



**BREZTRI**  
AEROSPHERE®

(budesonide 160 mcg, glycopyrrolate 9 mcg and formoterol fumarate 4.8 mcg) Inhalation Aerosol

# Exploring the Benefits of BREZTRI: AstraZeneca's Triple Therapy Treatment

## ATTENDEES WILL GAIN:



**An Overview of  
BREZTRI AEROSPHERE**



**A Review of Relevant  
Clinical Trial Data**



**Important Safety Information  
and Support Programs**

### TO FIND OUT MORE OR TO REGISTER PLEASE CONTACT

Monique Crenshaw  
1-571-480-1801

### DATE & TIME

November 18, 2021  
06:00 PM – 08:00 PM Eastern Standard Time

### LOCATION

Christiana Hilton  
100 Continental Drive  
Newark, DE 19713

### PLEASE RSVP BY

11/15/2021

### PRESENTED BY

Dr. Victor Banzon  
Pulmonologist  
Beebe HealthCare



### INDICATION

BREZTRI AEROSPHERE is indicated for the maintenance treatment of patients with chronic obstructive pulmonary disease (COPD).

### LIMITATIONS OF USE

Not indicated for the relief of acute bronchospasm or for the treatment of asthma.

## IMPORTANT SAFETY INFORMATION

- » BREZTRI is contraindicated in patients who have a hypersensitivity to budesonide, glycopyrrolate, formoterol fumarate, or product excipients
- » BREZTRI is not indicated for treatment of asthma. Long-acting beta<sub>2</sub>-adrenergic agonist (LABA) monotherapy for asthma is associated with an increased risk of asthma-related death. These findings are considered a class effect of LABA monotherapy. When a LABA is used in fixed-dose combination with ICS, data from large clinical trials do not show a significant increase in the risk of serious asthma-related events (hospitalizations, intubations, death) compared with ICS alone. Available data do not suggest an increased risk of death with use of LABA in patients with COPD

***Please see additional Important Safety Information on reverse.***

This program is intended for US healthcare professionals only.

AstraZeneca will comply with any and all federal or state reporting requirements regarding any value or expense associated with this event. AstraZeneca fully supports and abides by the PhRMA Code on Interactions With Healthcare Professionals (HCPs). This program is open only to HCP invitees.

AstraZeneca will not accommodate attendance of a spouse or other guest of any HCP attendee, nor will AstraZeneca pay for transportation or parking costs of attendees. If you are a prescriber and/or a Federal, State, or institution employee, you may be subject to laws, regulations, or rules that prohibit or limit your receipt of gifts, meals, or items of value. We ask that you comply with any such restrictions.

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## IMPORTANT SAFETY INFORMATION (CONTINUED)



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- » BREZTRI should not be initiated in patients with acutely deteriorating COPD, which may be a life-threatening condition
- » BREZTRI is NOT a rescue inhaler. Do NOT use to relieve acute symptoms; treat with an inhaled short-acting beta<sub>2</sub>-agonist
- » BREZTRI should not be used more often than recommended; at higher doses than recommended; or in combination with LABA-containing medicines, due to risk of overdose. Clinically significant cardiovascular effects and fatalities have been reported in association with excessive use of inhaled sympathomimetic drugs
- » Oropharyngeal candidiasis has occurred in patients treated with orally inhaled drug products containing budesonide. Advise patients to rinse their mouths with water without swallowing after inhalation
- » Lower respiratory tract infections, including pneumonia, have been reported following ICS. Physicians should remain vigilant for the possible development of pneumonia in patients with COPD as the clinical features of pneumonia and exacerbations frequently overlap
- » Due to possible immunosuppression, potential worsening of infections could occur. Use with caution. A more serious or fatal course of chickenpox or measles can occur in susceptible patients
- » Particular care is needed for patients transferred from systemic corticosteroids to ICS because deaths due to adrenal insufficiency have occurred in patients during and after transfer. Taper patients slowly from systemic corticosteroids if transferring to BREZTRI
- » Hypercorticism and adrenal suppression may occur with regular or very high dosage in susceptible individuals. If such changes occur, consider appropriate therapy
- » Caution should be exercised when considering the coadministration of BREZTRI with long-term ketoconazole and other known strong CYP3A4 Inhibitors. Adverse effects related to increased systemic exposure to budesonide may occur
- » If paradoxical bronchospasm occurs, discontinue BREZTRI immediately and institute alternative therapy
- » Anaphylaxis and other hypersensitivity reactions (eg, angioedema, urticaria or rash) have been reported. Discontinue and consider alternative therapy
- » Use caution in patients with cardiovascular disorders, especially coronary insufficiency, as formoterol fumarate can produce a clinically significant cardiovascular effect in some patients as measured by increases in pulse rate, systolic or diastolic blood pressure, and also cardiac arrhythmias, such as supraventricular tachycardia and extrasystoles
- » Decreases in bone mineral density have been observed with long-term administration of ICS. Assess initially and periodically thereafter in patients at high risk for decreased bone mineral content
- » Glaucoma and cataracts may occur with long-term use of ICS. Worsening of narrow-angle glaucoma may occur, so use with caution. Consider referral to an ophthalmologist in patients who develop ocular symptoms or use BREZTRI long term. Instruct patients to contact a healthcare provider immediately if symptoms occur
- » Worsening of urinary retention may occur. Use with caution in patients with prostatic hyperplasia or bladder-neck obstruction. Instruct patients to contact a healthcare provider immediately if symptoms occur
- » Use caution in patients with convulsive disorders, thyrotoxicosis, diabetes mellitus, and ketoacidosis or unusually responsive to sympathomimetic amines
- » Be alert to hypokalemia or hyperglycemia
- » Most common adverse reactions in a 52-week trial (incidence ≥ 2%) were upper respiratory tract infection (5.7%), pneumonia (4.6%), back pain (3.1%), oral candidiasis (3.0%), influenza (2.9%), muscle spasms (2.8%), urinary tract infection (2.7%), cough (2.7%), sinusitis (2.6%), and diarrhea (2.1%). In a 24-week trial, adverse reactions (incidence ≥ 2%) were dysphonia (3.3%) and muscle spasms (3.3%)
- » BREZTRI should be administered with extreme caution to patients being treated with monoamine oxidase inhibitors and tricyclic antidepressants, as these may potentiate the effect of formoterol fumarate on the cardiovascular system
- » BREZTRI should be administered with caution to patients being treated with:
  - › Strong cytochrome P450 3A4 inhibitors (may cause systemic corticosteroid effects)
  - › Adrenergic drugs (may potentiate effects of formoterol fumarate)
  - › Xanthine derivatives, steroids, or non-potassium sparing diuretics (may potentiate hypokalemia and/or ECG changes)
  - › Beta-blockers (may block bronchodilatory effects of beta-agonists and produce severe bronchospasm)
  - › Anticholinergic-containing drugs (may interact additively). Avoid use with BREZTRI
- » Use BREZTRI with caution in patients with hepatic impairment, as budesonide and formoterol fumarate systemic exposure may increase. Patients with severe hepatic disease should be closely monitored

**Please see accompanying full Prescribing Information, including Patient Information.**

You are encouraged to report negative side effects of AstraZeneca prescription drugs by calling **1-800-236-9933**.

If you prefer to report these to the FDA, either visit [www.FDA.gov/medwatch](http://www.FDA.gov/medwatch) or call **1-800-FDA-1088**.

