Relvar® Ellipta® (fluticasone furoate/ vilanterol [as trifenatate]) 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) 25mcg provides a delivered dose of 92mcg FF and 22mcg VI. Each single inhalation of FF 200mcg and VI 25mcg provides a delivered dose of 184mcg of FF and 22mcg of VI. **Indications:** *Asthma:* Regular treatment of asthma in patients ≥12 years and older where a long-acting β_2-agonist and inhaled corticosteroid combination is appropriate and where patients are not adequately controlled on inhaled corticosteroids and "as needed" short-acting inhaled β_2-agonists, or where patients are already controlled on both inhaled corticosteroid and long-acting β_2-agonist. *COPD (Relvar 92/22mcg 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. *Asthma:* Patients with asthma should be given the strength of Relvar Ellipta containing the appropriate fluticasone furoate (FF) dosage for the severity of their disease. Prescribers should be aware that in patients with asthma, FF 100 mcg once daily is approximately equivalent to fluticasone propionate (FP) 250 mcg twice daily, while FF 200 mcg once daily is approximately equivalent to FP 500 mcg twice daily. Adults and adolescents ≥12 years: one inhalation once daily of: Relvar 92/22mcg for patients who require a low to mid dose of inhaled corticosteroid in combination with a long-acting beta2-agonist. If patients are inadequately controlled then the dose can be increased to one inhalation once daily Relvar 184/22mcg. Relvar 184/22mcg can also be considered for patients who require a higher dose of inhaled corticosteroid in combination with a long-acting beta2-agonist. Regularly review patients and reduce dose to lowest that maintains effective symptom control. *COPD:* one inhalation once daily of Relvar 92/22mcg. **Contraindications:** Hypersensitivity to the active substances or to any of the excipients (lactose monohydrate & magnesium stearate). **Precautions**: Pulmonary tuberculosis, severe cardiovascular disorders, heart rhythm abnormalities, thyrotoxicosis, uncorrected hypokalaemia or patients predisposed to low levels of serum potassium. chronic or untreated infections, diabetes mellitus. Paradoxical bronchospasm – substitute alternative therapy if necessary. In patients with hepatic with moderate to severe impairment 92/22mcg dose should be used. *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 inhaled corticosteroids 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, cataract, glaucoma. 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, including pneumonia requiring hospitalisation, has been observed in patients with COPD receiving inhaled corticosteroids. If a patient presents with visual disturbance they should be considered for referral to an ophthalmologist for evaluation of possible causes which may include cataract, glaucoma, or rare diseases such as central serous chorioretinopathy. Physicians should remain vigilant for the

possible development of pneumonia in patients with COPD as the clinical features of such infections overlap with the symptoms of COPD exacerbations. Risk factors for pneumonia include: current smoking, older age, low body mass index and severe COPD. The incidence of pneumonia in patients with asthma was common at the higher dose of Relvar (184/22mcg). Patients with rare hereditary problems of galactose intolerance, the total lactase deficiency or glucose-galactose malabsorption should not use 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 CYP 3A4 inhibitors (e.g. ketoconazole, ritonavir, cobicistat-containing products). Concomitant administration of other sympathomimetic medicinal products may potentiate the adverse reactions of FF/VI. 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): Candidiasis of the mouth and throat, pneumonia, bronchitis, upper respiratory tract infection, influenza, oropharyngeal pain, sinusitis, pharyngitis, rhinitis, cough, dysphonia, abdominal pain, arthralgia, back pain, muscle spasms, fractures, 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 and urticaria; palpitations, tachycardia, tremor, anxiety, paradoxical bronchospasm. **Marketing authorisation (MA) Holder:** GlaxoSmithKline (Ireland) Limited, 12 Riverwalk, Citywest Business Campus, Dublin 24, Ireland. **MA Nrs:** 92/22mcg 1x30 doses [EU/1/13/886/002]; 184/22mcg 1x30 doses [EU/1/13/886/005]. **Legal category**: POM B. **Last date of revision:** January 2021. **Code:** PI-2046. Further information available on request from GlaxoSmithKline, 12 Riverwalk, Citywest Business Campus, Dublin 24. Tel: 01-4955000.

Adverse events should be reported directly to the Health Products Regulatory Authority (HPRA) on their website: www.hpra.ie. Adverse events should also be reported to GlaxoSmithKline on 1800 244 255.