Relvar: Controlling asthma and its underlying inflammation[1,2]

With Relvar, **25% more patients improve and achieve well-controlled asthma** vs Bud/For and other ICS/LABAs in everyday practice[3,4]

- **Long-lasting molecules with sustained efficacy over 24 hours[2,5]**
- **Improves all aspects of the ACT[6]**
- **High airway protection with low systemic effect[7]**
- **Good adherence with an easy-to-use device[8,9]**

If your asthma patients need an ICS/LABA, consider once-daily Relvar for proactive asthma control that lasts[5,10]

RELVAR ELLIPTA
fluticasone furoate and vilanterol inhalation powder

Hypothetical patient used for illustrative purposes only.
The primary endpoint was the proportion of patients who achieved an improvement in ACT score from baseline of ≥3 or a total ACT score of ≥20 in patients in the PEA population initiated on Relvar vs continuing on usual care at 24 weeks. The primary endpoint was met ($p<0.001$). Data presented are from a subset of patients prescribed ICS/LABA at baseline who were initiated on Relvar or continued on their ICS/LABA. Data showed a relative difference of 25% and an absolute difference of 14%.[1]

Bud/For: Budesonide/Formoterol

References: 1. Global Datasheet Fluticasone furoate/vilanterol: v11, March 2020. **2.** Bardsley G, *et al. Respir Res* 2018;19:133. **3.** Woodcock A, *et al. Lancet* 2017;390:2247-2255. **4.** GSK Clinical report. HZA 115150;2017. Assessed on April 2021. **5.** Berstein DI, et al. J Asthma 2015;52:1073-1083. **6.** Svedaster H, et al. Respir Med 2018;141:198-206. **7.** Daley-Yates P, *et al. Br J Clin Pharmacol* 2020;1-11. **8.** Parimi M, et al. Adv Ther 2020;37:2916-2931. **9.** Svedaster H, et al. NPJ Prim Care Respir Med 2014;24:14019. **10.** Relvar (Fluticasone Furoate/Vilanterol) Hong Kong Prescribing Information HK102018 (GDS10/EMC20180924).

RELVAR ELLIPTA ABBREVIATED PRESCRIBING INFORMATION

NAME OF THE PRODUCT RELVAR ELLIPTA **QUALITATIVE AND QUANTITIVATIVE COMPOSITION** Pre-dispensed dose of 100 mcg or 200mcg of fluticasone furoate and 25 mcg vilanterol (as trifenatate). Inhalation powder. **INDICATIONS** ***Asthma*** **Relvar Ellipta 100/25mcg & 200/25mcg** is indicated for the regular treatment of asthma in adults and adolescents aged 12 years and older where use of a combination medicinal product (long-acting beta$_2$-agonist and inhaled corticosteroid) is appropriate: • patients not adequately controlled with inhaled corticosteroids and 'as needed' inhaled short acting beta$_2$-agonists. • patients already adequately controlled on both inhaled corticosteroid and long-acting beta$_2$-agonist. **DOSAGE AND ADMINISTRATION** Asthma *Adults* and adolescents aged 12 years and over One inhalation of **Relvar Ellipta 100/25mcg or 200/25mcg** once daily. Patients usually experience an improvement in lung function within 15 minutes of inhaling Relvar Ellipta. A starting dose of **Relvar Ellipta 100/25mcg** should be considered for adults and adolescents 12 years and over who require a low to mid dose of inhaled corticosteroid in combination with a long-acting beta2-agonist. If patients are inadequately controlled on **Relvar Ellipta 100/25mcg,** the dose can be increased to **Relvar Ellipta 200/25mcg,** which may provide additional improvement in asthma control. The maximum recommended dose is **Relvar Ellipta 200/25mcg** once daily. *Children aged under 12 years.* The safety and efficacy of Relvar Ellipta in children under 12 years of age has not yet been established in the indication for asthma. *Elderly patients (>65 years) & renal impairment* No dose adjustment. Relvar Ellipta is for inhalation use only. After inhalation, theypatient should rinse their mouth with water without swallowing. Patients should be made aware that **Relvar Ellipta** must be used regularly, even when asymptomatic. Patients should be regularly reassessed by a healthcare professional so that the strength of **Relvar Ellipta** they are receiving remains optimal and is only changed on medical advice. **CONTRAINDICATIONS** Hypersensitivity to the active substances or to any of the excipients **WARNINGS AND PRECAUTIONS** Deterioration of disease Fluticasone furoate/vilanterol should not be used to treat acute asthma symptoms or an acute exacerbation in COPD, for which a short-acting bronchodilator is required. Increasing use of short-acting bronchodilators to relieve symptoms indicates deterioration of control and patients should be reviewed by a physician. Patients should not stop therapy with fluticasone furoate/vilanterol in asthma or COPD, without physician supervision since symptoms may recur after discontinuation. Asthma-related adverse events and exacerbations may occur during treatment with fluticasone furoate/vilanterol. Patients should be asked to continue treatment but to seek medical advice if asthma symptoms remain uncontrolled or worsen after initiation of treatment with Relvar Ellipta. Paradoxical bronchospasm Paradoxical bronchospasm may occur with an immediate increase in wheezing after dosing. This should be treated immediately with a short-acting inhaled bronchodilator. Relvar Ellipta should be discontinued immediately, the patient assessed and alternative therapy instituted if necessary. Cardiovascular effects Cardiovascular effects, such as cardiac arrhythmias e.g. supraventricular tachycardia and extrasystoles may be seen with sympathomimetic medicinal products including Relvar Ellipta. Therefore fluticasone furoate/ vilanterol should be used with caution in patients with severe cardiovascular disease, or heart rhythm abnormalities, thyrotoxicosis, uncorrected hypokalaemia or patients predisposed to low levels of serum potassium. Systemic corticosteroid effects Systemic effects may occur with any inhaled corticosteroid, particularly at high doses prescribed for long periods. These effects are much less likely to occur 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, cataract and glaucoma and more rarely, a range of psychological or behavioural effects including psychomotor hyperactivity, sleep disorders, anxiety, depression or aggression (particularly in children). Fluticasone furoate/vilanterol should be administered with caution in patients with pulmonary tuberculosis or in patients with chronic or untreated infections. The incidence of pneumonia in patients with asthma was common at the higher dose. The incidence of pneumonia in patients with asthma taking Relvar Ellipta 200/25mcg was numerically higher compared with those receiving Relvar Ellipta 100/ 25mcg or placebo. No risk factors were identified. **INTERACTIONS** Interaction with beta-blockers Beta$_2$- adrenergic blockers may weaken or antagonise the effect of beta$_2$-adrenergic agonists. Concurrent use of both non-selective and selective beta$_2$-adrenergic blockers should be avoided unless there are compelling reasons for their use. Interaction with CYP3A4 inhibitors Caution is advised when co-administering with strong CYP 3A4 inhibitors as there is potential for increased systemic exposure to both fluticasone furoate and vilanterol. Co-administration should be avoided unless the benefit outweighs the increased risk of systemic corticosteroid side effects, in which case patients should be monitored for systemic corticosteroid side effects. **PREGNANCY AND LACTATION** Pregnancy Administration of fluticasone furoate/vilanterol to pregnant women should only be considered if the expected benefit to the mother is greater than any possible risk to the foetus. Breast-feeding A decision must be made whether to discontinue breast-feeding or to discontinue fluticasone furoate/vilanterol therapy taking into account the benefit of breast-feeding for the child and the benefit of therapy for the woman. **ADVERSE REACTIONS** Pneumonia, upper respiratory tract infection, bronchitis, influenza, candidiasis of mouth and throat, headache, extrasystoles, nasopharyngitis, oropharyngeal pain, sinusitis, pharyngitis, rhinitis, cough, dysphonia, abdominal pain, arthralgia, back pain, fractures, muscle spasms, pyrexia. **OVERDOSE** There is no specific treatment for an overdose with fluticasone furoate/ vilanterol. If overdose occurs, the patient should be treated supportively with appropriate monitoring as necessary. Further management should be as clinically indicated or as recommended by the national poisons centre, where available. Abbreviated Prescribing Information based on Relvar Ellipta Hong Kong Prescribing Information HK102018 (GDS10/EMC20180924).

Please read the full prescribing information prior to administration.
Full prescribing information is available on request from
GlaxoSmithKline Ltd, 23/F, Tower 6, The Gateway, 9 Canton Road, Tsimshatsui, Kowloon, Hong Kong
or Level 20, AIA Tower, Nos 251A-301 Avenida Commercial de Macau, Macau.
For adverse event reporting, please call GlaxoSmithKline Limited at (852) 3189 8989 (Hong Kong)
[or (853) 2871 5569 (Macau)], or send an email to us at HKAdverseEvent@gsk.com.

RELVAR ELLIPTA SAFETY INFORMATION

Safety Profile of Relvar Ellipta Inhalation Powder, Pre-dispensed 100 mcg/25 mcg and **200 mcg/ 25 mcg (100/200 mcg** fluticasone furoate and 25 mcg vilanterol**)**

- Hypersensitivity to the active substances or to any of the excipients is contraindicated to Relvar
- Relvar should not be used to treat acute asthma symptoms, for which a short-acting bronchodilator is required
- Relvar should be used with caution in patients with severe cardiovascular disease, pulmonary tuberculosis or in patients with chronic or untreated infections
- Systemic effects may occur with any inhaled corticosteroids, particularly at high doses prescribed for long periods. Possible systemic effects include Cushing's syndrome, Cushingoid features, adrenal suppression, growth retardation in children and adolescents and decrease in bone mineral density
- Patients should not stop therapy with Relvar in asthma without physician supervision.

Adverse effects observed with Relvar in clinical studies and post-marketing		
Frequency Category	**Number of Subjects**	**Adverse reaction(s)**
Very common	≥1/10	Headache, nasopharyngitis
Common	≥1/100 to <1/10	Pharyngitis, rhinitis, candidiasis of mouth and throat, pneumonia, arthralgia, pyrexia
Uncommon	≥1/1,000 to <1/100	Extrasystoles
Rare	≥1/10,000 to <1/1,000	Hypersensitivity reactions including anaphylaxis, angioedema, rash, and urticaria, Palpitations

For Healthcare Professionals only. Images used are for illustrative purposes only.
If symptoms arise in the period between doses, an inhaled, short-acting beta$_2$-agonist should be taken for immediate relief.
Relvar Ellipta was developed in collaboration with INNOVIVA

PM-HK-FFV-ADVT-210001 (04/2023) Date of preparation: 27/04/2021