Please refer to the next page for the Trelegy (fluticasone furoate/umeclidinium/vilanterol) Ellipta Prescribing Information for Northern Ireland (NI)

Trelegy Ellipta (fluticasone furoate/umeclidinium/vilanterol) Prescribing Information for Great Britain (GB)

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

Trelegy Ellipta (fluticasone furoate/ umeclidinium/ vilanterol [as trifenatate]) inhalation powder. Each single inhalation of fluticasone furoate (FF) 100 micrograms (mcg), umeclidinium (UMEC) 62.5 mcg and vilanterol (VI) 25 mcg provides a delivered dose (dose leaving the mouthpiece) of 92 mcg FF, 55 mcg UMEC and 22 mcg VI. **Indications**: Maintenance treatment in adult patients with moderate to severe Chronic Obstructive Pulmonary Disease (COPD) who are not adequately treated by a combination of an inhaled corticosteroid (ICS) and a long-acting β_2-agonist (LABA) or a combination of a LABA and a long-acting muscarinic antagonist (LAMA). **Dosage and administration**: One inhalation once daily. **Contraindications**: Hypersensitivity to the active substances or to any of the excipients (lactose monohydrate & magnesium stearate). **Precautions**: Unstable or life-threatening cardiovascular disease or heart rhythm abnormalities, convulsive disorders or thyrotoxicosis and in patients who are unusually responsive to β_2-adrenergic agonists, pulmonary tuberculosis or patients with chronic or untreated infections, urinary retention, hypokalaemia, patients predisposed to low levels of serum potassium, diabetes mellitus. If paradoxical bronchospasm occurs, discontinue Trelegy immediately. Patients with narrow-angle glaucoma should be informed to stop using Trelegy and contact their doctor immediately should any of the signs and symptoms of acute narrow-angle glaucoma develop. Patients with moderate to severe hepatic impairment should be monitored for systemic corticosteroid-related adverse reactions. 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. Increased incidence of pneumonia has been observed in patients with COPD receiving inhaled corticosteroids. *Risk factors for pneumonia include:* current smoking, older age, low body mass index and severe COPD. Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take Trelegy. Not for acute use. 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. ***Systemic effects****:* Systemic effects of ICSs may occur, particularly at high doses for long periods, but much less likely than with oral corticosteroids. **Interactions with other medicinal products**: Caution should be exercised during concurrent use of non-selective and selective beta-blockers; when co-administering with strong CYP3A4 inhibitors (e.g. ketoconazole, ritonavir, cobicistat-containing products); hypokalaemic treatments or non-potassium-sparing diuretics. Co-administration with other LAMAs or LABAs has not been studied and is not recommended. **Pregnancy and breast-feeding**: Experience limited. Balance risks against benefits. **Side effects**: *Common (≥1/100 to <1/10):* pneumonia, upper respiratory tract infection, bronchitis, pharyngitis, rhinitis, sinusitis, influenza, nasopharyngitis, candidiasis of mouth and throat, urinary tract infection, headache, cough, oropharyngeal pain, constipation, arthralgia, back pain. Other important side effects include: *Uncommon (≥1/1,000 to <1/100):* supraventricular tachyarrhythmia, tachycardia, atrial fibrillation, vision blurred, glaucoma, eye pain; *Rare (≥1/10,000 to <1/1,000):* hypersensitivity reactions, including anaphylaxis, angioedema, urticaria and rash; hyperglycaemia; palpitations and urinary retention. See Summary of Product Characteristics for other adverse reactions. **Legal category**: POM. **Presentation and Basic NHS cost**: *Trelegy Ellipta 92/55/22 mcg* - £44.50**.** 1 inhaler x 30 doses. **Marketing authorisation (MA) number**: PLGB 19494/0287; **MA holder**: GlaxoSmithKline UK Limited, 980 Great West Road, Brentford, Middlesex, TW8 9GS, UK. **Last date of revision**: October 2023. **CL reference**: PI-9015 v7.0.

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.

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