Incruse▼ Ellipta (umeclidinium bromide) Prescribing information.

(Please consult the full Summary of Product Characteristics (SmPC) before prescribing)

Incruse Ellipta (umeclidinium) 55 micrograms inhalation powder, pre-dispensed. Each single inhalation provides a delivered dose (the dose leaving the mouthpiece of the inhaler) of 55 micrograms umeclidinium (equivalent to 65 micrograms of umeclidinium bromide). This corresponds to a pre-dispensed dose of 62.5 micrograms umeclidinium equivalent to 74.2 micrograms umeclidinium bromide. **Indications:** *COPD*: Maintenance bronchodilator treatment to relieve symptoms in adult patients with chronic obstructive pulmonary disease (COPD). **Dosage and administration**: Inhalation only. *COPD*: One inhalation of Incruse Ellipta at the same time of the day each day. If a dose is missed the next dose should be inhaled at the usual time the next day. **Contraindications:** Hypersensitivity to the active substance or to any of the excipients (lactose monohydrate and magnesium stearate). **Precautions**: Incruse Ellipta should not be used in patients with asthma. Treatment with Incruse 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, therefore Incruse Ellipta should be used with caution in patients with severe cardiovascular disorders, particularly cardiac arrhythmias. Incruse Ellipta should be used with caution in patients with urinary retention or narrow angle glaucoma. No dose adjustment is required in renal or mild to moderate hepatic impairment. **Acute symptoms:** Incruse 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**: Co-administration of umeclidinium bromide with other long-acting muscarinic antagonists or medicinal products containing this active substance has not been studied and therefore, is not recommended. **Fertility, pregnancy, and breast-feeding**: No or limited available human *in vivo* data. Balance risks against benefits. **Side effects**: *Common:* Nasopharyngitis, upper respiratory tract infection, cough, oropharyngeal pain, constipation, sinusitis, headache, tachycardia, urinary tract infection, *Uncommon:* Pharyngitis, dysgeusia, dysphonia, atrial fibrillation, rhythm idioventricular, supraventricular tachycardia, supraventricular extrasystoles, dry mouth, rash, hypersensitivity reactions. *Rare:* Anaphylaxis, eye pain. *Frequency unknown:* Dizziness**,** glaucoma, vision blurred, intraocular pressure increased, urinary retention, dysuria. **Marketing Authorisation (MA) Holder**: GlaxoSmithKline (Ireland) Limited,12 Riverwalk, Citywest Business Campus, Dublin 24, Ireland. **MA No. 55mcg 1x30 doses:** EU/1/14/922/002**. Legal Category:** POM B. **Last date of revision:** January 2024. **Job Ref:** PI-3828. Further information available on request from GlaxoSmithKline, 12 Riverwalk, Citywest Business Campus, Dublin 24. Tel: 01-4955000.

Adverse events should be reported 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.

▼This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse reactions.