Incruse (umeclidinium bromide) Ellipta Prescribing Information for United Kingdom (UK)

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

Incruse Ellipta 55 micrograms inhalation powder, pre-dispensed: Each inhalation delivers 55 mcg umeclidinium (equivalent to 65 mcg umeclidinium bromide), corresponding to pre-dispensed dose of 62.5 mcg umeclidinium (equivalent to 74.2 mcg umeclidinium bromide).

Indications: Maintenance bronchodilator treatment to relieve symptoms in adults with chronic obstructive pulmonary disease (COPD).

Dosage and administration: Inhalation only. One inhalation once daily at the same time 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 Ellipta may cause life-threatening paradoxical bronchospasm. Discontinue Incruse Ellipta immediately and institute alternative therapy if necessary.

Incruse Ellipta 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.

Cardiovascular effects such as cardiac arrhythmias e.g. atrial fibrillation and tachycardia may be seen after administration of muscarinic receptor antagonists including Incruse Ellipta. Use with caution in patients with severe cardiovascular disorders, particularly cardiac arrhythmias, as patients with clinically significant uncontrolled cardiovascular disease were excluded from clinical studies.

Due to antimuscarinic activity, Incruse Ellipta should be used with caution in patients with urinary retention or narrow-angle glaucoma.

Use with caution in severe hepatic impairment as Incruse Ellipta has not been studied in this population.

Do not use in patients with galactose intolerance, total lactase deficiency or glucose-galactose malabsorption.

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 (≥1/100 to <1/10): Nasopharyngitis, upper respiratory tract infection, urinary tract infection, sinusitis, headache, tachycardia, cough, oropharyngeal pain, constipation.

Other side effects include:

Uncommon (≥1/1,000 to <1/100): Hypersensitivity reactions including rash, urticaria and pruritus, atrial fibrillation, dysgeusia, dysphonia, dry mouth, pharyngitis, idioventricular rhythm, supraventricular tachycardia, supraventricular extrasystoles.

Rare (≥1/10,000 to <1/1,000): Anaphylaxis, eye pain.

Frequency not Known (cannot be estimated from available data): Dizziness, dysuria, glaucoma, intraocular pressure increased, urinary retention and vision blurred.

See SmPC for other adverse reactions.

Legal category: POM.

Presentation and Basic NHS cost: 1 x 30 dose inhaler - £27.50.

Marketing authorisation (MA) number: 1 x 30 dose inhaler: PLGB 19494/0273.

MA holder: GlaxoSmithKline UK Limited, 70 New Oxford St, London. WC1A 1DG United Kingdom

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Reference: PI 3769

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