

BREZTRI AEROSPHERE® 160/7.2/5

budesonide, glycopyrronium, and formoterol (eformoterol) fumarate dihydrate

Consumer Medicine Information

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?
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1. Why am I using BREZTRI AEROSPHERE?

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

COPD (which includes chronic bronchitis and emphysema) is a serious long-term lung disease that slowly gets worse. COPD 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 (eformoterol) 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-agonists (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 (eformoterol) 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 asthma, 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?

BREZTRI AEROSPHERE is not recommended for use in children or adolescents under 18 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, umeclidinium, 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.