Relvar (fluticasone furoate/vilanterol) Ellipta Prescribing Information United Kingdom (UK)

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

Relvar Ellipta 92 micrograms/22 micrograms inhalation powder, pre-dispensed: Each inhalation delivers 92 mcg fluticasone furoate (FF) and 22 mcg vilanterol (as trifenatate), corresponding to pre-dispensed dose of 100 mcg FF and 25 mcg vilanterol (as trifenatate).

Relvar Ellipta 184 micrograms/22 micrograms inhalation powder, pre-dispensed: Each inhalation delivers 184 mcg fluticasone furoate (FF) and 22 mcg vilanterol (as trifenatate), corresponding to pre-dispensed dose of 200 mcg FF and 25 mcg vilanterol (as trifenatate).

Indications:

Asthma: 92/22 mcg or 184/22 mcg - Regular treatment of asthma in patients ≥12 years where a long-acting β_2-agonist (LABA) and inhaled corticosteroid (ICS) combination is appropriate, i.e., patients not adequately controlled on ICS and "as needed" short-acting inhaled β_2-agonists or patients already adequately controlled on both ICS and LABA.

COPD: 92/22 mcg only - Symptomatic treatment of adults with COPD with a FEV_1<70% predicted normal (post-bronchodilator) and an exacerbation history despite regular bronchodilator therapy.

Dosage and administration: Inhalation only. Administered at the same time each day. If a dose is missed the next dose should be taken at the usual time the next day.

Asthma: Patients ≥12 years: starting dose of one inhalation once daily of 92/22 mcg for patients who require a low to mid dose of ICS in combination with a LABA. If patients are inadequately controlled, then dose can be increased to 184/22 mcg one inhalation once daily. 184/22 mcg one inhalation once daily should be considered for patients who require a higher dose of ICS in combination with a LABA. Patients should be regularly reassessed and reduced to lowest dose that maintains effective symptom control.

COPD: Adults ≥18 years: One inhalation once daily of 92/22 mcg. 184/22 mcg is not indicated in COPD.

Contraindications: Hypersensitivity to the active substances or any excipients (lactose monohydrate and magnesium stearate).

Precautions: Relvar Ellipta should not be used to treat acute asthma or acute exacerbation in COPD, for which a short-acting bronchodilator is required. Increasing use of short-acting bronchodilators indicates deterioration of control and patients should be reviewed by a physician.

Patients should not stop therapy in asthma or COPD without physician supervision.

Patients should continue treatment but seek medical advice if asthma remains uncontrolled or worsens after initiation of Relvar Ellipta.

Paradoxical bronchospasm may occur after dosing - treat immediately with short-acting inhaled bronchodilator and discontinue Relvar Ellipta.

Use with caution in patients with severe cardiovascular disease, heart rhythm abnormalities, thyrotoxicosis, uncorrected hypokalaemia, or patients predisposed to low levels of serum potassium.

Exercise caution in patients with hepatic impairment. Patients with moderate to severe hepatic impairment, should use the 92/22 mcg dose and be monitored for systemic corticosteroid related adverse reactions.

Systemic effects of ICS may occur particularly at high doses prescribed for long periods. Possible systemic effects include Cushing's syndrome, Cushingoid features, adrenal suppression, decrease in bone mineral density, growth retardation, cataract, glaucoma, psychomotor hyperactivity, sleep disorders, anxiety, depression, or aggression. Use with caution in patients with pulmonary tuberculosis or with chronic or untreated infections.

Patients presenting with blurred vision or other visual disturbances with corticosteroid use should be considered for referral to an ophthalmologist for evaluation of possible causes which may include cataract, glaucoma or central serous chorioretinopathy (CSCR). Increases in blood glucose levels in diabetic patients have been reported. Remain vigilant for the possible development of pneumonia in COPD patients receiving ICS as the clinical features of pneumonia overlap with the symptoms of COPD exacerbations. The incidence of pneumonia in patients with asthma was common at the 184/22 mcg dose and numerically higher compared with those receiving 92/22 mcg or placebo.

Patients with galactose intolerance, total lactase deficiency or glucose-galactose malabsorption should not use Relvar Ellipta.

Interactions with other medicinal products: Interaction studies have only been performed in adults.

Avoid concurrent use of Relvar Ellipta with β_2-adrenergic blockers. Caution is advised when co-administering with strong CYP3A4 inhibitors (e.g., ketoconazole, ritonavir, cobicistat-containing products).

Concomitant administration of other sympathomimetic medicinal products may potentiate the adverse reactions of Relvar Ellipta.

Relvar Ellipta should not be used in conjunction with other medicinal products containing long-acting β_2-adrenergic agonists.

Fertility, pregnancy, and lactation: Experience limited. Balance risks against benefits.

Side effects: Very Common (≥1/10): headache, nasopharyngitis. Common (≥1/100 to <1/10): pneumonia, upper respiratory tract infection, bronchitis, influenza, candidiasis of mouth and throat, oropharyngeal pain, sinusitis, pharyngitis, rhinitis, cough, dysphonia, abdominal pain, arthralgia, back pain, fractures, muscle spasms, pyrexia. Uncommon (≥1/1,000 to <1/100): hyperglycaemia, vision blurred, extrasystoles. Rare (≥1/10,000 to <1/1,000): hypersensitivity reactions including anaphylaxis, angioedema, rash & urticaria, anxiety, tremor, palpitations, tachycardia, paradoxical bronchospasm. See SmPC for other adverse reactions.

Legal category: POM.

Presentation and Basic NHS cost: 1 x 30 dose inhaler. 92/22 mcg: £22.00. 184/22 mcg: £29.50.

Marketing authorisation (MA) Numbers: 1 x 30 dose inhaler. 92/22 mcg: PLGB 19494/0277. 184/22 mcg: PLGB 19494/0278

MA holder: GlaxoSmithKline UK Limited, 79 New Oxford St, London, WC1A1DG, United Kingdom.

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Relvar Ellipta was developed in collaboration with Innoviva Inc.

Adverse events should be reported. Reporting forms and information can be found at https://yellowcard.mhra.gov.uk/ or search for MHRA Yellowcard in the Google Play or Apple App store. Adverse events should also be reported GlaxoSmithKline on 0800 221 441 UKSafety@gsk.com