

Incruse ▼ Ellipta (umeclidinium bromide) Prescribing information

(Please consult the full Summary of Product Characteristics (SPC) 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: Maintenance bronchodilator treatment to relieve symptoms in adult patients with chronic obstructive pulmonary disease (COPD).

Dosage and administration: Inhalation only. One inhalation once daily 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. Incruse may cause life-threatening paradoxical bronchospasm. Discontinue Incruse and initiate alternative therapy if necessary. Cardiovascular effects e.g. arrhythmias. Incruse should be used with caution in patients with severe cardiovascular disorders, particularly cardiac arrhythmias as this group was excluded from clinical studies. Incruse 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. Use with caution in severe hepatic impairment. Do not use in patients with rare hereditary problems of galactose intolerance, total lactase deficiency or glucose-galactose malabsorption.

Acute symptoms:

Incruse is not indicated for acute episodes of bronchospasm. Warn patients to seek medical advice if short-acting inhaled bronchodilator use increases, for a re-evaluation of the COPD treatment regimen.

Interactions with other medicinal products: Co-administration with other long-acting muscarinic antagonists or products containing them has not been studied and is not recommended.

Fertility, pregnancy, and breast-feeding: No available human *in vivo* data. Balance risks against benefits.

Side effects:
Common ($\geq 1/100$ to $< 1/10$): Nasopharyngitis, upper respiratory tract infection, urinary tract infection, sinusitis, headache, tachycardia, cough, constipation.
Other Important side effects include.
Uncommon ($\geq 1/1,000$ to $< 1/100$): Cardiac arrhythmias. Hypersensitivity reactions including rash, urticaria, pruritus.
Not Known (cannot be estimated from available data): Dizziness, glaucoma, vision blurred, and urinary retention.

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: GlaxoSmithKline (Ireland) Limited, 12 Riverwalk, Citywest Business Campus, Dublin 24, Ireland

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Adverse events should be reported. Reporting forms and information can be found at 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.