

**Trelegy ▼ Ellipta (fluticasone furoate/umeclidinium/vilanterol [as trifenate]) Prescribing information**

Please consult the full Summary of Product Characteristics (SmPC) before prescribing. **Trelegy Ellipta (fluticasone furoate/umeclidinium/vilanterol [as trifenate]) inhalation powder.** Each single inhalation of fluticasone furoate (FF) 100 micrograms (mcg), umeclidinium (UMEC) 62.5 micrograms and vilanterol (VI) 25 mcg provides a delivered dose of 92 mcg FF, 55 mcg UMEC and 22 mcg VI. **Indications:** Maintenance treatment in adult patients with moderate to severe COPD who are not adequately treated by a combination of an inhaled corticosteroid (ICS) and a long-acting  $\beta_2$ -agonist (LABA). **Dosage and administration:** One inhalation once daily. **Contraindications:** Hypersensitivity to the active substances or to any of the excipients (lactose monohydrate & magnesium stearate). **Precautions:** Paradoxical bronchospasm, unstable or life-threatening cardiovascular disease or heart rhythm abnormalities, convulsive disorders or thyrotoxicosis, pulmonary tuberculosis or patients with chronic or untreated infections, narrow-angle glaucoma, urinary retention, hypokalaemia, patients predisposed to low levels of serum potassium, diabetes mellitus. In patients with moderate to severe hepatic impairment patients 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 smokers, older age, patients with a 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. *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. *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 and 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 long-acting muscarinic antagonists or long acting  $\beta_2$ -adrenergic agonists has not been studied and is not recommended. **Pregnancy and breast-feeding:** Experience limited. Balance risks against benefits. **Side effects:** *Common ( $\geq 1/100$  to  $< 1/10$ ):* pneumonia, upper respiratory tract infection, pharyngitis, rhinitis, influenza, nasopharyngitis, headache, cough, arthralgia, back pain. Other important side effects include: *Uncommon ( $\geq 1/1,000$  to  $< 1/100$ )* supraventricular tachyarrhythmia, tachycardia, atrial fibrillation; *Not known (cannot be estimated from the available data)* vision blurred; See SmPC 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) nos. 92/55/22 mcg 1x30 doses [EU/1/17/1236/02]; MA holder:** GSK Trading Services Ltd., Currabinny, Co. Cork Ireland. **Last date of revision:** November 2017. UK/TLY/0031/17. Trademarks are owned by or licensed to the GSK group of companies. 2017 GSK group of companies or its licensor Trelegy Ellipta was developed in collaboration with Innoviva Inc.

**Adverse events should be reported. Reporting forms and information can be found at [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) 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.**