Finding the Right Balance: Choosing an Inhaled Corticosteroid/Inhaled Long-Acting β_2-Agonist for Your Patients with Moderate Asthma

This promotional GSK-sponsored symposium intended for healthcare professionals took place on 9th September 2024 as part of the European Respiratory Society (ERS) Congress held in Vienna, Austria.

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Disclosure:	Woodcock is Co-chair of the Montreal Protocol Technology and Economic Assessment Panel; member of the Medical Technical Options Committee; board member for the North-West Lung Centre Charity; co-chair of Moulton Charitable Trust; Chairman of the Medicines Evaluation Unit; Chairman/shareholder of Axalbion and Reacta Biotech; and has received consultant/travel support from GSK and Orion. Singh is the Medical Director of the Medicines Evaluation Unit; member of the Global Initiative for Chronic Obstructive Lung Disease (GOLD) Science Committee; former Chair of the European Respiratory Society (ERS) airway pharmacology group; Editor of the *European Respiratory Journal* and *European Respiratory Review*; fellow of the European Respiratory Society and British Pharmacological Society; and has received consultancy fees from Aerogen, AstraZeneca, Boehringer Ingelheim, Chiesi, Cipla, CSL Behring, EpiEndo, Genentech, GSK, Glenmark, Gossamer Bio, Kinaset Therapeutics, Menarini, Novartis, Orion, Pulmatrix, Sanofi, Teva, Theravance Biopharma, and Verona Pharma. Domingo has received consultancy fees from ALK-Abelló, Allergy Therapeutics, Almirall, AstraZeneca, Boehringer Ingelheim, Chiesi, Esteve, Ferrer, GSK, Hall Allergy, Immunotek, Menarini, Novartis, Pfizer, Sanofi, Stallergenes, Takeda, and Teva. All speakers received an honorarium from GSK for this symposium.
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Meeting Summary

A promotional GSK-sponsored symposium invited three experts to discuss their main considerations when selecting an inhaled corticosteroid (ICS)/inhaled long-acting β_2-agonist (LABA) combination for patients with moderate asthma. Ashley Woodcock, Professor of Respiratory Medicine, University of Manchester; and Consultant Physician at The North-West Lung Centre, Wythenshawe Hospital, Manchester, UK, explained why timely assessment is critical for ICS/LABA initiation. Dave Singh, Professor of Clinical Pharmacology and Respiratory Medicine, University of Manchester, UK, described factors to consider when selecting an ICS/LABA. Christian Domingo, Professor of Medicine, Autonomous University of Barcelona; Consultant of Pulmonary Medicine, Sabadell Hospital, Barcelona; Professor of the Department of Anatomy and Physiology, International University of Catalonia, Barcelona; and Professor of the master's degree programme in Health Economy, University of Malaga, Spain, presented real-world cases illustrating ICS/LABA selection in different patients. The experts agreed that once-daily (OD) dosing with fluticasone furoate/vilanterol (FF/VI) may be a suitable option for many patients with moderate asthma.

Introduction

Asthma causes substantial morbidity and mortality worldwide.[1] Steps 3 and 4 of the Global Initiative for Asthma (GINA) strategy recommend an ICS and inhaled LABA as maintenance therapy for moderate asthma.[2] Inhaler devices with various ICS/LABA combinations are available.[3] Choosing an ICS/LABA inhaler should consider efficacy, effectiveness, safety, patient characteristics/phenotype, patient views, and practical issues.[2]

Why is Timely Assessment Critical For ICS/LABA Initiation in Moderate Asthma?

Ashley Woodcock

Asthma is poorly controlled in the real world; in one study, 90% of patients experienced daytime symptoms more than twice weekly.[4] An accurate diagnosis requires timely, careful assessment,[2] including evaluation of risk factors for asthma development/progression[5-7] and exacerbations.[8] Woodcock emphasised the importance of understanding each patient's circumstances.

Better therapeutic adherence to ICS was associated with reduced asthma-related mortality in a retrospective cohort study.[9] However, many patients have low adherence and suboptimal asthma control.[10] Retrospective, observational studies have reported better adherence to combination ICS/LABA inhalers than to separate ICS and LABA inhalers[11] and better adherence to FF/VI OD than to budesonide/formoterol (BUD/Form) twice daily (BD).[12-14]

The Salford Lung Study (SLS), a Phase III randomised controlled trial, compared FF/VI (100/25 or 200/25 µg OD) with usual care in patients with asthma.[4] Usual care was ICS monotherapy (including beclomethasone

dipropionate [BDP], BUD, ciclesonide, and fluticasone propionate [FP]) or ICS/LABA therapy (including BDP/Form, BUD/Form, FP/Form, and FP/salmeterol).[15] The FF/VI group had higher odds of being a responder (Asthma Control Test [ACT] total score ≥20 and/or increase from baseline ≥3%) than the usual care group at 24 weeks (adjusted odds ratio: 1.91; 95%CI: 1.57–2.33; p<0.001).[16] Note: no comparative studies of FF/VI versus BUD/Form and BDP/Form are included in the Relvar (fluticasone furoate/vilanterol) Summary of Product Characteristics.[17,18] In two studies, FF/VI was superior to FF or FP for the primary endpoint (FEV_1), except FF/VI 92/22 µg OD versus FF 92 µg OD (not significant).[19,20] In another study, severe asthma exacerbation risk was 20% lower in patients receiving FF/VI 92/22 µg compared with FF 92 µg alone (hazard ratio: 0.795; 95% CI: 0.642–0.985; p=0.036).[21] A randomised controlled trial comparing FF/VI versus FP/salmeterol did not show a superior reduction in FEV_1 (FF/VI n=403 versus FP/salmeterol n=403, least-squares mean change from baseline in serial [0–24 hours] FEV_1 at Week 24, -37 mL; 95%CI: -88–15 mL; p=0.162).[22]

Dry powder inhalers (DPI) have a lower carbon footprint than pressurised metered dose inhalers.[23] The carbon footprint of maintenance therapy was lower for FF/VI (i.e., DPI) than for usual care in the SLS.[16] Most surveyed patients prefer a DPI for everyday use (approximately 80%)[24] and would consider switching to a DPI for environmental reasons (approximately 60%).[25]

Woodcock concluded that once-daily dosing with FF/VI is a sustainable treatment approach that may promote adherence and help patients achieve good asthma control.

What is the Right Balance to Look for While Selecting an Inhaled Corticosteroid/Inhaled Long-Acting β_2-Agonist?

Dave Singh

In vitro, FF has a higher glucocorticoid receptor binding affinity than mometasone furoate (MF), FP, BDP, ciclesonide, BUD, triamcinolone acetonide, flunisolide, or prednisolone,[26] and a longer retention time in human lung epithelial cells than MF, FP, or BUD.[27] A randomised, cross-over study found that FF reduced airway hyperresponsiveness in patients with asthma more effectively than FP or BUD while causing less cortisol suppression.[28]

Asthma control was numerically better for FF/VI than for usual care in the SLS (see above for details).[16] In retrospective cohort studies, FF/VI was associated with fewer relapses[29] and greater FEV_1 improvement[30] than BDP/Form, and better therapeutic adherence than BUD/Form,[12,14,31] BDP/Form,[12,31] or FP/salmeterol.[14,31]

A mathematical model comparing bronchoprotective effects between ICS regimens was developed using pharmacokinetics/pharmacodynamics data, built using datasets from six real-world studies,[4,12-14,31,32] and validated using data from four additional studies.[33] The model's real-world simulations predicted that FF/VI might exert a numerically stronger bronchoprotective effect and cause less cortisol suppression than BUD/Form.[34] Note: the results were based on modelling data and cannot be extrapolated to clinical outcomes. The study evaluated the efficacy (bronchoprotection) and systemic activity (cortisol suppression) profiles of FF and BUD across a range of adherence scenarios. Simulations were performed using a previously published and validated pharmacokinetics/pharmacodynamics model using data from six real-world studies. Bronchoprotection was defined as the ability of an ICS to prevent a drop of >20% in FEV_1 in an adenosine monophosphate challenge test.[33,34] The study limitations include: lung binding assumptions were not validated by measurements in human lung tissue; bronchoprotective effects were only estimated through anti-inflammatory mechanisms; only widely available ICS and ICS-containing regimens were included; p-values were not calculated; and conclusions about statistical significance could not be made.[33,34] Clinical studies are required to corroborate these findings.

A previous modelling study reported that higher BMI, poorer symptom control (higher five-component Asthma Control Questionnaire score), current smoking (versus never smoked), and being female (versus male) increased asthma exacerbation risk.[8] A more recent modelling study, using data from 24,292 patients with moderate-to-severe asthma in ten Phase III/IV trials, ran simulations to evaluate the impact of baseline characteristics and treatment choices on outcomes.[35] Regardless of exacerbation history, the risk of exacerbation within 1 year of treatment was predicted to be lower for FF/VI than for BUD/Form (33.6% versus 56.3% in patients with more than one exacerbation in the previous year; p<0.01). In patients with asthma uncontrolled by FP monotherapy, step-up at 3 months to FF/VI was predicted to result in fewer patients experiencing an exacerbation at 1 year than step-up to BUD/Form (17.2% versus 26.5% in patients with poorly controlled asthma; p<0.01). This study's limitations include: results were based on simulations rather than direct *in vivo* patient observations; only studies for which GSK had individual-level patient data were included, so the findings cannot be generalised; clinical trials may not reflect clinical practice; simulations were based on specific scenarios/baseline characteristics, but the results might vary if these characteristics were weighted differently or other characteristics were considered; and the effects of step-up to FF/VI and BUD/Form were assumed to be consistent over the 1-year period, which may not be the case in real-world settings. Clinical studies are needed to corroborate this model's findings.

In Singh's opinion, both patient characteristics and drug molecular characteristics must be considered when selecting an ICS/LABA. Singh suggested that FF/VI might be a suitable option for many patients with moderate asthma, given the evidence from real-world studies and simulations described above.

Choosing the First Inhaled Corticosteroid/Inhaled Long-Acting β_2-Agonist for Your Patients: From Evidence To Practice

Christian Domingo

In the 2024 GINA strategy, the 'preferred' maintenance option (Track 1) for moderate asthma is low-dose (Step 3) or medium-dose (Step 4) ICS/Form, while the 'alternative' option (Track 2) is low-dose (Step 3) or medium/high-dose (Step 4) ICS/LABA other than Form.[2] Domingo considered three real-world cases to explore whether FF/VI (Track 2) might be more appropriate than BUD/Form (Track 1) for some patients. The cases were presented with the permission of the patients, and patient identifiers were removed.

Case 1 (35 years old) had uncontrolled moderate asthma despite good therapeutic adherence (BUD 400 µg/day plus as-needed salbutamol). Domingo considered whether FF/VI (Track 2) might be a more suitable option than ICS/Form (Track 1). Possible advantages of FF/VI, when compared with some other types of ICS/LABA, include higher asthma control rate (71% versus 56% for usual care; see above for SLS details),[4] higher exacerbation-free rate at 12 months (86.5% versus 84.7% for BUD/Form; retrospective cohort study),[36] lower exacerbation rate following step-up from ICS monotherapy (17.2% versus 26.5% for BUD/Form; modelling study),[35] lower cortisol suppression rate (7–14% for FF versus 13–44% for BUD; randomised cross-over study),[28] higher Asthma Quality of Life questionnaire score improvement rate (56% versus 44% for other ICS/LABA; see above for SLS design),[37] and lower reliever canister use by patients with poorly controlled asthma (1.47/year versus 1.64/year for BUD/Form; retrospective cohort study).[36] According to Domingo, FF/VI could be an appropriate option for this patient, given that asthma management should aim for symptom control and risk minimisation.

Case 2 (28 years old) had moderate asthma uncontrolled on ICS monotherapy (BUD 800 µg/day plus as-needed salbutamol) and struggled using their inhaler.

Domingo discussed how several aspects of inhaler use can cause issues for patients, including preparation/timing of a second dose.[38] This may not be an issue with FF/VI, which delivers the full dose in one inhalation.[17,18,39] Two multicentre, randomised, cross-over studies found a lower critical error rate for FF/VI than for MF/indacaterol/glycopyrronium bromide (6% versus 26%; p<0.01)[40] or BUD/Form (5% versus 33%; p<0.01).[41] Domingo suggested that FF/VI might be a good option in this case.

Case 3 (74 years old) had moderate asthma but poor adherence to ICS monotherapy (BUD 400 µg four times daily). A prospective cohort study suggested that non-adherence contributes to exacerbations.[42] Aspects influencing adherence include dosing schedule, duration of action, device ease-of-use, patient satisfaction, and patient preference.[41,43] A retrospective cohort study reported that, compared with BUD/Form or BDP/Form, FF/VI was associated with higher rates of adherence (after propensity score matching: 58.1% versus 48.3% for BUD/Form and 45.8% for BDP/Form) and treatment persistence at 12 months (69% versus 53% for BUD/Form and 57% for BDP/Form).[12]

Domingo indicated that FF/VI may be a suitable choice in this case given its once-daily dosing.

Domingo emphasised that ICS/LABA selection should aim for a balance between efficacy and practicality/convenience. Taking into consideration drug efficacy, safety profile, patient behaviours, and adherence, FF/VI may be a more suitable option than GINA Track 1 for many patients with moderate asthma.

Conclusion

Timely assessment and partnering with patients are essential for early therapy initiation, good adherence, and effective asthma control. Patient characteristics and drug molecular properties should be considered, as they can impact outcomes. Given the data presented at the symposium, FF/VI may be a preferred choice for moderate asthma, depending on patient characteristics.

Additional information

Indications and prescribing information are available here for Relvar, here for Seretide (fluticasone propionate/salmeterol), here for Flixotide (fluticasone propionate), and here for Ventolin (salbutamol sulfate).[17,18,44-49]

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

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

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

Relvar Ellipta 92 micrograms/22 micrograms inhalation powder, pre-dispensed: Each inhalation delivers 92 mcg fluticasone furoate (FF) and 22 mcg vilanterol (as trifenatate), corresponding to pre-dispensed dose of 100 mcg FF and 25 mcg vilanterol (as trifenatate).

Relvar Ellipta 184 micrograms/22 micrograms inhalation powder, pre-dispensed: Each inhalation delivers 184 mcg fluticasone furoate (FF) and 22 mcg vilanterol (as trifenatate), corresponding to pre-dispensed dose of 200 mcg FF and 25 mcg vilanterol (as trifenatate).

Indications:

Asthma: 92/22 mcg or 184/22 mcg - Regular treatment of asthma in patients ≥12 years where a long-acting β_2-agonist (LABA) and inhaled corticosteroid (ICS) combination is appropriate, i.e., patients not adequately controlled on ICS and "as needed" short-acting inhaled β_2-agonists or patients already adequately controlled on both ICS and LABA.

COPD: 92/22 mcg only - 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. Administered at the same time each day. If a dose is missed the next dose should be taken at the usual time the next day.

Asthma: Patients ≥12 years: starting dose of one inhalation once daily of 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 dose can be increased to 184/22 mcg one inhalation once daily. 184/22 mcg one inhalation once daily should be considered for patients who require a higher dose of ICS in combination with a LABA. Patients should be regularly reassessed and reduced to lowest dose that maintains effective symptom control.

COPD: Adults ≥18 years: One inhalation once daily of 92/22 mcg. 184/22 mcg is not indicated in COPD.

Contraindications: Hypersensitivity to the active substances or any excipients (lactose monohydrate and magnesium stearate).

Precautions: Relvar Ellipta should not be used to treat acute asthma or acute exacerbation in COPD, for which a short-acting bronchodilator is required. Increasing use of short-acting bronchodilators indicates deterioration of control and patients should be reviewed by a physician.

Patients should not stop therapy in asthma or COPD without physician supervision.

Patients should continue treatment but seek medical advice if asthma remains uncontrolled or worsens after initiation of Relvar Ellipta.

Paradoxical bronchospasm may occur after dosing - treat immediately with short-acting inhaled bronchodilator and discontinue Relvar Ellipta.

Use with caution in patients with severe cardiovascular disease, heart rhythm abnormalities, thyrotoxicosis, uncorrected hypokalaemia, or patients predisposed to low levels of serum potassium.

Exercise caution in patients with hepatic impairment. Patients with moderate to severe hepatic impairment, should use the 92/22 mcg dose and be monitored for systemic corticosteroid related adverse reactions.

Systemic effects of ICS may occur particularly at high doses prescribed for long periods. Possible systemic effects include Cushing's syndrome, Cushingoid features, adrenal suppression, decrease in bone mineral density, growth retardation, cataract, glaucoma, psychomotor hyperactivity, sleep disorders, anxiety, depression, or aggression. Use with caution in patients with pulmonary tuberculosis or with chronic or untreated infections.

Patients presenting with blurred vision or other visual disturbances with corticosteroid use should be considered for referral to an ophthalmologist for evaluation of possible causes which may include cataract, glaucoma or central serous chorioretinopathy (CSCR). Increases in blood glucose levels in diabetic patients have been reported. Remain vigilant for the possible development of pneumonia in COPD patients receiving ICS as the clinical features of pneumonia overlap with the symptoms of COPD exacerbations. The incidence of pneumonia in patients with asthma was common at the 184/22 mcg dose and numerically higher compared with those receiving 92/22 mcg or placebo.

Patients with galactose intolerance, total lactase deficiency or glucose-galactose malabsorption should not use Relvar Ellipta.

Interactions with other medicinal products: Interaction studies have only been performed in adults.

Avoid concurrent use of Relvar Ellipta with β_2-adrenergic 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 Relvar Ellipta.

Relvar Ellipta should not be used in conjunction with other medicinal products containing long-acting β_2-adrenergic agonists.

Fertility, pregnancy, and lactation: Experience limited. Balance risks against benefits.

Side effects: Very Common (≥1/10): headache, nasopharyngitis. Common (≥1/100 to <1/10): pneumonia, upper respiratory tract infection, bronchitis, influenza, candidiasis of mouth and throat, oropharyngeal pain, sinusitis, pharyngitis, rhinitis, cough, dysphonia, abdominal pain, arthralgia, back pain, fractures, muscle spasms, pyrexia. Uncommon (≥1/1,000 to <1/100): hyperglycaemia, vision blurred, extrasystoles. Rare (≥1/10,000 to <1/1,000): hypersensitivity reactions including anaphylaxis, angioedema, rash & urticaria, anxiety, tremor, palpitations, tachycardia, paradoxical bronchospasm. See SmPC for other adverse reactions.

Legal category: POM.

Presentation and basic NHS cost: 1 x 30 dose inhaler. 92/22 mcg: £22.00. 184/22 mcg: £29.50.

Marketing authorisation (MA) Numbers: 1 x 30 dose inhaler. 92/22 mcg: PLGB 19494/0277. 184/22 mcg: PLGB 19494/0278

MA holder: GlaxoSmithKline UK Limited, 980 Great West Road, Brentford, Middlesex, TW8 9GS, United Kingdom.

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Reference: PI 6277

Relvar Ellipta was developed in collaboration with Innoviva Inc.

Adverse events should be reported. Reporting forms and information can be found at https://yellowcard.mhra.gov.uk/ or search for MHRA Yellowcard in the Google Play or Apple App store. Adverse events should also be reported GlaxoSmithKline on 0800 221 441 UKSafety@gsk.com

Please refer to the previous page for the Relvar (fluticasone furoate/vilanterol) Ellipta Prescribing Information for Great Britain (GB)

Relvar (fluticasone furoate/vilanterol) Ellipta Prescribing Information for Northern Ireland (NI)

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

Relvar Ellipta 92 micrograms/22 micrograms inhalation powder, pre-dispensed: Each inhalation delivers 92 mcg fluticasone furoate (FF) and 22 mcg vilanterol (as trifenatate), corresponding to pre-dispensed dose of 100 mcg FF and 25 mcg vilanterol (as trifenatate).

Relvar Ellipta 184 micrograms/22 micrograms inhalation powder, pre-dispensed: Each inhalation delivers 184 mcg fluticasone furoate (FF) and 22 mcg vilanterol (as trifenatate), corresponding to pre-dispensed dose of 200 mcg FF and 25 mcg vilanterol (as trifenatate).

Indications:

Asthma: 92/22 mcg or 184/22 mcg - Regular treatment of asthma in patients ≥12 years where a long-acting β_2-agonist (LABA) and inhaled corticosteroid (ICS) combination is appropriate; i.e. patients not adequately controlled on ICS and "as needed" short- acting inhaled β_2-agonists or patients already adequately controlled on both ICS and LABA.

COPD: 92/22 mcg only - 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. Administered at the same time each day. If a dose is missed the next dose should be taken at the usual time the next day.

Asthma: Patients ≥12 years: starting dose of one inhalation once daily of 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 dose can be increased to 184/22 mcg one inhalation once daily. 184/22 mcg one inhalation once daily should be considered for patients who require a higher dose of ICS in combination with a LABA. Patients should be regularly reassessed and reduced to lowest dose that maintains effective symptom control.

COPD: Adults ≥18 years: One inhalation once daily of 92/22 mcg. 184/22 mcg is not indicated in COPD.

Contraindications: Hypersensitivity to the active substances or any excipients (lactose monohydrate and magnesium stearate).

Precautions: Relvar Ellipta should not be used to treat acute asthma or acute exacerbation in COPD, for which a short-acting bronchodilator is required. Increasing use of short-acting bronchodilators indicates deterioration of control and patients should be reviewed by a physician.

Patients should not stop therapy in asthma or COPD without physician supervision.

Patients should continue treatment but seek medical advice if asthma remains uncontrolled or worsens after initiation of Relvar Ellipta.

Paradoxical bronchospasm may occur after dosing - treat immediately with short-acting inhaled bronchodilator and discontinue Relvar Ellipta.

Use with caution in patients with severe cardiovascular disease, heart rhythm abnormalities, thyrotoxicosis, uncorrected hypokalaemia or patients predisposed to low levels of serum potassium.

Exercise caution in patients with hepatic impairment. Patients with moderate to severe hepatic impairment, should use the 92/22 mcg dose and be monitored for systemic corticosteroid related adverse reactions.

Systemic effects of ICS may occur particularly at high doses prescribed for long periods. Possible systemic effects include Cushing's syndrome, Cushingoid features, adrenal suppression, decrease in bone mineral density, growth retardation, cataract, glaucoma, psychomotor hyperactivity, sleep disorders, anxiety, depression or aggression.

Use with caution in patients with pulmonary tuberculosis or with chronic or untreated infections.

Patients presenting with blurred vision or other visual disturbances with corticosteroid use should be considered for referral to an ophthalmologist for evaluation of possible causes which may include cataract, glaucoma or central serous chorioretinopathy (CSCR).

Increases in blood glucose levels in diabetic patients have been reported.

Remain vigilant for the possible development of pneumonia in COPD patients receiving ICS as the clinical features of pneumonia overlap with the symptoms of COPD exacerbations.

The incidence of pneumonia in patients with asthma was common at the 184/22 mcg dose and numerically higher compared with those receiving 92/22 mcg or placebo.

Patients with galactose intolerance, total lactase deficiency or glucose-galactose malabsorption should not use Relvar Ellipta.

Interactions with other medicinal products: Interaction studies have only been performed in adults.

Avoid concurrent use of Relvar Ellipta with β_2-adrenergic 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 Relvar Ellipta.

Relvar Ellipta should not be used in conjunction with other medicinal products containing long-acting β_2-adrenergic agonists.

Fertility, pregnancy, and lactation: Experience limited. Balance risks against benefits.

Side effects: Very Common (≥1/10): headache, nasopharyngitis. Common (≥1/100 to <1/10): pneumonia, upper respiratory tract infection, bronchitis, influenza, candidiasis of mouth and throat, oropharyngeal pain, sinusitis, pharyngitis, rhinitis, cough, dysphonia, abdominal pain, arthralgia, back pain, fractures, muscle spasms, pyrexia. Uncommon (≥1/1,000 to <1/100): hyperglycaemia, vision blurred, extrasystoles. Rare (≥1/10,000 to <1/1,000): hypersensitivity reactions including anaphylaxis, angioedema, rash & urticaria, anxiety, tremor, palpitations, tachycardia, paradoxical bronchospasm. See SmPC for other adverse reactions.

Legal category: POM.

Presentation and basic NHS cost: 1 x 30 dose inhaler. 92/22 mcg: £22.00. 184/22 mcg: £29.50.

Marketing authorisation (MA) Numbers: 1 x 30 dose inhaler. 92/22 mcg: EU/1/13/886/002; 184/22 mcg: EU/1/13/886/005.

MA holder: GlaxoSmithKline (Ireland) Limited. 12 Riverwalk, Citywest Business Campus, Dublin 24, Ireland.

Last revised: June 2024.

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