Incruse ▼ Ellipta (umeclidinium bromide) Prescribing information

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

Incruse Ellipta 55mcg (umeclidinium) inhalation powder. 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). **Indications:** Incruse 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 Incruse Ellipta at the same time of the day each day. **Contraindications:** Hypersensitivity to the active substances 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 dosage 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 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 available human *in vivo* data. Balance risks against benefits. **Side effects**: *Common* (≥1/100 to <1/10): Nasopharyngitis, upper respiratory tract infection, urinary tract infection, sinusitis, headache, tachycardia, cough. *Other Important side effects include. Uncommon* (≥1/1,000 to <1/100): Atrial fibrillation, rhythm idioventricular, supraventricular tachycardia, supraventricular extrasystoles. Hypersensitivity reactions including rash, urticaria, pruritus. *Not Known* (cannot be estimated from available data): Glaucoma and vision blurred. **Legal category**: POM. **Presentation and Basic NHS cost:** Incruse Ellipta**.** 1 inhaler x 30 doses. Incruse Ellipta 55mcg - £27.50. **Marketing authorisation (MA) nos. 55mcg 1x30 doses [EU/1/14/922/002]; MA holder**: Glaxo Group Ltd, 980 Great West Road, Brentford, Middlesex TW8 9GS, UK. **Last date of revision:** July 2018. UK/INC/0001/17(1)a. Incruse and Ellipta are registered trademarks of the GlaxoSmithKline group of companies.

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