

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

תאריך 9 ליוני 2016

שם תכשיר באנגלית ומספר הרישום

NEXIUM I.V. 135-56-31128-00

שם בעל הרישום אסטרזניקה ישראל

טופס זה מיועד לפרוט ההחמרות בלבד !

ההחמרות המבוקשות		
פרק בעלון	טקסט נוכחי	טקסט חדש
Indication		
contraindications		
Posology, dosage & administration		
Special Warnings and Special Precautions for Use		<p>Subacute cutaneous lupus erythematosus (SCLE) Proton pump inhibitors are associated with very infrequent cases of SCLE. If lesions occur, especially in sun-exposed areas of the skin, and if accompanied by arthralgia, the patient should seek medical help promptly and the health care professional should consider stopping Nexium. SCLE after previous treatment with a proton pump inhibitor may increase the risk of SCLE with other proton pump inhibitors</p>
Interaction with Other Medicaments and Other Forms of Interaction		<p>A reinforced monitoring of tacrolimus concentrations as well as renal function (creatinine clearance) should be performed, and dosage of tacrolimus adjusted if needed.</p>
Fertility, pregnancy and Lactation		<p><i>Skin and subcutaneous tissue disorders</i></p> <p>Subacute cutaneous lupus erythematosus (see section 4.4)</p>
Adverse events		

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