Anoro▼Ellipta (umeclidinium bromide/vilanterol [as trifenatate]) Prescribing information
(Please consult the full Summary of Product Characteristics (SmPC) before prescribing)

Anoro Ellipta 55/22mcg (umeclidinium bromide /vilanterol [as trifenatate]) inhalation powder. Each single inhalation provides a delivered dose (the dose leaving the mouthpiece) of 55 micrograms umeclidinium (equivalent to 65 micrograms of umeclidinium bromide) and 22 micrograms of vilanterol (as trifenatate). **Indications:** Anoro is indicated as a maintenance bronchodilator treatment to relieve symptoms in adult patients with chronic obstructive pulmonary disease (COPD). **Dosage and administration**: Inhalation only. One inhalation once daily of Anoro. **Contraindications:** Hypersensitivity to the active substances or to any of the excipients (lactose monohydrate and magnesium stearate). **Precautions**: Anoro should not be used in patients with asthma. Treatment with Anoro should be discontinued in the event of paradoxical bronchospasm and alternative therapy initiated if necessary. Cardiovascular effects may be seen after the administration of muscarinic receptor antagonists and sympathomimetics therefore Anoro should be used with caution in patients with severe cardiovascular disease. Anoro should be used with caution in patients with urinary retention, narrow angle glaucoma, convulsive disorders, thyrotoxicosis, hypokalaemia, hyperglycaemia and severe hepatic impairment. No dosage adjustment is required in renal or mild to moderate hepatic impairment. **Acute symptoms:** Anoro is not indicated for acute episodes of bronchospasm. Warn patients to seek medical advice if short-acting inhaled bronchodilator use increases, a re-evaluation of the patient and of the COPD treatment regimen should be undertaken. **Interactions with other medicinal products**: Avoid β-blockers. Caution is advised when co-administering with strong CYP3A4 inhibitors (e.g. ketoconazole, clarithromycin, itraconazole, ritonavir, telithromycin). Anoro should not be used in conjunction with other long-acting β_2-adrenergic agonists or medicinal products containing long-acting muscarinic antagonists. Caution is advised with concomitant use with methylxanthine derivatives, steroids or non-potassium-sparing diuretics as it may potentiate possible hypokalaemic effect of β_2-adrenergic agonists. **Fertility, pregnancy, and breast-feeding**: No available data. Balance risks against benefits. **Side effects**: *Common (≥1/100 to <1/10):* urinary tract infection, sinusitis, nasopharyngitis, pharyngitis, upper respiratory tract infection, headache, cough, oropharyngeal pain, constipation and dry mouth. *Other important side effects include: Uncommon (≥1/1,000 to <1/100)* atrial fibrillation, supraventricular tachycardia, rhythm idioventricular, tachycardia, supraventricular extrasystoles, palpitations, and hypersensitivity reactions including rash. *Rare* (≥1/10,000 to <1/1,000) anaphylaxis, angioedema, and urticaria. Glaucoma, vision blurred, intraocular pressure increased and paradoxical bronchospasm. See SmPC for other adverse reactions. **Legal category**: POM. **Presentation and Basic NHS cost:** Anoro Ellipta**.** 1 inhaler x 30 doses. Anoro Ellipta 55/22mcg - £32.50. **Marketing authorisation (MA) no. 55/22mcg 1x30 doses [EU/1/14/898/002]; MA holder**: Glaxo Group Ltd, 980 Great West Road, Brentford, Middlesex TW8 9GS, UK. **Last date of revision:** July 2018. UK/UCV/0095/15(2)b. Anoro was developed in collaboration with Innoviva Inc.

Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard **or search for MHRA Yellowcard in the Google Play or Apple App store. Adverse events should also be reported to GlaxoSmithKline on 0800 221 441**