

הודעה על החמרה (מידע בטיחות) בעלון לרופא
(מעדכן 05.2013)

אוסר – 9.16

תאריך 07.2016

שם תכשיר באנגלית ומספר הרישום:

Relvar Ellipta 92/22mcg (151-45-33982), Relvar Ellipta 184/22mcg (151-46-33981)

שם בעל הרישום : GlaxoSmithKline (ISRAEL) Ltd

טופס זה מיועד לפרוט ההחמרות בלבד !

בעלון לרופא

ההחמרות המבוקשות		
פרק בעלון	טקסט נוכחי	טקסט חדש
Special warnings and precautions for use	<u>Pneumonia in patients with COPD</u> 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 (see section 4.8). 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 $<25 \text{ kg/m}^2$ and patients with a (forced expiratory volume) $\text{FEV}_1 < 50\%$ predicted. These factors should be considered when fluticasone furoate/vilanterol is prescribed and treatment should be re-evaluated if pneumonia occurs.	<u>Pneumonia in patients with COPD</u> 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 .

מצ"ב העלון, שבו מסומנות ההחמרות המבוקשות על רקע צהוב.
שינויים שאינם בגדר החמרות סומנו (בעלון) בצבע ירוק.