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:** Maintenance bronchodilator treatment to relieve symptoms in adult patients with chronic obstructive pulmonary disease (COPD). **Dosage and administration**: Inhalation only. One inhalation once daily. Administer at the same time of day each day. Inhaler contains pre-dispensed doses and is ready to use. **Contraindications:** Hypersensitivity to the active substances or to any of the excipients (lactose monohydrate and magnesium stearate). **Precautions**: Should not be used in patients with asthma. Treatment should be immediately discontinued in the event of paradoxical bronchospasm and alternative therapy initiated if necessary. Cardiovascular effects (eg arrhythmias) may be seen after administration of muscarinic receptor antagonists and sympathomimetics. Use with caution in patients with severe cardiovascular disease; urinary retention; narrow angle glaucoma; convulsive disorders; thyrotoxicosis; severe hepatic impairment and in patients who are unusually responsive to β_2-adrenergic agonists. Caution with other medicines which can cause hypokalaemia. More closely monitor plasma glucose in diabetic patients upon initiation of Anoro. No dosage adjustment is required in the elderly; renal or mild to moderate hepatic impairment. Do not use in patients with rare hereditary problems of galactose intolerance, total lactase deficiency or glucose-galactose malabsorption. **Acute symptoms:** Not indicated for acute episodes of bronchospasm. Patients should seek medical advice if short-acting inhaled bronchodilator use increases and re-evaluation of the patient and 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). Co-administration with other long-acting muscarinic antagonists, long-acting β_2-adrenergic agonists or products containing either of these is not recommended. Caution if using concomitantly with methylxanthine derivatives, steroids or non-potassium-sparing diuretics as they may potentiate possible hypokalaemic effect of β_2-adrenergic agonists. **Fertility, pregnancy, and breast-feeding**: No data in pregnant woman or human fertility. Animal studies (at exposures not clinically relevant) have shown reproductive toxicity. Should only use in pregnancy if expected benefit to the mother justifies potential risk to fetus. Unknown whether excreted in breast milk; risk to newborns cannot be excluded; balance risks for child against benefits for mother. **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 less frequent side effects include:* cardiac arrhythmias, hypersensitivity reactions (including rash, anaphylaxis, angioedema, urticaria), glaucoma, paradoxical bronchospasm, urinary retention, bladder outlet obstruction, dizziness and tremor. *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**: GlaxoSmithKline (Ireland) Limited,12 Riverwalk, Citywest Business Campus, Dublin 24, Ireland **Last date of revision:** September 2020. Anoro-PI-3768. Anoro was developed in collaboration with Innoviva Inc.

Adverse events should be reported. Reporting forms and information can be found at https://yellowcard.mhra.gov.uk/ or search for MHRA Yellow Card in the Google Play or Apple App Store. Adverse events should also be reported to GlaxoSmithKline on 0800 221 441.