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BREZTRI
AEROSPHERE

(budesonide, glycopyrronium, and formoterol fumarate) Inhalation Aerosol

PBS Information: Authority required (STREAMLINED) for the treatment of COPD. Refer to PBS Schedule for full authority information.

BEFORE PRESCRIBING PLEASE REVIEW FULL PRODUCT INFORMATION AVAILABLE
ON REQUEST FROM ASTRAZENECA ON 1800 805 342 OR www.astrazeneca.com.au/PI

BREZTRI AEROSPHERE® (budesonide 160µg/ glycopyrronium 7.2µg/ formoterol (eformoterol) fumarate dihydrate 5µg) pressurised metered dose inhaler for oral inhalation. Therapeutic indications: Maintenance treatment to prevent exacerbations and relieve symptoms in adults with moderate, severe, or very severe chronic obstructive pulmonary disease (COPD) who require treatment with a combination of an inhaled corticosteroid (ICS), a long-acting β_2 -agonist (LABA), and a long-acting muscarinic antagonist (LAMA). BREZTRI is not indicated for the initiation of therapy in COPD. **Dosage:** Adults \geq 18 years: 2 actuations twice daily. **Contraindications:** Hypersensitivity to any of the ingredients. **Special Warning and Precautions: Not indicated** for the treatment of asthma, or for the treatment of acute episodes of bronchospasm, or as rescue therapy to treat an acute COPD exacerbation; patients transferring from oral corticosteroids (OCS) may remain at risk of impaired adrenal function - additional systemic corticosteroid cover should be considered during periods of stress or elective surgery; discontinue BREZTRI immediately should paradoxical bronchospasm occur (as with other inhaled medicines, bronchospasm may be life-threatening); not for use with other medicines containing a LABA or LAMA; caution in patients with clinically significant cardiovascular disease, thyrotoxicosis or prolonged QTc interval; possible systemic effects of ICS (see full PI); consider referral to an ophthalmologist in patients who develop ocular symptoms or use BREZTRI long term; hypokalaemia; hyperglycaemia; caution in patients with symptomatic prostatic hyperplasia, urinary retention or narrow-angle glaucoma; an increase in the incidence of pneumonia, including requiring hospitalisation, has been observed in patients with COPD receiving inhaled corticosteroids - physicians should remain vigilant for the possible development of pneumonia in patients with COPD as the clinical features of such infections can overlap with symptoms of COPD; oropharyngeal candidiasis; severely impaired renal or hepatic function – monitor closely and use only if benefit outweighs risk; BREZTRI should only be used during pregnancy if the expected benefits outweigh the potential risks (category B3); lactation - use only if the expected benefit to the mother outweigh potential risk to the child; no relevant use in children $<$ 18 years in COPD. See full PI for further information. **Interactions:** Not for use with other LABA and/or LAMA containing medicines; strong CYP3A4 inhibitors, e.g. itraconazole, ketoconazole, HIV protease inhibitors, cobicistat containing products; beta-receptor blockers; medicines known to prolong QTc interval, e.g. MAOIs, tricyclic antidepressants; if hypokalaemic, drugs that may potentiate hypokalaemia, e.g. non-potassium sparing diuretics; other antimuscarinics and sympathomimetics. **Adverse effects: Very common (\geq 10%):** nasopharyngitis. **Common (\geq 1%):** COPD, upper respiratory tract infection, pneumonia, bronchitis, back pain, hypertension, dyspnoea, headache, urinary tract infection, influenza, sinusitis, muscle spasm, cough, oral candidiasis, diarrhoea, hyperglycaemia, anxiety, insomnia, palpitations, dysphonia, nausea; others, see full PI. **Date of first approval:** 19 July 2021.

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