# BREZTRI AEROSPHERE®

160/7.2/5 mcg/actuation, Pressurised inhalation, suspension
budesonide/glycopyrronium/formoterol fumarate dihydrate

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## What BREZTRI AEROSPHERE is used for

BREZTRI AEROSPHERE is an inhaler that is used for adults with a lung disease called 'chronic obstructive pulmonary disease' (or 'COPD'), a long-term disease of the airways in the lungs.

BREZTRI AEROSPHERE is used to make breathing easier and improve symptoms of COPD such as shortness of breath, wheezing and cough. BREZTRI AEROSPHERE can also prevent flare-ups (exacerbations) of COPD.

BREZTRI AEROSPHERE delivers the active substances into your lungs as you breathe in. If you use this medicine regularly twice a day, it will help to reduce the effects of COPD on your everyday life.

## How BREZTRI AEROSPHERE works

BREZTRI AEROSPHERE contains three active substances: formoterol fumarate dihydrate, glycopyrronium, and budesonide.

- Formoterol fumarate dihydrate and glycopyrronium belong to a group of medicines called 'bronchodilators'. They work in different ways to prevent tightening of the muscles around the airways, making it easier for air to get in and out of the lungs.
- Budesonide belongs to a group of medicines called 'corticosteroids'. These work by reducing inflammation in your lungs.

## Before you use BREZTRI AEROSPHERE

*- When you must not use it:*

**Do not use BREZTRI AEROSPHERE**

- if you are allergic to formoterol fumarate dihydrate, glycopyrronium, budesonide or any of the other ingredients of this medicine (see "Ingredient" section).

*- Before you start to use it*

Talk to your doctor before using BREZTRI AEROSPHERE if you have:

- high blood pressure or heart problems
- diabetes
- lung infection
- problems with your thyroid gland
- low levels of potassium in your blood
- prostate problems or any problems passing urine
- an eye problem called 'angle-closure glaucoma'
- kidney or liver problems.

Talk to your doctor if you think any of these may apply to you.

Some medicines may increase the effects of BREZTRI AEROSPHERE and your doctor may wish to monitor you carefully if you are taking these medicines (including some medicines for HIV such as cobicistat) (see subsection "Taking other medicines")

*- Taking other medicines*

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes medicines obtained without a prescription, and herbal medicines. This is because BREZTRI AEROSPHERE can affect the way some medicines work. Also some medicines can affect how BREZTRI AEROSPHERE works, or make it more likely that you will have side effects.

Tell your doctor or pharmacist if you are taking any of the following:

- medicines called beta-blockers (such as atenolol or propranolol), that may be used for high blood pressure or heart problems, or to treat glaucoma (such as timolol)
- medicines which are used to treat fungal infections – such as ketoconazole or itraconazole
- medicines which are used to treat HIV infection – such as ritonavir or cobicistat
- medicines that lower the amount of potassium in your blood, such as:
  - corticosteroids that you take by mouth (such as prednisolone),
  - diuretics – medicines that increase urine production (such as furosemide or hydrochlorothiazide), which can be used for treating high blood pressure,
  - some medicines used to treat breathing problems (such as theophylline) – called 'methylxanthines',
- any medicines that work in the same way as BREZTRI AEROSPHERE – such as tiotropium, ipratropium, aclidinium, umeclidinium or salmeterol, arformoterol, vilanterol, olodaterol or indacaterol. Do not use BREZTRI AEROSPHERE if you already use these medicines.
- medicines which are used to treat heart rhythm problems – such as amiodarone
- medicines which can change some electrical activity of the heart (called the 'QT interval') – such as medicines for:
  - depression (such as monoamine oxidase inhibitors or tricyclic antidepressants),

- bacterial infections (such as erythromycin, clarithromycin or telithromycin),
- allergic reactions (anti-histamines).

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

**How to use BREZTRI AEROSPHERE**

*- How much to use & when to use it*

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 two puffs twice a day – two puffs in the morning and two puffs in the evening.

It is important to use BREZTRI AEROSPHERE every day – even if you have no COPD symptoms at the time.

**Remember**: Always rinse your mouth with water after using BREZTRI AEROSPHERE. This is to remove any medicine which is left in the mouth. Spit this water out – do not swallow.

*- Using BREZTRI AEROSPHERE with a spacer*

You may find it difficult breathing in and pressing the inhaler at the same time. If this happens, talk to your doctor or pharmacist. It may help to use a 'spacer' with your inhaler.

This medicine is for long-term use. Use this medicine for as long as your doctor tells you to. It will only be effective as long as you are using it.

Do not stop unless your doctor tells you to – even if you feel better – as your symptoms may get worse. If you want to stop treatment, talk to your doctor first.

If you have any further questions on the use of this medicine, talk to your doctor or pharmacist.

*- If you forget to use it*

Do not take a double dose to make up for a forgotten 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 more than two puffs twice a day on the same day.

*- If you use too much (overdose)*

If you have used more BREZTRI AEROSPHERE than you should, talk to a doctor or pharmacist straight away. You may need medical attention. You may notice that your heart is beating faster than usual, you feel shaky, you have problems with your sight, you have a dry mouth or you have a headache or feel sick (nausea).

**While you are using it**

*- Things you must do*

Use BREZTRI AEROSPHERE as directed by your doctor.

If your breathlessness, tightness of the chest, wheezing or coughing is getting worse while using BREZTRI AEROSPHERE, you should continue to use BREZTRI AEROSPHERE but contact your doctor as soon as possible, as you may need additional treatment.

*- Things you must not do*

BREZTRI AEROSPHERE is used as a long-term maintenance treatment for COPD. **Do not use it to treat a sudden attack of breathlessness or wheezing.**

*- Things to be careful of*

*Pregnancy*

Do not use BREZTRI AEROSPHERE if you are pregnant unless your doctor tells you that you can.

*Breast-feeding*

Do not use this medicine if you are breast-feeding unless your doctor tells you that you can.

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 taking this medicine.

*Driving and using machines*

It is unlikely that this medicine will affect your ability to drive or use machines. However, dizziness is an uncommon side effect which should be taken into account when driving or using machines.

*Children and adolescents*

BREZTRI AEROSPHERE has not been studied in children and adolescents. Do not give this medicine to children or adolescents below the age of 18 years.

**Side effects**

*- Serious side effect*

Like all medicines, this medicine can cause side effects, although not everybody gets them. The following side effects may happen with this medicine:

**Uncommon** (may affect up to 1 in 100 people)

**Immediate breathing difficulties**:

- if you get breathing difficulties straight after using BREZTRI AEROSPHERE, such as tightness of the chest, coughing, wheezing or feeling breathless, **stop using this medicine** and **tell your doctor straight away**.

**Allergic reactions**:

- swelling of your face, particularly around your mouth (swelling of your tongue or throat may make it difficult to swallow)
- rash or hives together with difficulty breathing
- suddenly feeling faint

These symptoms may be signs of an allergic reaction which may become serious. Stop using this medicine and call for medical help straight away if you notice the serious side effects above.

*- Other side effects*

Tell your doctor or pharmacist if you notice any of the following side effects:

**Common** (may affect up to 1 in 10 people)

- thrush in the mouth (a fungal infection). Rinsing your mouth out with water immediately after

using BREZTRI AEROSPHERE may help prevent this.
- feeling anxious
- difficulty sleeping
- feeling sick (nausea)
- headache
- coughing or a hoarse voice
- muscle cramps
- awareness of your heart beating (palpitations)
- high blood sugar levels (as shown in tests)
- painful and frequent urination (may be signs of a urinary tract infection)
- pneumonia (infection of the lung).

  Tell your doctor if you have any of the following while using BREZTRI AEROSPHERE, they could be symptoms of a lung infection:
  - fever or chills,
  - increased mucus production, change in mucus colour,
  - increased cough or increased breathing difficulties.

**Uncommon** (may affect up to 1 in 100 people)
- shaking, tremor or feeling dizzy
- dry mouth, or mild irritation in the throat
- bruising of the skin
- feeling restless, nervous or agitated
- depression
- fast heart beat or uneven heart beat
- chest pain or tightening in the chest (angina pectoris)

**Very rare** (may affect up to 1 in 10,000 people)
- changes in behaviour
- an effect on the adrenal gland

**Not known** (frequency cannot be estimated from the available data):
- blurred vision
- clouding of the lens of your eyes (signs of cataract)
- increased pressure in the eye (glaucoma)
- swelling of your face, particularly around your mouth (swelling of your tongue or throat may make it difficult to swallow)

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers→ Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

**Storage & Disposal of BREZTRI AEROSPHERE**

*Storage*
- Keep this medicine out of the sight and reach of children.
- Do not use BREZTRI AEROSPHERE after the expiry date which is stated on the carton, pouch and pressurised container after 'EXP'. The expiry date refers to the last day of that month.
- After opening the pouch, the inhaler must be used within 3 months.
- Keep the inhaler inside the sealed pouch – only remove the inhaler from the sealed pouch immediately before first use. On the day the pouch is opened, write the date on the inhaler label in the space provided.
- Do not store above 30°C. Store in a dry place.
- For best results, the inhaler should be at room temperature before you use it.
- Do not break, puncture or burn the pressurised container, even when apparently empty. Do not use or store near heat or open flames.

*- Disposal*

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

**Product Description**

*- What it looks like*

BREZTRI AEROSPHERE comes as a canister with a dose indicator, supplied with a yellow plastic actuator body and white mouthpiece. The mouthpiece is covered with a removable grey protective cap.

BREZTRI AEROSPHERE is supplied in a foil pouch that contains a drying packing (desiccant) and packed into a carton.

Each inhaler contains 120 puffs.

*- Ingredients*
- *Active Ingredients*
  - *1 puff of* BREZTRI AEROSPHERE delivers budesonide 160 micrograms, glycopyrronium bromide 9.0 micrograms, equivalent to 7.2 micrograms of glycopyrronium and formoterol fumarate dihydrate 5.0 micrograms, equivalent to 4.8 micrograms of formoterol fumarate.
- *Inactive Ingredients*
  - Norflurane (HFA-134a), 1,2-distearoyl-sn-glycero-3-phosphocholine [DSPC], Calcium chloride

**MAL number**

MALXXXXXXXXAZ

**Manufacturer**

AstraZeneca Dunkerque Production, 224 Avenue de la Dordogne, 59640 Dunkerque, France.

**Product Registration Holder**

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