Relvar® (fluticasone furoate/vilanterol) Ellipta® Prescribing Information

Please consult the full Summary of Product Characteristics (SmPC) before prescribing**. Relvar® Ellipta® (fluticasone furoate/vilanterol [as trifenatate]) inhalation powder.** Each single inhalation of fluticasone furoate (FF) 100 micrograms (mcg) and vilanterol (VI) 25 mcg provides a delivered dose of 92 mcg FF and 22 mcg VI. Each single inhalation of FF 200 mcg and VI 25 mcg provides a delivered dose of 184 mcg of FF and 22 mcg of VI. **Indications:** Asthma*:* 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*:* 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. Asthma*:* Adults and adolescents ≥12 years: one inhalation once daily of Relvar 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 the dose can be increased to Relvar 184/22mcg one inhalation once daily. Relvar 184/22 mcg can also be considered for patients who require a higher dose of ICS in combination with a LABA. Regularly review patients and reduce to lowest dose that maintains effective symptom control. COPD*:* One inhalation once daily of Relvar 92/22 mcg. Relvar 184/22 mcg is not indicated for patients with COPD. **Contraindications:** Hypersensitivity to the active substances or to any of the excipients (lactose monohydrate & magnesium stearate). **Precautions**: In patients with Pulmonary tuberculosis, severe cardiovascular disorders or heart rhythm abnormalities, thyrotoxicosis, uncorrected hypokalaemia, patients predisposed to low levels of serum potassium, chronic or untreated infections, diabetes mellitus. Paradoxical bronchospasm may occur with after dosing. Treat immediately with short-acting inhaled bronchodilator. In patients with moderate to severe hepatic impairment 92/22 mcg dose should be used and monitor for systemic corticosteroid-related adverse reactions. *Acute symptoms:* Not for acute symptoms, use short-acting inhaled bronchodilator. Warn patients to seek medical advice if short-acting inhaled bronchodilator use increases. Therapy should not be abruptly stopped without physician supervision due to risk of symptom recurrence. Asthma-related adverse events and exacerbations may occur during treatment. Patients should continue treatment but seek medical advice if asthma symptoms remain uncontrolled or worsen after initiation of Relvar. *Systemic effects:* Systemic effects of ICSs may occur, particularly at high doses for long periods, but much less likely than with oral corticosteroids. Possible systemic effects include Cushing's syndrome, Cushingoid features, adrenal suppression, decrease in bone mineral density, growth retardation in children and adolescents. Eye symptoms such as blurred vision may be due to underlying serious conditions such as cataract, glaucoma or central serous chorioretinopathy (CSCR); consider referral to ophthalmologist. More rarely, a range of psychological or behavioural effects including psychomotor hyperactivity, sleep disorders, anxiety, depression or aggression (particularly in children). Increased incidence of pneumonia has been observed in patients with COPD receiving ICS. Risk factors for pneumonia include current smokers, older age, patients with a history of prior pneumonia, patients with a low body mass index and patients with severe COPD. If pneumonia occurs with Relvar treatment should be re-evaluated. Patients with rare hereditary problems of galactose intolerance, the total lactase deficiency or glucose-galactose malabsorption should not take Relvar. **Interactions with other medicinal products**: Interaction studies have only been performed in adults. Avoid β-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. Relvar should not be used in conjunction with other long-acting β_2-adrenergic agonists or medicinal products containing long-acting β_2-adrenergic agonists. **Pregnancy and breast-feeding**: 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 the mouth and throat oropharyngeal pain, sinusitis, pharyngitis, rhinitis, cough, dysphonia, abdominal pain, arthralgia, back pain, fractures, muscle spasms, pyrexia. Other important side effects include: Uncommon (≥1/1,000 to <1/100): hyperglycaemia, blurred vision, extrasystoles. Rare (≥1/10,000 to <1/1,000): paradoxical bronchospasm and hypersensitivity reactions including anaphylaxis, angioedema, rash & urticaria, anxiety, temor, palpitations, tachycardia. See SmPC for other adverse reactions. **Legal category**: POM. **Presentation and Basic NHS cost:** Relvar Ellipta**.** 1 inhaler x 30 doses. Relvar Ellipta 92/22: £22.00. Relvar Ellipta 184/22: £29.50. **Marketing authorisation (MA) Number:** 92/22mcg 1x30doses [EU/1/13/886/002]; 184/22mcg 1x30doses [EU/1/13/886/005]. **MA holder**: GlaxoSmithKline (Ireland) Limited. 12 Riverwalk, Citywest Business Campus, Dublin 24, Ireland. **Last revised:** August 2020. **CL Reference:** PI-6277 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 to GlaxoSmithKline on 0800 221 441