

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

אושר – 3.16

תאריך: 02.2016

שם תכשיר באנגלית ומספר הרישום:

Flixotide Inhaler 50 mcg 131-50-31008

Flixotide Inhaler 125 mcg 129-81-30973

Flixotide Inhaler 250 mcg 129-80-30974

שם בעל הרישום : GlaxoSmithKline (ISRAEL) Ltd

טופס זה מיועד לפרוט החמרות בלבד !

בעלון לרופא

ההחמרות המבוקשות		
פרק בעלון	טקסט נוכחי	טקסט חדש
Fertility, Pregnancy and Lactation	<i>Breast-feeding</i> 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.	<i>Breast-feeding</i> 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.

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