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Relvar Ellipta, יעילות מתמשכת ל- 24 שעות, פעם ביום, לחולי אסתמה ו- COPD[1,2,3]

24 HOUR EFFICACY

- הקומבינציה הראשונה של ICS/LABA* המעניקה יעילות מתמשכת ל- 24 שעות[1,2]
- במינון של פעם ביום בלבד[3]
- במשאף קל לשימוש המועדף ע"י החולים[4,5,6]

Asthma		COPD
Relvar Ellipta is for patients (≥12 years) in need of asthma maintenance therapy[3]		Relvar Ellipta is for symptomatic treatment of patients with COPD with a FEV_1 <70% predicted normal (post-bronchodilator) and an exacerbation history despite regular bronchodilator therapy[3]
רשום: Relvar Ellipta 92/22 mcg שאיפה אחת, פעם ביום[3]	רשום: Relvar Ellipta 184/22 mcg שאיפה אחת, פעם ביום[3]	רשום: Relvar Ellipta 92/22 mcg** שאיפה אחת, פעם ביום[3]
Asthma patients who require a low to mid dose of ICS/LABA[3]	Asthma patients who require a higher dose of ICS/LABA[3]	COPD patients with a history of exacerbations who need maintenance therapy[3]

** 184/22 mcg dose is not indicated in COPD.
* ICS/LABA: Inhaled corticosteroid in combination with a long-acting $beta_2$- agonist.

כלול בסל התרופות

RELVAR™ ELLIPTA™
(fluticasone furoate and vilanterol inhalation powder)
Practical efficacy

RELVAR- abbriviated PI

Therapeutic indications

Asthma

Relvar Ellipta 92/22 mcg and Relvar Ellipta 184/22 mcg 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.

COPD (Chronic Obstructive Pulmonary Disease)

Relvar Ellipta 92/22 mcg is indicated for the symptomatic treatment of adults with COPD with a FEV$_1$<70% predicted normal (post-bronchodilator) with an exacerbation history despite regular bronchodilator therapy.

Relvar Ellipta – Abbreviated PI

For full information see MOH approved prescribing information

Generic name of the drug and active ingredients

Relvar Ellipta 92/22 mcg: Each single inhalation provides a delivered dose (the dose leaving the mouthpiece) of 92 micrograms of fluticasone furoate and 22 micrograms of vilanterol (as trifenatate).This corresponds to a pre-dispensed dose of 100 micrograms of fluticasone furoate and 25 micrograms vilanterol (as trifenatate).

Relvar Ellipta 184/22 mcg: Each single inhalation provides a delivered dose (the dose leaving the mouthpiece) of 184 micrograms of fluticasone furoate and 22 micrograms of vilanterol (as trifenatate). This corresponds to a pre-dispensed dose of 200 micrograms of fluticasone furoate and 25 micrograms vilanterol (as trifenatate).

Excipients with known effect:

Each delivered dose contains approximately 25 mg of lactose (as monohydrate).

Dosage and method of administration

Asthma*: Adults and adolescents aged 12 years and over*

One inhalation of Relvar Ellipta 92/22 micrograms once daily or one inhalation of Relvar Ellipta 184/22 micrograms once daily.

COPD*: Adults aged 18 years and over*

One inhalation of Relvar Ellipta 92/22 micrograms once daily.

Contraindications: Hypersensitivity to the active substances or to any of the excipients

Special warnings and precautions for use

Deterioration of disease: Fluticasone furoate/vilanterol should not be used to treat acute asthma symptoms or an acute exacerbation in COPD. 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: Relvar Ellipta should be discontinued immediately, the patient assessed and alternative therapy instituted if necessary. Cardiovascular effects: fluticasone furoate/vilanterol should be used with caution in patients with severe cardiovascular disease or heart rhythm abnormalities, thyrotoxicosis, uncorrected hypokaleamia or patients pre disposed to low levels of serum potassium. Patients with hepatic impairment: For patients with moderate to severe hepatic impairment, the 92/22 micrograms dose should be used and patients should be monitored for systemic corticosteroid-related adverse reactions. Systemic corticosteroid effects: 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). Hyperglycaemia: There have been reports of increases in blood glucose levels in diabetic patients and this should be considered when prescribing to patients with a history of diabetes mellitus. Pneumonia in patients with COPD: An increase in the incidence of pneumonia, including pneumonia requiring hospitalisation, has been observed in patients with COPD receiving inhaled corticosteroids. There is some evidence of an increased risk of pneumonia with increasing steroid dose but this has not been demonstrated conclusively across all studies. There is no conclusive clinical evidence for intra-class differences in the magnitude of the pneumonia risk among inhaled corticosteroid products. Physicians should remain vigilant for the possible development of pneumonia in patients with COPD as the clinical features of such infections overlap with the symptoms of COPD exacerbations. Risk factors for pneumonia in patients with COPD include current smoking, older age, low body mass index (BMI) and severe COPD. Relvar Ellipta 184/22 micrograms is not indicated for patients with COPD. There is no additional benefit of the 184/22 micrograms dose compared to the 92/22 micrograms dose and there is a potential increased risk of systemic corticosteroid-related adverse reactions (see section 4.8).

Interaction with other medicinal products and other forms of interaction

Interaction with beta-blockers: Concurrent use of both non-selective and selective beta$_2$-adrenergic blockers should be avoided unless there are compelling reasons for their use. Caution is advised when co-administering with strong CYP 3A4 inhibitors (e.g. ketoconazole, ritonavir) as there is potential for increased systemic exposure to both fluticasone furoate and vilanterol, and concomitant use should be avoided. Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicinal product.

Women of chilbearing potential/Contraception in females

Pregnancy: There are no or limited data from the use of fluticasone furoate and vilanterol trifenatate in pregnant women. 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: There is insufficient information on the excretion of fluticasone furoate or vilanterol trifenatate and/or metabolites in human milk. 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. Fertility: There are no fertility data in humans.

Undesirable effects

The most commonly reported adverse reactions with fluticasone furoate and vilanterol were headache and nasopharyngitis. Common adverse reaction: Candidiasis of mouth and throat, Bronchitis, Influenza, Oropharyngeal pain, Sinusitis, Pharyngitis, Rhinitis, Cough, Dysphonia, Abdominal pain, Arthralgia, Back pain, Pyrexia, Upper respiratory tract infection, pneumonia, fractures and muscle spasms. With the exception of pneumonia and fractures, the safety profile was similar in patients with asthma and COPD. During clinical studies, pneumonia and fractures were more frequently commonly observed in patients with COPD.

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Medical information service: il.medinfo@gsk.com

Adverse events reporting service: il.safety@gsk.com, Tel: 03-9297100

References: 1. Bleecker ER *et al.* Fluticasone furoate/vilanterol 100/25 mcg compared with fluticasone furoate 100 mcg in asthma: a randomized trial. JACI In Practice 2014 :2(5):553-561. **2.** Boscia JA *et al.* Effect of once-daily fluticasone furoate/vilanterol on 24-hour pulmonary function in patients with chronic obstructive pulmonary disease: a randomized, three-way, incomplete block, crossover study. Clin Ther. 2012; 34(8): 1655-66. **3.** Relvar Ellipta Approved PI by MOH. **4.** Riley JH *et al.* Delivery of umeclidinium/vilanterol using a new twin strip device (ELLIPTA™) to COPD patients. Eur Respir J.2013:42(Suppl 57):P4145. **5.** Woepse M *et al.* Qualitative assessment of a two-strip dry powder inhaler (ELLIPTA™) for COPD and asthma. BMC Pulm Med. 2013 13:72. **6.** Svedstater H *et al.* Easy of use of the ELLIPA dry powder inhaler. npj Prim Care Resp Med. 2014:24:14019

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