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 of umeclidinium bromide (UMEC) 62.5 micrograms (mcg) and vilanterol (VI) 25mcg provides a delivered dose of UMEC 55mcg and VI 22mcg. **Indications:** *COPD*: Maintenance bronchodilator treatment to relieve symptoms in adult patients with COPD. **Dosage and administration**: Inhalation only. *COPD*: One inhalation once daily of Anoro Ellipta. **Contraindications:** Hypersensitivity to the active substances or to any of the excipients (lactose monohydrate and magnesium stearate). **Precautions**: Anoro Ellipta should not be used in patients with asthma. Treatment with Anoro Ellipta 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 Ellipta should be used with caution in patients with severe cardiovascular disease. Anoro Ellipta 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 Ellipta 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**: Interaction studies have only been performed in adults. Avoid β-blockers. Caution is advised when co-administering with strong CYP3A4 inhibitors (e.g. ketoconazole, clarithromycin, itraconazole, ritonavir, telithromycin). Anoro Ellipta 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: Urinary tract infection, sinusitis, nasopharyngitis, pharyngitis, upper respiratory tract infection, headache, cough, oropharyngeal pain, constipation and dry mouth. Uncommon: Atrial fibrillation, supraventricular tachycardia, rhythm idioventricular, tachycardia, supraventricular extrasystoles and rash. **Legal category**: POM. **Presentation and Basic NHS cost:** Anoro® Ellipta®**.** 1 inhaler x 30 doses. Anoro Ellipta 55/22mcg - £32.50. **Marketing authorisation (MA) nos. 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:** October 2014. UK/RESP/0077/14c. Anoro® Ellipta® was developed in collaboration with Theravance,Inc.

Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard. Adverse events should also be reported to GlaxoSmithKline on 0800 221 441.