Relvar Ellipta Prescribing information

Please consult the full Summary of Product Characteristics (SmPC) before prescribing. Relvar Ellipta (fluticasone furoate/vilanterol [as triflartenate]) 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 β2-agonist (LABA) and inhaled corticosteroid (ICS) combination is appropriate; i.e. patients not adequately controlled on ICS and “as needed” short-acting inhaled β2-agonists or patients already adequately controlled on both ICS and LABA. COPD: Symptomatic treatment of adults with COPD with a FEV1 <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 one inhalation once daily Relvar 184/22 mcg. 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 dose to lowest 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: 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. In patients with moderate to severe hepatic impairment 92/22 mcg 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 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 (CSR); 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 inhaled corticosteroids. Risk factors for pneumonia include: current smokers, old age, patients with a history of prior pneumonia, patients with a body mass index <25 kg/m2 and patients with a FEV1 <50% predicted. If pneumonia occurs with Relvar treatment should be re-evaluated. Patients with rare hereditary problems of galactose intolerance, the Lapp 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 FF/VI. Relvar should not be used in conjunction with other long-acting β2-adrenergic agonists or medicinal products containing long-acting β2-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, dysphonia, pneumonia, bronchitis, upper respiratory tract infection, influenza, oropharyngeal pain, sinusitis, pharyngitis, rhinitis, cough, abdominal pain, arthralgia, back pain, fractures, pyrexia, muscle spasms. Other important side effects include: Uncommon (≥1/1,000 to <1/100): blurred vision, hyperglycaemia. Rare (≥1/10,000 to <1/1,000) paradoxical bronchospasm and hypersensitivity reactions including anaphylaxis, angioedema, rash, urticaria. 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) nos. 92/22 mcg 1x30 doses [EU/1/13/886/002]; 184/22 mcg 1x30 doses [EU/1/13/886/005]. MA holder: Glaxo Group Ltd, 980 Great West Road, Brentford, Middlesex TW8 9GS, UK. Last date of revision: September 2018. UK/FFT/0227/15(6). 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Adverse events should be reported. Reporting forms and information can be found at 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
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 (UME) 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 β₂-agonist (LABA) or a combination of a long-acting β₂-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 COPO 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 β₂-adrenergic agonists 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; 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., Currawbinny, Co. Cork Ireland. Last date of revision: November 2018. UK/TLY/0031/17(1). Trademarks are owned by or licensed to the GSK group of companies. 2018 GSK group of companies or its licensor Trelegy Ellipta was developed in collaboration with Innoviva Inc.

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Anoro ▼ Ellipta (umeclidinium bromide/vilanterol [as trifenatate]) Prescribing information

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

Anoro Ellipta 55/22mcg (umeclidinium bromide /vilanterol [as trifenatate]) inhalation powder. Each single inhalation provides a delivered dose (the dose leaving the mouthpiece) of 55 micrograms umeclidinium (equivalent to 65 micrograms of umeclidinium bromide) and 22 micrograms of vilanterol (as trifenatate).

**Indications:** Anoro is indicated as a maintenance bronchodilator treatment to relieve symptoms in adult patients with chronic obstructive pulmonary disease (COPD). **Dosage and administration:** Inhalation only. One inhalation once daily of Anoro. **Contraindications:** Hypersensitivity to the active substances or to any of the excipients (lactose monohydrate and magnesium stearate). **Precautions:** Anoro should not be used in patients with asthma. Treatment with Anoro should be discontinued in the event of paradoxical bronchospasm and alternative therapy initiated if necessary. Cardiovascular effects may be seen after the administration of muscarinic receptor antagonists and sympathomimetics therefore Anoro should be used with caution in patients with severe cardiovascular disease. Anoro should be used with caution in patients with urinary retention, narrow angle glaucoma, convulsive disorders, thyrotoxicosis, hypokalaemia, hyperglycaemia and severe hepatic impairment. No dosage adjustment is required in renal or mild to moderate hepatic impairment. **Acute symptoms:** Anoro is not indicated for acute episodes of bronchospasm. Warn patients to seek medical advice if short-acting inhaled bronchodilator use increases, a re-evaluation of the patient and of the COPD treatment regimen should be undertaken. **Interactions with other medicinal products:** Avoid β-blockers. Caution is advised when co-administering with strong CYP3A4 inhibitors (e.g. ketoconazole, clarithromycin, itraconazole, ritonavir, telithromycin). Anoro should not be used in conjunction with other long-acting β-adrenergic agonists or medicinal products containing long-acting muscarinic antagonists. Caution is advised with concomitant use with methyloxanthine derivatives, steroids or non-potassium-sparing diuretics as it may potentiate possible hypokalaemic effect of β-adrenergic agonists. **Fertility, pregnancy, and breast-feeding:** No available data. Balance risks against benefits. **Side effects:** Common (≥1/100 to <1/10): urinary tract infection, sinusitis, nasopharyngitis, pharyngitis, upper respiratory tract infection, headache, cough, oropharyngeal pain, constipation and dry mouth. Other important side effects include: Uncommon (≥1/1,000 to <1/100) atrial fibrillation, supraventricular tachycardia, rhythm idioventricular, tachycardia, supraventricular extrasystoles, palpitations, and hypersensitivity reactions including rash. Rare (≥1/10,000 to <1/1,000) anaphylaxis, angioedema, and urticaria. Glaucoma, vision blurred, intraocular pressure increased and paradoxical bronchospasm. See SmPC for other adverse reactions. **Legal category:** POM. **Presentation and Basic NHS cost:** Anoro Ellipta. 1 inhaler x 30 doses. Anoro Ellipta 55/22mcg - £32.50. **Marketing authorisation (MA) no.** 55/22mcg 1x30 doses [EU/1/14/898/002]; MA holder: Glaxo Group Ltd, 980 Great West Road, Brentford, Middlesex TW8 9GS, UK. **Last date of revision:** July 2018. UK/UCV/0095/15(2)b. Anoro and Ellipta are registered trademarks of the GlaxoSmithKline group of companies. All rights reserved. Anoro 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 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