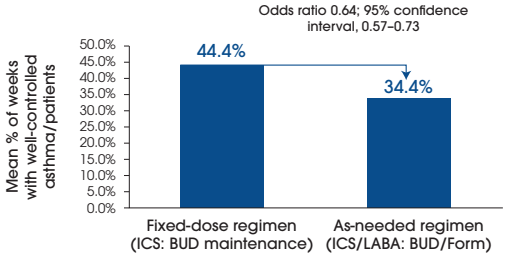
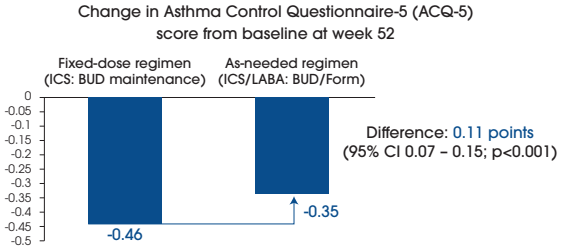
For better asthma control: Select a fixed-dose regimen*[1]

In the **SYGMA 1** study, patients with mild asthma receiving fixed-dose inhaled corticosteroid had **significantly better asthma control** than those who received as-needed regimen.[2†]



SYGMA 2 demonstrated that in patients with mild asthma, fixed-dose regimen resulted in significantly greater improvements in the severity of asthma symptoms.[3]



Scores on the ACQ-5 was measured after a run-in period of 2 to 4 weeks. The ACQ-5 consists of five questions about asthma symptoms in the previous week, each of which is scored on a range from 0 (no impairment) to 6 (maximum impairment).[3]

Fixed-dose regimen is superior to as-needed dosing regimen on asthma control[3]

ACQ-5, Asthma Control Questionnaire-5; BUD, budesonide; CI, confidence interval; Form, formoterol; ICS, inhaled corticosteroid; LABA, long-acting β-agonist.

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References

1. Woodcock A, et al. *Lancet* 2017;390:2247–2255. **2.** O'Byrne PM, et al. *N Engl J Med* 2018;378:1856–1876. **3.** Bateman ED, et al. *N Engl J Med* 2018;378:1877–1887. **4.** Relvar (fluticasone furoate/vilanterol) Hong Kong Prescribing Information (HK032018GDS09v2/EMA201803). **5.** Budesonide/formoterol 200/6 mg inhalation powder, Product Information, AstraZeneca.

*Data from the Salford Lung Study in over 4,000 patients. Proportion of Asthma Control Test responders at 6 months for Relvar was 70% vs 56% for other ICS/LABA arms, with an absolute different of 14%. Study population ≥18 years. The most commonly used ICS/LABAs in the intention-to-treat population were: Fluticasone propionate/salmeterol) 30%, budesonide/formoterol 15% and beclomethasone/formoterol 12%.

†Patients were randomly assigned to one of three regimens: twice-daily placebo plus terbutaline (0.5 mg) used as needed (terbutaline group), twice-daily placebo plus budesonide–formoterol (200 µg of budesonide and 6 µg of formoterol) used as needed (budesonide–formoterol group), or twice-daily budesonide (200 µg) plus terbutaline used as needed (budesonide maintenance group). Data based on the results of the budesonide–formoterol group versus budesonide maintenance group.

ACQ-5, Asthma Control Questionnaire-5; BUD, budesonide; Form formoterol; ICS, inhaled corticosteroid; LABA, long-acting β-agonist.

Safety Profile of Relvar Ellipta Inhalation Powder, Pre-dispensed 100/25 mcg and 200/25 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 urticarial, palpitations

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 beta2-agonist and inhaled corticosteroid) is appropriate: • patients not adequately controlled with inhaled corticosteroids and 'as needed' inhaled short acting beta2-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, the patient 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 Beta2-adrenergic blockers may weaken or antagonise the effect of beta2-adrenergic agonists. Concurrent use of both non-selective and selective beta2-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 HK032018GDS09v2/EMA201803.

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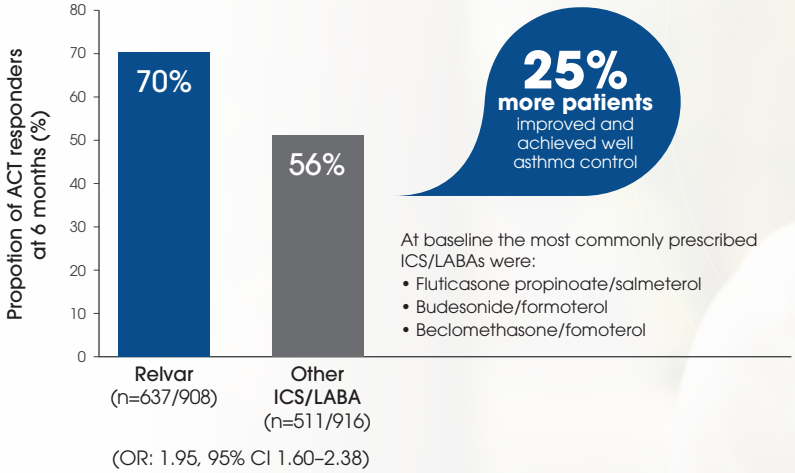
For better asthma control: Select a fixed-dose regimen*[1]

Real-world data from the Salford Lung Study demonstrated that fixed-dose RELVAR treatment offers patients superior asthma control compared with other ICS/LABAs.[1]

- Fixed-dose RELVAR regimen **reduced exacerbation rate** in a patient's everyday life[1]
- Relvar is associated with **fewer occurrences of palpitation/ tachycardia and lower risk of serious adverse events** compared with BUD/Form[4,5]



25% **more patients** improved and achieved well asthma control

At baseline the most commonly prescribed ICS/LABAs were:
- Fluticasone propinoate/salmeterol
- Budesonide/formoterol
- Beclomethasone/fomoterol

ACT, Asthma Control Test; CI, confidence interval; ICS, inhaled corticosteroid; LABA, long-acting β-agonist; OR, odds ratio.