Relvar Ellipta, יעילות מתמשכת ל- 24 שעות,
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 נוח 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[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.

חדש בישראל
כלול בסל התרופות

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

Relvar summary from approved PI May 2014:

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). **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, 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. 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: 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). 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 pneumonia has been observed in patients with COPD receiving fluticasone furoate/vilanterol. There was also an increased incidence of pneumonias resulting in hospitalisation. In some incidences these pneumonia events were fatal. 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 receiving fluticasone furoate/vilanterol include current smokers, patients with a history of prior pneumonia, patients with a body mass index <25 kg/m^2 and patients with a (forced expiratory volume) FEV_1<50% predicted. These factors should be considered when fluticasone furoate/vilanterol is prescribed and treatment should be re-evaluated if pneumonia occurs. 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. The incidence of pneumonia in patients with asthma was common at the higher dose. The incidence of pneumonia in patients with asthma taking fluticasone furoate/vilanterol 184/22 micrograms was numerically higher compared with those receiving fluticasone furoate/vilanterol 92/22 micrograms or placebo (see section 4.8). No risk factors were identified. Excipients: Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicinal product. **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 and fractures. 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.

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 2013 (in press). **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. 2013 (in press). **5.** Woepse M *et al.* Qualitative assessment of a two-strip dry powder inhaler (ELLIPTA™) for COPD and asthma. EAACI. 2013 (await status). **6.** Svedstater H *et al.* Ease of use of a two-strip dry powder inhaler (DPI) to deliver fluticasone furoate/vilanterol (FF/VI) and FF alone in asthma. ERS 23rd Annual Congress Barcelona, Spain. 2013. Abstract P701.

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