

## Trelegy ▼ Ellipta (fluticasone furoate/umeclidinium/vilanterol) 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 mcg 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) or a combination of a long-acting  $\beta_2$ -agonist and a long-acting muscarinic antagonist. **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, 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 ( $\geq 1/1,000$  to  $< 1/100$ ):* supraventricular tachyarrhythmia, tachycardia, atrial fibrillation; *Rare ( $\geq 1/10,000$  to  $< 1/1,000$ ):* hypersensitivity reactions, including anaphylaxis, angioedema, urticaria, and rash; *Frequency 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) number:** 92/55/22 mcg 1x30 doses [EU/1/17/1236/002]; **MA holder:** GlaxoSmithKline Trading Services Limited, 12 Riverwalk, Citywest Business Campus, Dublin 24, Ireland. **Last date of revision:** October 2020. **CL reference:** PI-6650. Trademarks are owned by or licensed to the GSK group of companies. 2020 GSK group of companies. All rights reserved. Trelegy Ellipta was developed in collaboration with Innoviva Inc.

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