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

תאריך: 02.2016
שם תכשיר באנגלית ומספר הרישום:

Flixotide Diskus 50 mcg 069-98-28477
Flixotide Diskus 100 mcg 069-97-28478
Flixotide Diskus 250 mcg 069-96-28479
Flixotide Diskus 500 mcg 069-95-28480

שם בעל הרישום : GlaxoSmithKline (ISRAEL) Ltd

טופס זה מיועד לפרוט ההחמרות בלבד !

בעלון לרופא

ההחמרות המבוקשות		
טקסט חדש	**טקסט נוכחי**	**פרק בעלון**
Breast-feeding The excretion of fluticasone propionate into human breast milk has not been investigated. When measurable plasma levels were obtained in lactating laboratory rats following subcutaneous administration there was evidence of fluticasone propionate in the breast milk. However, plasma levels in patients following inhaled application of fluticasone propionate at recommended doses are likely to be low. Administration during lactation should only be considered if the expected benefit to the mother is greater than any possible risk to the child.	*Breast-feeding* The excretion of fluticasone propionate into human breast milk has not been investigated. When measurable plasma levels were obtained in lactating laboratory rats following subcutaneous administration there was evidence of fluticasone propionate in the breast milk. However, plasma levels in patients following inhaled application of fluticasone propionate at recommended doses are likely to be low.	**Fertility, Pregnancy and Lactation**

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