

הודעה על החמרה (מידע בטיחות)

12/11/2012

תאריך:

Actemra®

שם התכשיר באנגלית:

142.21.31931.00

מספרי רישום:

רוש פרמצבטיקה (ישראל) בע"מ

שם בעל הרישום:

ההחמרות בעלון מסומנות על רקע צהוב

בעלון לרופא

פרטים על השינויים המבוקשים		
טקסט חדש	טקסט נוכחי	פרק בעלון
Healthcare professionals should exercise caution when considering the use of Actemra in patients with a history of recurring or chronic infections or with underlying conditions (e.g. diverticulitis, diabetes and interstitial lung disease) which may predispose patients to infections.	Healthcare professionals should exercise caution when considering the use of Actemra in patients with a history of recurring or chronic infections or with underlying conditions (e.g. diverticulitis, diabetes) which may predispose patients to infections.	4.4 Special warnings and precautions for use
RA Patients <i>Interstitial Lung Disease</i> Impaired lung function may increase the risk for developing infections. There have been post-marketing reports of interstitial lung disease (including pneumonitis and pulmonary fibrosis), some of which had fatal outcomes.		4.8 Undesirable effects

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