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. Each delivered dose contains approx. 24 mg lactose. **Indications:** *COPD*: Maintenance bronchodilator treatment to relieve symptoms in adult patients with COPD. **Dose and administration**: Inhalation only. *COPD*: One inhalation once daily at the same time of the day. **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 dose adjustment is required in renal or mild to moderate hepatic impairment. Patients with rare hereditary problems of galactose intolerance, the Lapp total lactase deficiency or glucose-galactose malabsorption should not use Anoro Ellipta. **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**: Clinically significant interactions mediated by umeclidinium/vilanterol at clinical doses are considered unlikely due to the low plasma concentrations achieved after inhaled dosing. 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: Hypersenstivity reactions including rash, muscle spasms, tremor, dysgeusia, dysphonia, atrial fibrillation, supraventricular tachycardia, rhythm idioventricular, tachycardia, supraventricular extrasystoles and palpitations. Rare: Anaphylaxis, angioedema, urticaria, vision blurred, glaucoma, intraocular pressure increased, eye pain, paradoxical bronchospasm, urinary retention, dysuria and bladder outlet obstruction. Frequency not known: Dizziness. **Marketing Authorisation (MA) Holder**: GlaxoSmithKline (Ireland) Limited, 12 Riverwalk, Citywest Business Campus, Dublin 24, Ireland. **MA Nr:** 55/22mcg 1x30 doses [EU/1/14/898/002]. **Legal category:** POM B. **Last date of revision:** November 2023. **Job Ref:** PI-3826. Further information available on request from GlaxoSmithKline, 12 Riverwalk, Citywest Business Campus, Dublin 24, Tel: 01-4955000.

Adverse events should be reported directly to the Health Products Regulatory Authority (HPRA) on their website: www.hpra.ie. Adverse events should also be reported to GlaxoSmithKline on 1800 244 255.