

BREZTRI AEROSPHERE[®] 160/7.2/5 and 160/14.4/5

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.

1. Why am I using BREZTRI AEROSPHERE?

BREZTRI AEROSPHERE contains three active ingredients in the one puffer: budesonide, glycopyrronium, and formoterol fumarate dihydrate. BREZTRI AEROSPHERE is used to treat chronic obstructive pulmonary disease (COPD) and asthma.

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

2. What should I know before I use BREZTRI AEROSPHERE?

Do not use if you have ever had an allergic reaction to BREZTRI AEROSPHERE or any of the ingredients listed at the end of 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 BREZTRI AEROSPHERE?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with BREZTRI AEROSPHERE 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 BREZTRI AEROSPHERE?

- The recommended dose is 2 puffs (actuations) of BREZTRI AEROSPHERE twice a day (2 puffs in the morning, 2 puffs at night).
- Each pack of BREZTRI AEROSPHERE contains an instruction leaflet that tells you the correct way to use your inhaler. Please read this carefully.

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

5. What should I know while using BREZTRI AEROSPHERE?

Things you should do	• Remind any doctor, dentist or pharmacist you visit that you are using BREZTRI AEROSPHERE • See your doctor regularly to make sure that your COPD or asthma is not getting worse. If you find that your symptoms are worsening or not as well controlled as usual contact your doctor as it's important that your COPD or asthma is controlled properly
Things you should not do	• Do not stop taking BREZTRI AEROSPHERE, or lower the number of puffs or times you take it each day, unless your doctor tells you to (even if you are feeling well) • Do not use BREZTRI AEROSPHERE to relieve an acute attack of breathlessness or wheezing. BREZTRI AEROSPHERE is for regular long-term use only. You should have a separate reliever inhaler to treat sudden episodes or flare-ups of breathlessness or wheezing, as recommended by your doctor
Looking after your medicine	• Store BREZTRI AEROSPHERE in a cool dry place away from moisture, heat or sunlight where the temperature stays below 30°C. Do not expose to temperatures higher than 50°C and do not freeze • Store in the original carton and foil until you are ready to use it for the first time to protect it from moisture

For more information, see Section [5. What should I know while using BREZTRI AEROSPHERE?](#) 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. The most common side effects are headache, painful and/or frequent urination, muscle cramps/spasms, thrush, feeling anxious, problems sleeping, cough and/or hoarse voice, and feeling sick. The more serious side effects are chest pain, fast/irregular heartbeat, fever or chills and increased phlegm/sputum production or a change in colour, difficulty breathing, swelling of face, chest tightness or shortness of breath.

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.

BREZTRI AEROSPHERE® 160/7.2/5 and 160/14.4/5

Active ingredient(s): budesonide, glycopyrronium, and formoterol fumarate dihydrate

Consumer Medicine Information (CMI)

This leaflet provides important information about using BREZTRI AEROSPHERE. **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 BREZTRI AEROSPHERE.**

Where to find information in this leaflet:

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

1. Why am I using BREZTRI AEROSPHERE?

BREZTRI AEROSPHERE is used to treat chronic obstructive pulmonary disease (COPD) and asthma.

COPD (which includes chronic bronchitis and emphysema) and asthma are serious long-term diseases of the airways of the lungs. COPD and asthma can cause difficulty in breathing (breathlessness, wheezing or chest tightening/discomfort), constant coughing and coughing up of mucus (phlegm/sputum).

BREZTRI AEROSPHERE contains three active ingredients in the one puffer: budesonide, glycopyrronium, and formoterol fumarate dihydrate.

- **budesonide** – an inhaled corticosteroid which works by reducing and preventing inflammation in your lungs
- **glycopyrronium** – a long-acting muscarinic antagonist (or LAMA)
- **formoterol** – a fast and long-acting beta-2-agonist (or LABA)

Glycopyrronium and formoterol belong to a group of medicines called bronchodilators, and work together in different ways to stop the tightening of the muscles in the lungs, making it easier for air to get in and out of the lungs.

When used regularly, BREZTRI AEROSPHERE helps to make breathing easier and also helps to prevent flare-ups of symptoms (exacerbations).

BREZTRI AEROSPHERE should not be used to relieve a sudden episode or flare-up of breathlessness or wheezing. If this occurs, you should use your reliever medicine recommended by your doctor or pharmacist (e.g. Ventolin puffer).

2. What should I know before I use BREZTRI AEROSPHERE?

Warnings

Do not use BREZTRI AEROSPHERE if:

- you are allergic to budesonide, glycopyrronium, or formoterol fumarate dihydrate or any of the ingredients listed at the end of this leaflet

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

Check with your doctor if you:

- have allergies to any other medicines or foods
- have any other medical conditions such as high blood pressure (hypertension) or heart problems, thyroid problems (thyrotoxicosis), low potassium in your blood (hypokalaemia), diabetes or high blood glucose (hyperglycaemia), prostate problems, problems passing urine, eye problems (glaucoma), severe kidney or liver problems
- take any medicines for any other condition

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?](#)

For COPD, BREZTRI AEROSPHERE is not recommended for use in children or adolescents under 18 years of age.

For asthma, BREZTRI AEROSPHERE is not recommended for use in children under 12 years of age.

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.

Do not take BREZTRI AEROSPHERE if you are pregnant or breastfeeding unless your doctor says so.

It is not known if it is safe for you to take BREZTRI AEROSPHERE while you are pregnant. It may affect your baby.

It is not known if your baby can take in BREZTRI AEROSPHERE from breast milk if you are breastfeeding.

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 BREZTRI AEROSPHERE and affect how it works.

This includes:

- other medicines used regularly to treat your breathing problems that contain glycopyrronium, formoterol or other bronchodilators (such as ipratropium, tiotropium, aclidinium, umecclidinium, salmeterol, indacaterol, vilanterol, olodaterol)
- medicines that lower the amount of potassium in your blood such as diuretics (e.g. frusemide or hydrochlorothiazide)
- medicines used to treat heart problems or high blood pressure such as beta-blockers (e.g. atenolol, propranolol), antiarrhythmics (e.g. amiodarone) and diuretics
- medicines used to treat glaucoma such as beta-blockers (e.g. timolol)
- medicines used to treat depression or other mood/mental disorders such as tricyclic antidepressants and monoamine oxidase inhibitors
- medicines used to treat fungal infections (e.g. ketoconazole, itraconazole)
- medicines used to treat HIV (e.g. cobicistat and protease inhibitors such as ritonavir)
- medicine to use stomach ulcers (e.g. cimetidine)

These medicines may be affected by BREZTRI AEROSPHERE or may affect how well it works. You may need different amounts of your medicine or you may need to take different medicines. Your doctor can tell you what to do if you are taking other 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 BREZTRI AEROSPHERE.

4. How do I use BREZTRI AEROSPHERE?

How much to take

- **COPD:** The recommended dose is 2 puffs (actuations) of BREZTRI AEROSPHERE 160/7.2/5 twice a day (i.e. 2 puffs in the morning and 2 puffs at night)
- **Asthma:** The recommended dose is 2 puffs (actuations) of BREZTRI AEROSPHERE 160/14.4/5 twice a day (i.e. 2 puffs in the morning and 2 puffs at night)
- Your doctor should tell you the best way to manage your COPD and asthma symptoms and any flare-ups. This may include additional medicines (such as reliever medicines) to use when you have sudden episodes or flare-ups of breathlessness or wheezing
- If you are using more puffs of your reliever medicine or you are wheezing or breathless more than usual, tell your doctor
- If your COPD or asthma gets worse, your doctor may give you some additional medicines (such as oral corticosteroids or antibiotics)

When to take BREZTRI AEROSPHERE

- Take BREZTRI AEROSPHERE at about the same time each day (i.e. 2 puffs in the morning and 2 puffs at night)
- BREZTRI AEROSPHERE is a regular long-term medicine used to help control your COPD or asthma symptoms.

You need to use it every day even if you are feeling well

- BREZTRI AEROSPHERE helps control your COPD or asthma symptoms and prevent flare-ups, but does not cure COPD or asthma
- Follow the instructions provided and use BREZTRI AEROSPHERE until your doctor tells you to stop

How to take BREZTRI AEROSPHERE

- BREZTRI AEROSPHERE is for oral inhalation only
- Each pack of BREZTRI AEROSPHERE contains an instruction leaflet that tells you the correct way to use your inhaler. Please read this carefully
- If you are not sure how to use your inhaler, ask your doctor or pharmacist to show you how
- If you find it difficult breathing in and pressing the inhaler at the same time, talk to your doctor or pharmacist. You may be able to use a spacer with your inhaler. A spacer is a holding chamber shaped like a football or a tube, which can attach to your inhaler

If you forget to use BREZTRI AEROSPHERE

BREZTRI AEROSPHERE should be used regularly at the same time each day. If you miss your dose at the usual time, take it as soon as you remember, and then go back to taking it as you would normally.

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. Do not take more than two puffs twice a day on the same day.

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

If you use too much BREZTRI AEROSPHERE

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

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), 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. You may need urgent medical attention.

Symptoms of an overdose may include blurred vision, dry mouth, nausea, muscle cramps, shaking, headache, fast or irregular heartbeat, and changes in blood pressure.

5. What should I know while using BREZTRI AEROSPHERE?

Things you should do

- Take BREZTRI AEROSPHERE exactly as your doctor has prescribed
- If you are about to be started on any new medicine (including any for COPD, asthma or other

- lung/breathing problems), remind your doctor and pharmacist that you are taking BREZTRI AEROSPHERE
- Tell your doctor if you become pregnant while you are taking BREZTRI AEROSPHERE
- 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
- Tell your doctor if you need to have any medical tests while you are taking BREZTRI AEROSPHERE
- Have your reliever medicine with you at all times
- Rinse your mouth out with water after taking your daily morning and evening dose of BREZTRI AEROSPHERE and spit this out. This helps to reduce the chance of you developing thrush (fungal infection) in your mouth
- **Tell your doctor if you notice any of the following symptoms:**
 - weight gain
 - roundness of face
 - acne
 - a tendency to bruise easily

Call your doctor straight away if you:

- Find that your symptoms are worsening or not as well controlled as usual (or if you find the treatment ineffective at the recommended dose) as it's important that your COPD or asthma is controlled properly
- See your doctor regularly to make sure that your COPD or asthma is not getting worse

Remind any doctor, dentist or pharmacist you visit that you are using BREZTRI AEROSPHERE.

Things you should not do

- Do not stop taking BREZTRI AEROSPHERE, or lower the number of puffs or times you take it each day, unless your doctor tells you to
- Do not take BREZTRI AEROSPHERE to treat any other conditions unless your doctor tells you to
- Do not give BREZTRI AEROSPHERE to anyone else, even if their symptoms are similar to yours
- Do not use BREZTRI AEROSPHERE to relieve an acute attack of breathlessness or wheezing. BREZTRI AEROSPHERE is for regular long-term use only. You should have a separate reliever inhaler to treat sudden episodes or flare-ups of breathlessness or wheezing, as recommended by your doctor or pharmacist.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how BREZTRI AEROSPHERE affects you.

BREZTRI AEROSPHERE is unlikely to affect your ability to drive or operate machinery.

Looking after your medicine

- Store in the original carton and foil until you are ready to use it for the first time to protect it from moisture

- Always replace the mouthpiece cap after using BREZTRI AEROSPHERE

Follow the instructions in the carton on how to clean and take care of your medicine properly.

Store BREZTRI AEROSPHERE in a cool dry place away from moisture, heat or sunlight where the temperature stays below 30°C. For example, do not store it:

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

Keep BREZTRI AEROSPHERE where young children cannot reach it.

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

When to discard your medicine

Discard BREZTRI AEROSPHERE within 3 months (120 actuations pack) or 3 weeks (28 actuations sample pack) after removal from the foil pouch.

WARNING

The canister in BREZTRI AEROSPHERE contains a pressurised liquid. Do not expose to temperatures higher than 50°C and do not freeze. Do not pierce the canister. The canister should not be broken, punctured or burnt, even when it seems empty. If exposed to freezing temperatures, the inhaler should be kept at room temperature for 1 hour prior to taking a dose.

Getting rid of any unwanted medicine

Your BREZTRI AEROSPHERE should always be returned to your pharmacist for disposal, including:

- when you have taken all your puffs and the dose indicator reaches zero ('0') - see instructions in the pack, or
- 3 months (120 actuations pack) or 3 weeks (28 actuations sample pack) after removal from the foil pouch. **Note:** When you first opened the foil pouch to remove your inhaler, you may have written the date you opened it onto the carton to remind you when to stop using the inhaler, or
- it is damaged or past its expiry date, or
- your doctor has told you to stop using it

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
• headache • painful and/or frequent urination (signs of urinary tract infection)	Speak to your doctor if you have any of these less

Less serious side effects	What to do
- muscle cramps/spasms - thrush (a fungal infection) in your mouth – you may notice sore, yellowish, raised patches in the mouth, hoarse voice, irritation of the tongue and mouth or coughing - feeling anxious - problems sleeping (insomnia) - cough and/or hoarse voice - feeling sick (nausea) - decreased bone density	serious side effects and they worry you.

The above list includes the more common side effects of your medicine. They are usually mild and short-lived.

Serious side effects

Serious side effects	What to do
- any side effects affecting your chest or heart such as chest pain or a fast, irregular or skipping / fluttering heart beat (tachycardia, palpitations) - fever or chills, increased phlegm/sputum production or a change in colour, increased cough or difficulties breathing – these may be a sign of pneumonia (a lung infection) - chest tightness, coughing, wheezing or breathlessness immediately after inhalation of BREZTRI AEROSPHERE (these might be signs of a serious type of bronchospasm) - signs and symptoms of an allergic reactions such as 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	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.

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

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.

Other side effects

Adrenal glands

Your adrenal glands may be affected by taking high doses of corticosteroids over a long period of time or if you change from or use high doses of oral corticosteroids. Your doctor may do tests to check how the adrenal glands are working.

Your doctor may also tell you to take additional oral corticosteroids during period of stress such as trauma, surgery and infection.

Growth

Corticosteroids taken into the lungs for long periods (eg 12 months) may affect how adolescents grow. In rare cases, some adolescents may be sensitive to the growth effects of corticosteroids, so the doctor may monitor an adolescent's height.

Tell your doctor if you notice any issues with your eyes such as blurred vision or other problems with your eyesight.

Your doctor may need to send you to an ophthalmologist (eye doctor) to check that you don't have eye problems such as cataracts (clouding of the eye lens), glaucoma (increased pressure in your eyeballs) or other rare eye conditions reported with corticosteroid use.

Some side effects (for example, changes in thyroid function, blood sugar levels or blood potassium levels) can only be found when your doctor does tests from time to time to check your progress.

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. 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 BREZTRI AEROSPHERE contains

Active ingredients (main ingredients)	budesonide, glycopyrronium (as glycopyrronium bromide), and formoterol fumarate dihydrate
Other ingredients (inactive ingredients)	- propellant (norflurane [HFA-134a]) or propellant ((E)-1,3,3,3-tetrafluoroprop-1-ene [HFO-1234ze(E)]) - calcium chloride dihydrate - distearoylphosphatidylcholine (DSPC)

Each actuation (puff) contains:

- 160 micrograms of budesonide
- 7.2 or 14.4 micrograms of glycopyrronium
- 5 micrograms of formoterol fumarate dihydrate

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

This medicine does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

What BREZTRI AEROSPHERE looks like

BREZTRI AEROSPHERE is a pressurised metered dose inhaler (pMDI). There are two types of pMDIs registered*:

Bespak / Trudell device

This inhaler comes as a pressurised canister with a dose indicator on top inside a white plastic actuator body and mouthpiece. The mouthpiece is covered with a removable grey protective dust cap.

DFP-EvoCap XS / EvoCap XS device

This inhaler comes as a pressurised canister with a dose indicator on top inside a yellow plastic actuator body and white mouthpiece. The mouthpiece is covered with a removable grey protective dust cap.

The 120 actuations (puffs) pack size also contains a plastic collar inside the actuator body.

Each inhaler is individually wrapped in a foil laminate pouch (containing a sachet of drying agent).

BREZTRI AEROSPHERE 160/7.2/5 (AUST R 339070), BREZTRI AEROSPHERE 160/7.2/5 DFP-EvoCap (AUST R 386646) and BREZTRI AEROSPHERE 160/14.4/5 DFP-EvoCap (AUST R 510325) with norflurane propellant come in two pack sizes* - 120 actuations (puffs) inhaler and a 28 actuations (puffs) inhaler (sample pack).

BREZTRI AEROSPHERE 160/7.2/5 DFP-EvoCap with (E)-1,3,3,3-tetrafluoroprop-1-ene propellant (AUST R 475305) come in a pack of 120 actuations inhaler.

* Not all pMDIs or pack sizes may be available in Australia.

Who distributes BREZTRI AEROSPHERE

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