PRESCRIBING INFORMATION

BEVESPI AEROSPHERE 7.2 MICROGRAMS/5 MICROGRAMS PRESSURISED INHALATION, SUSPENSION
(glycopyrronium/formoterol fumarate dihydrate)

Consult Summary of Product Characteristics before prescribing.

**Indication:** Bevespi Aerosphere is indicated as a maintenance bronchodilator treatment to relieve symptoms in adult patients with chronic obstructive pulmonary disease (COPD).

**Presentation:** Pressurised inhalation, suspension. Each single actuation (delivered dose) contains glycopyrronium bromide 9 mcg equivalent to 7.2 mcg of glycopyrronium, and 5 mcg of formoterol fumarate dihydrate.

**Dosage and Administration:** Recommended dose is two inhalations twice daily. Patients should be advised not to take more than 2 inhalations twice daily. **Elderly:** No dose adjustment necessary. **Renal impairment:** No dose adjustment necessary in patients with mild to moderate renal impairment. Only use in patients with severe renal impairment or end-stage disease requiring dialysis if benefits outweigh risks. **Hepatic impairment:** No dose adjustment necessary in patients with mild to moderate hepatic impairment. Use with caution in patients with severe hepatic impairment. **Paediatric population:** There is no relevant use (under 18 years) for the indication of COPD.

**Contraindications:** Hypersensitivity to the active substances or excipients.

**Warnings and Precautions:** Bevespi Aerosphere should not be used to treat Asthma. If paradoxical bronchospasm occurs, Bevespi Aerosphere should be discontinued immediately, and an alternative therapy instituted, if necessary. Bevespi is not indicated as rescue therapy for the treatment of acute episodes of bronchospasms. Cardiovascular effects, such as cardiac arrhythmias e.g. atrial fibrillation and tachycardia, may be seen after administration of muscarinic receptor antagonists and sympathomimetics, including glycopyrronium or formoterol. Use with caution in patients with severe cardiovascular disorders such as ischaemic heart disease, tachyarrhythmias or severe heart failure. Exercise caution in patients with thyrotoxicosis or known/suspected prolongation of the QTc interval. β2-adrenergic agonists may produce significant hypokalaemia, which may increase the susceptibility to cardiac arrhythmias. The decrease in serum potassium is usually transient, not requiring supplementation. In patients with severe COPD, hypokalaemia may be potentiated by hypoxia and concomitant treatment. Inhalation of high doses of β2-adrenergic agonists may produce increases in plasma glucose. Use with caution in patients with symptomatic prostatic hyperplasia, urinary retention or with narrow-angle glaucoma. Bevespi Aerosphere should be used only if the expected benefit outweighs the potential risk for patients with severe renal impairment [(creatinine clearance of <30mL/min), including those with end-stage renal disease requiring dialysis] and for patients with severe hepatic impairment. For severe hepatic impairment patients, monitor for potential adverse reactions.

**Drug Interactions:** Drug interactions may occur with medicinal products affecting renal excretion mechanisms. Concomitant use/co-administration with anticholinergic and/or long-acting β2-adrenergic agonist containing medicinal products is not recommended as it may potentiate known inhaled muscarinic antagonist or β2-adrenergic agonist adverse reactions. Caution is advised with concomitant use with methylxanthine derivatives, steroids or non-potassium-sparing diuretics may potentiate the possible initial hypokalaemic effect of β2-adrenergic agonists. Not to be given together with β2-adrenergic blockers (including eye
drops) as can weaken or inhibit the effect of β-adrenergic agonists such as formoterol unless compelling reasons for their use. If β-adrenergic blockers are required (including eye drops), cardioselective β-adrenergic blockers are preferred, although they should also be administered with caution. Bevespi Aerosphere should be administered with caution to patients being treated with medicinal products known to prolong the QTc interval.

**Pregnancy and Lactation:** Administration to pregnant or breast-feeding women should only be considered if the expected benefit to the mother is greater than any possible risk to the foetus or child.

**Ability to Drive and Use Machines:** Dizziness and nausea are common side effects and patients who experience these symptoms should observe caution when driving or using machines.

**Undesirable Events:** Consult SmPC for full list of adverse events. **Common:** Anxiety, headache, dizziness, dry mouth, nausea, muscle spasms, urinary tract infection, chest pain. **Uncommon:** Hypersensitivity reactions including rash and pruritus, hyperglycaemia, agitation, restlessness, insomnia, tremor, tachycardia, palpitations, cardiac arrhythmias (atrial fibrillation, supraventricular tachycardia and extrasystoles), urinary retention.

**Legal Category:** POM.

**Marketing Authorisation Numbers:** EU/1/18/1339/001

**Presentation & Basic NHS Cost:** 1 inhaler with 120 actuations: £32.50

**Further Information is Available From:** AstraZeneca UK Ltd., 600 Capability Green, Luton LU1 3LU, UK.

Bevespi Aerosphere is a trade mark of the AstraZeneca group of companies.

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Adverse events should be reported. Reporting forms and information can be found at [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple App Store. Adverse events should also be reported to AstraZeneca by visiting [https://contactazmedical.astrazeneca.com](https://contactazmedical.astrazeneca.com) or by calling 0800 783 0033.