using machines
The occurrence of dizziness, blurred vision, or headache may influence the ability to drive and use machinery.

Braltus contains lactose
Lactose is a type of sugar found in milk. If you have been told by your doctor that you have an allergy to some sugars, contact your doctor before using this inhaler. Lactose may contain very small amounts of milk protein, which may cause reactions in those who have severe hypersensitivity or allergy to milk proteins.
When used according to the dose recommendation of one capsule once a day, each dose supplies up to 18 mg of lactose monohydrate.

3. HOW TO USE BRALTUS
Always use this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose is to inhale the contents of **one** capsule **once daily** with the Zonda® inhaler. **One** capsule provides the required daily dose of tiotropium (a delivered dose of 10 micrograms of tiotropium); do **not** use more than the recommended dose.

You should try to use this medicine at the same time every day. This is important because this medicine is effective over 24 hours.

The capsules are only for inhalation and not for oral intake.
Do not swallow the capsules.

The Zonda® inhaler, which you should put the Braltus capsule into, makes holes in the capsule and allows you to breathe in the powder. The capsules must only be inhaled using the Zonda® inhaler. Do not use any other inhalers to administer Braltus capsules.

Make sure you know how to use the Zonda® inhaler properly. The instructions for use of the Zonda® inhaler are provided on the other side of this leaflet. Remember to carefully follow these instructions for use. Pictures for the correct insertion of the capsule into the inhaler are also provided on the inside of the lid of the carton. **To avoid the risk of choking NEVER place a capsule directly into the mouthpiece.** If you have any problems using the Zonda® inhaler, ask your doctor, pharmacist or nurse to show you how it works.

If necessary, you may wipe the mouthpiece of your Zonda® inhaler after use with a dry cloth or tissue.

Make sure you do not blow into the Zonda® inhaler. When using Braltus, take care not to let any of the powder enter your eyes. If any powder does get into your eyes, you may get blurred vision, eye pain and/or red eyes; you should wash your eyes in warm water **immediately**. Then talk to your doctor **immediately** for further advice.

If you feel that your breathing is worsening, you should tell your doctor as soon as possible.

Use in children and adolescents
Braltus should not be used in children and adolescents under the age of 18 years.

If you use more Braltus than you should
If you inhale the contents of more than 1 capsule of Braltus in a day, you should talk to your doctor **immediately.** You may be at a higher risk of experiencing side effects such as dry mouth, constipation, difficulties passing urine, increased heart beat, or blurred vision.

If you forget to use Braltus
If you forget to administer a dose, do this as soon as you remember, but do **not** administer two doses at the same time or on the same day. Then administer your next dose as usual.

Do **not** administer a double dose to make up for a forgotten dose.

If you stop using Braltus
Before you stop using Braltus, you should talk to your doctor or pharmacist. If you stop using this medicine, the signs and symptoms of COPD may get worse.
If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

4. POSSIBLE SIDE EFFECTS
Like all medicines, this medicine can cause side effects, although not everybody gets them.

Serious side effects including allergic reactions which cause swelling of the face or throat (angioedema) or other hypersensitivity reactions (such as sudden reduction of your blood pressure or dizziness) or increased wheezing and shortness of breath may occur individually or as part of severe allergic reaction (anaphylactic reaction) after using this medicine. Such serious side effects are rare. In addition, in common with all inhaled medicines, some patients may experience unexpected tightness of the chest, coughing, wheezing or breathlessness immediately after inhalation (known as bronchospasm).
If any of these side effects occur, please consult your doctor **immediately**.
Do not use your Braltus, inhaler again until you have seen or at least spoken with, your doctor.
If you are wheezy and short of breath you should use your fast-acting 'reliever' (rescue) inhaler straightaway.

Other side effects have been experienced by people using this medicine, and they are listed below according to their frequency.

Common: may affect up to 1 in 10 people
- Dry mouth: this is usually mild

Uncommon: may affect up to 1 in 100 people
- Dizziness
- Headache
- Taste disorders
- Blurred vision
- Irregular heart beat (atrial fibrillation)
- Sore throat (pharyngitis)
- Hoarseness (dysphonia)
- Cough
- Heart burn (gastro-oesophageal reflux disease)
- Constipation
- Fungal infections of the mouth and throat (oropharyngeal candidiasis)
- Rash
- Difficulty passing urine (urinary retention)
- Painful urination (dysuria)

Rare: may affect up to 1 in 1,000 people
- Difficulty in sleeping (insomnia)
- Seeing halos around lights or coloured images in association with red eyes (glaucoma)
- Increase of the measured eye pressure
- Irregular heart beat (supraventricular tachycardia)
- Faster heart beat (tachycardia)
- Feeling your heart beat (palpitations)
- Tightness of the chest, associated with coughing, wheezing or breathlessness immediately after inhalation (bronchospasm)
- Nosebleed (epistaxis)
- Inflammation of the larynx (laryngitis)
- Inflammation of the sinuses (sinusitis)
- Blockage of intestines or absence of bowel movements (intestinal obstruction including ileus paralytic)
- Inflammation of the gums (gingivitis)
- Inflammation of the tongue (glossitis)
- Difficulties swallowing (dysphagia)
- Inflammation of the mouth (stomatitis)
- Feeling sick (nausea)
- Nettle rash (urticaria)
- Itching (pruritus)
- Infections of the urinary tract

Frequency cannot be estimated from the available data:
- Depletion of body water (dehydration)
- Tooth decay (dental caries)
- Infections or ulcerations of the skin
- Dryness of the skin
- Swelling of joints

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. 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 BRALTUS
- **Keep out of the sight and reach of children.**
- Keep the bottle tightly closed.
- Store in the original package to protect from moisture.
- **Do not refrigerate or freeze**.
- Use the product within 60 days of opening the bottle.
- The Zonda® inhaler should only be used with the bottle of capsules provided. Do not reuse the inhaler for another bottle of capsules.
- Do not take Braltus after the expiry date which is stated on the bottle label or carton. The expiry date refers to the last day of the month.
- If the capsule becomes discoloured or shows any other signs of deterioration, you should seek the advice of your pharmacist who will tell you what to do.
- Medicines should not be disposed of via waste water or household waste. Ask your pharmacist how to dispose of medicines that are no longer required. These measures will help to protect the environment.
- The inhaler device should be disposed of in accordance with local requirements.

6. CONTENTS OF THE PACK AND OTHER INFORMATION
What Braltus contains
- The active substance is tiotropium bromide.
- Each capsule contains 13 micrograms of tiotropium (as bromide).
- During inhalation, 10 micrograms of tiotropium are delivered to the patient from each capsule from the mouthpiece of the Zonda® inhaler and are inhaled into the lungs.
- The other ingredients are lactose monohydrate (capsule content) and hypromellose (capsule shell).

What Braltus looks like and contents of the pack
- Braltus 10 microgram per delivered dose inhalation powder, hard capsule is a colourless and transparent hard capsule, containing white powder.
- This medicine is provided in bottles, with a screw-cap closure. The bottle is supplied in a carton with a Zonda® inhaler. The Zonda® inhaler has a green body and cap with a white push button.
- Braltus is available in packs containing 30 capsules and a Zonda® Inhaler.

Manufacturer
Manufactured by: Laboratorios LICONSA S.A., Avda. Miralcampo, No. 7, Poligono Industrial Miralcampo, 19200 Azuqueca de Henares, Guadalajara, Spain.

Procured from within the EU and repackaged by: BModesto B.V., Minervaweg 2, 8239 DL, Lelystad, Netherlands.

Product Licence holder: Doncaster Pharma Limited, Crompton Road, Doncaster, DN2 4PW, UK.

PL: 56830/0027 POM

Braltus® is a registered trademark of Chemo Iberica, S.A.
Zonda® is a registered trademark of Laboratorios LICONSA S.A.

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Blind or partially sighted?
Is this leaflet hard to see or read?
Call +44 (0) 1302 365000 (Regulatory)

Please be ready to give the following information:
Product name: Braltus® 10 microgram per delivered dose inhalation powder, hard capsule
Reference No: 56830/0027

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.

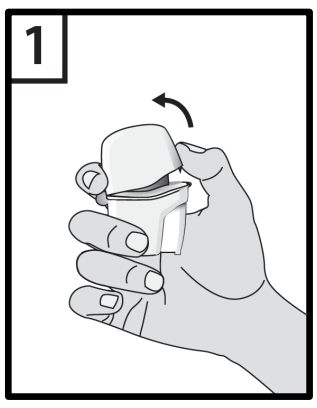
Remember to carefully follow your doctor's instructions for using Braltus. The Zonda® inhaler is especially designed for Braltus capsules: you must not use it to take any other medication. The capsules must only be inhaled using the Zonda® inhaler. Do **not** use any other inhalers to administer Braltus 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.

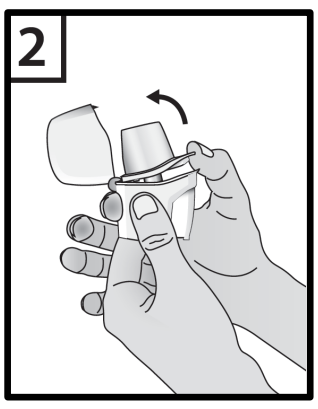


1. Dust cap
2. Mouthpiece
3. Base
4. Piercing button
5. Centre chamber

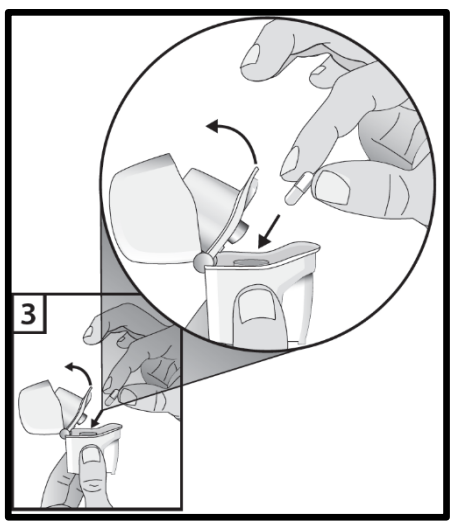
1. Pull the dust cap upwards.



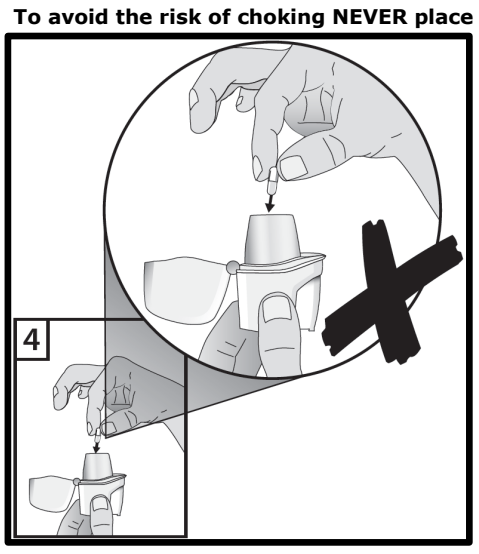
2. Hold the base of the inhaler firmly and open the mouthpiece by pulling it upwards, in the direction of the arrow.



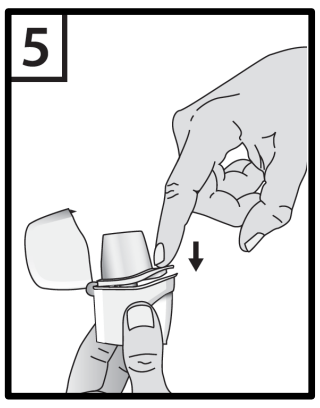
3. Remove a Braltus capsule from the bottle immediately before use and close the bottle tightly. Place one capsule in the centre chamber in the base of the inhaler.
Do **not** store the capsule in the Zonda® inhaler.



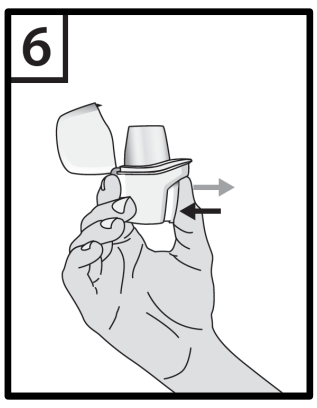
4. **To avoid the risk of choking NEVER place a capsule directly into the mouthpiece.**



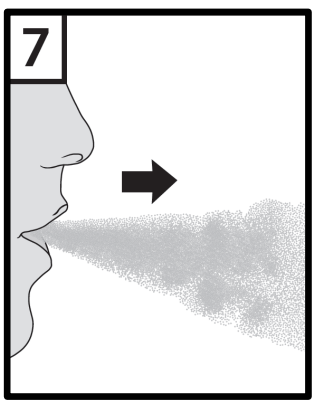
5. Close the mouthpiece until you hear a click, leaving the dust cap open.



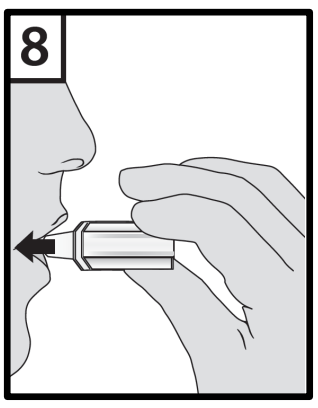
6. Hold the inhaler with the mouthpiece upwards, and firmly press the piercing button completely in once. Release the button. This will pierce the capsule and allows the medication to be released when you breathe in.



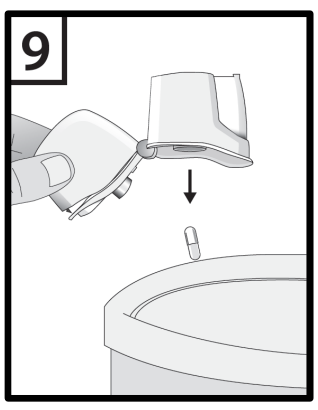
7. Breathe out fully. It is important to do this away from the mouthpiece. Avoid breathing into the mouthpiece at any time.



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 centre chamber. 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 dust cap, and store your Zonda® inhaler.



The Zonda® inhaler is a Medical Device (CE)

Manufacturer: Plastiape S.p.A., Via 1 Maggio, 8, 23875 Osnago LC, Italy.
Or
Laboratorios LICONSA S.A., Avda. Miralcampo, No. 7, Poligono Industrial Miralcampo, 19200 Azuqueca de Henares, Guadalajara, Spain.