TRELEGY ELLIPTA

fluticasone furoate/umeclidinium/vilanterol

LESS TO TAKE. MORE TO TAKE IN.

The only COPD Triple Therapy delivered in a single daily inhalation.[1]
Improvement in quality of life vs. ICS/LABA.[2]

Trelegy Ellipta is indicated for maintenance treatment in adult patients with moderate-to-severe COPD who are not adequately treated by a combination of an ICS and a LABA or a combination of a LAMA and a LABA.[1]

Trelegy Ellipta was developed in collaboration with INNOVIVA

Discover more at www.trelegy.co.uk

COPD, chronic obstructive pulmonary disease; ICS, inhaled corticosteroid; LABA, long-acting β_2-agonist; LAMA, long-acting muscarinic antagonist

UK/TLY/0020/17(2)a(3) | Date of preparation: October 2018

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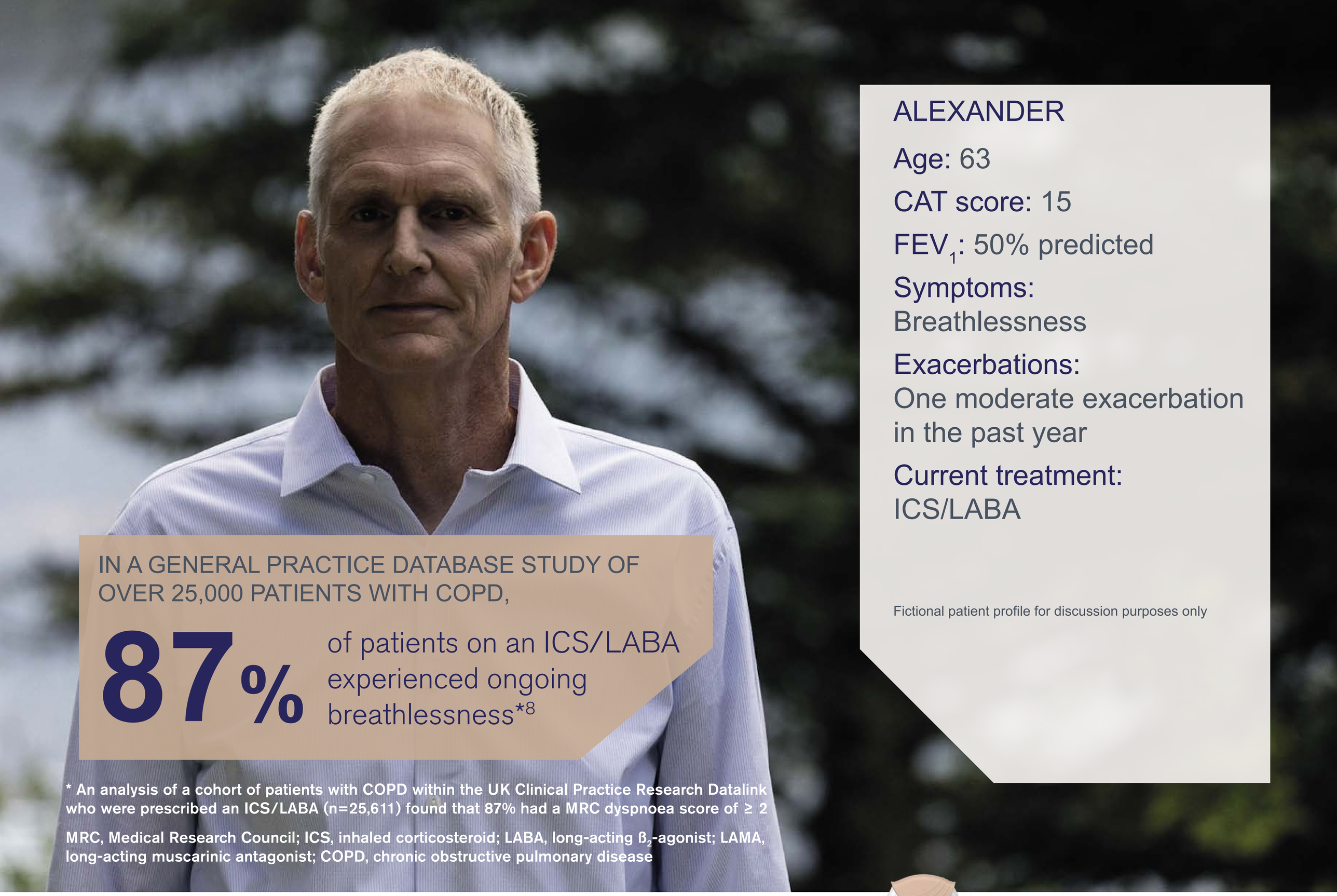

ALEXANDER

Age: 63

CAT score: 15

FEV_1: 50% predicted

Symptoms:
Breathlessness

Exacerbations:
One moderate exacerbation in the past year

Current treatment:
ICS/LABA

Fictional patient profile for discussion purposes only

IN A GENERAL PRACTICE DATABASE STUDY OF OVER 25,000 PATIENTS WITH COPD,

87% of patients on an ICS/LABA experienced ongoing breathlessness*[8]

*** An analysis of a cohort of patients with COPD within the UK Clinical Practice Research Datalink who were prescribed an ICS/LABA (n=25,611) found that 87% had a MRC dyspnoea score of ≥ 2**

MRC, Medical Research Council; ICS, inhaled corticosteroid; LABA, long-acting ß$_2$-agonist; LAMA, long-acting muscarinic antagonist; COPD, chronic obstructive pulmonary disease

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TRELEGY ELLIPTA – A COMBINATION OF ICS/LAMA/LABA WITH PROVEN EFFICACY[2]

In IMPACT, Trelegy Ellipta FF/UMEC/VI 92/55/22 mcg demonstrated significant improvements in lung function, health-related quality of life and moderate/severe exacerbation rate vs. Relvar Ellipta (fluticasone furoate/vilanterol) 92/22 mcg[2]

Trelegy Ellipta vs. Relvar Ellipta demonstrated ...

SUPERIOR IMPROVEMENT IN LUNG FUNCTION

A significant

97 mL

Change from baseline trough FEV_1 at 52 weeks

(n=3,366) 94 mL vs. (n=3,060) -3 mL trough FEV_1 change, respectively (95% CI: 85, 109 $p<0.001$)[2]

SUPERIOR IMPROVEMENT IN QUALITY OF LIFE

Statistically greater

1.8 units

improvement from baseline in SGRQ total score* at 52 weeks

(n=3,318) 5.5 vs. (n=3,026) 3.7 unit improvement, respectively (95% CI: –2.4, –1.1 $p<0.001$)[2]

SUPERIOR EXACERBATION RATE REDUCTION

15%

relative reduction in mean annual rate of moderate/severe COPD exacerbations, calculated at 52 weeks (Primary endpoint)

(n=4,145) 0.91 vs. (n=4,133) 1.07 respectively (95% CI: 10%, 20% $p<0.001$)[2]

Relvar 92/22 mcg is indicated for the symptomatic treatment of adults with COPD with a FEV_1 <70% predicted normal (post-bronchodilator) and an exacerbation history despite regular bronchodilator therapy.[9]

Relvar 184/22 is not indicated in COPD. There are no additional benefits compared to 92/22 and there is a potential risk of adverse reactions.

IMPACT - InforMing the PAthway of COPD treatment - is a study to assess, over 52 weeks, the efficacy and safety of the single-inhaler triple therapy Trelegy Ellipta (FF/UMEC/VI) vs. an ICS/LABA, Relvar Ellipta (FF/VI), in symptomatic patients on COPD maintenance treatments who had experienced at least one exacerbation in the last 12 months.[2]

In the IMPACT study, the adverse-event (AE) profile of Trelegy Ellipta was similar to Relvar Ellipta and there were no new safety findings. The most frequently reported on-treatment AEs were viral upper respiratory tract infection (URTI) (FF/UMEC/VI 521, 13%; FF/VI 479, 12%) and COPD (FF/UMEC/VI 455, 11%; FF/VI 472, 11%). Pneumonia (FF/UMEC/VI 298, 7%; FF/VI 264, 6%) and oral candidiasis (FF/UMEC/VI 161, 4%; FF/VI 146, 4%) had higher incidences and exposure-adjusted rates in the ICS-containing groups. Pneumonia is a common AE for all ICS-containing medications indicated for use in patients with COPD.

CAT, COPD Assessment Test; CI, confidence interval; EXT, extension; FEV_1, forced expiratory volume in one second; FF, fluticasone furoate; ICS, inhaled corticosteroid; LABA, long-acting $ß_2$-agonist; LAMA, long-acting muscarinic antagonist; SGRQ, St. George's Respiratory Questionnaire; UMEC, umeclidinium; VI, vilanterol. *The SGRQ is a validated disease-specific health status assessment for use in asthma and COPD and a difference of 4 units or more is considered clinically meaningful[3]

Relvar Ellipta and Trelegy Ellipta were developed in collaboration with INNOVIVA.

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…ADMINISTERED THROUGH A **SINGLE DAILY INHALATION**, IN **THE EASY-TO-USE ELLIPTA** INHALER[1,4,5]

ICS (FLUTICASONE FUROATE 92 mcg)

LAMA (UMECLIDINIUM 55 mcg)

LABA (VILANTEROL 22 mcg)

SAFETY PROFILE OF TRELEGY ELLIPTA[1]

	Trelegy Ellipta
POPULATION	The safety profile of Trelegy Ellipta is based on safety data from 911 patients with COPD who received Trelegy Ellipta once-daily for up to 24 weeks, of whom 210 patients received Trelegy Ellipta once-daily for up to 52 weeks[1]
COMMON ARs (≥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 and back pain.
OTHER IMPORTANT SIDE EFFECTS	Uncommon (≥1/1,000 to <1/100): supraventricular tachyarrhythmia, tachycardia atrial fibrillation; not known (cannot be estimated from the available data): vision blurred

A full list of adverse reactions can be found in the Summary of Product Characteristics.[1]

In common with other corticosteroid-containing medicines, there is an increased risk of pneumonia in patients with COPD treated with Trelegy Ellipta.[1]

ICS, inhaled corticosteroid; LABA, long-acting β_2-agonist; LAMA, long-acting muscarinic antagonist

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PRESCRIBE **TRELEGY ELLIPTA** IN APPROPRIATE PATIENTS

A COPD TRIPLE THERAPY THAT OFFERS:

Proven efficacy
A combination of an ICS/LAMA/LABA with proven efficacy[2]

A single daily inhalation, for a simple medication routine[1]

An easy-to-use inhaler to help your patients receive the benefit of their COPD medication[4–6]

A lower cost (at £44.50) than commonly prescribed multiple inhaler Triple Therapy[7]

Discover more at **www.trelegy.co.uk**

TRELEGY ELLIPTA
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Relvar Ellipta 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) 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 b_2-agonist (LABA) and inhaled corticosteroid (ICS) combination is appropriate; i.e. patients not adequately controlled on ICS and "as needed" short-acting inhaled $ß_2$-agonists or patients already adequately controlled on both ICS and LABA. *COPD:* 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:* 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, 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, old age, patients with a history of prior pneumonia, patients with a body mass index <25 kg/m^2 and patients with a FEV_1<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 ß-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 $ß_2$-adrenergic agonists or medicinal products containing long-acting $ß_2$-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, 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). Trademarks are owned by or licensed to the GSK group of companies. © 2018 GSK group of companies or its licensor. Relvar Ellipta was developed in collaboration with Innoviva Inc.

Trelegy ▽ Ellipta (fluticasone furoate/umeclidinium/vilanterol [as trifenatate]) Prescribing information

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 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 β_2-agonist (LABA) or a combination of a long-acting β_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 β_2-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., Currabinny, 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.

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.

AR, adverse reaction

Relvar Ellipta and Trelegy Ellipta were developed in collaboration with INNOVIVA

References: 1. Trelegy Ellipta SmPC. 2. Lipson DA *et al.* NEJM; Published online 18 April 2018. DOI: 10.1056/NEJMoa1713901. 3. Jones PW. *COPD* 2005; 2:75–79. 4. van der Palen J *et al. NPJ Prim Care Respir Med* 2016; 26:16079. 5. Svedsater H *et al. BMC Pulm Med* 2013; 13:72–86. 6. Riley J *et al. Int J Chron Obstruct Pulmon Dis* 2016; 11: 1873–1880. 7. Data on file. UK/TLY/0089/18. 8. Mullerova H *et al*. PLoS One 2014; 9:e85540 9. Relvar Ellipta SmPC Relvar, Trelegy and Ellipta are registered trademarks of the GlaxoSmithKline Group of Companies.

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