

# הודעה על החמרה (מידע בטיחות) בעלון לרופא

(מעודכן 05.2013)

תאריך 17/09/2014

שם תכשיר באנגלית ומספר הרישום [142-21-31931-00] Actemra 20 mg/ml

שם בעל הרישום רש פרמצבטיקה (ישראל) בע"מ

טופס זה מיועד לפרוט ההחמרות בלבד !

## ההחמרות המבוקשות - עלון לרופא

טקסט חדש	טקסט נוכחי	פרק בעלון
<p><b>Vaccinations</b> Live and live attenuated vaccines should not be given concurrently with Actemra as clinical safety has not been established. In a randomized open-label study, adult RA patients treated with Actemra and MTX were able to mount an effective response to both the 23-valent pneumococcal polysaccharide and tetanus toxoid vaccines which was comparable to the response seen in patients on MTX only. It is recommended that all patients, particularly sJIA and pJIA patients, be brought up to date with all immunisations in agreement with current immunisation guidelines prior to initiating Actemra therapy. The interval between live vaccinations and initiation of Actemra therapy should be in accordance with current vaccination guidelines regarding immunosuppressive agents.</p>	<p><b>Vaccinations</b> Live and live attenuated vaccines should not be given concurrently with Actemra as clinical safety has not been established. It is recommended that all patients, particularly sJIA and pJIA patients, be brought up to date with all immunisations in agreement with current immunisation guidelines prior to initiating Actemra therapy. The interval between live vaccinations and initiation of Actemra therapy should be in accordance with current vaccination guidelines regarding immunosuppressive agents.</p>	<p><b>Special warnings and precautions for use</b></p>
<p><b>Skin Reactions</b> Very rare reports of Stevens-Johnson Syndrome have occurred in the post marketing setting.</p>		<p><b>Undesirable effects</b></p>
<p><b>Paediatric population</b>  No case of an overdose in the paediatric population has been observed.</p>		<p><b>4.9 Overdose</b></p>

מצ"ב העלון, שבו מסומנות ההחמרות המבוקשות על רקע צהוב.

שינויים שאינם בגדר החמרות סומנו (בעלון) בצבע שונה. יש לסמן רק תוכן מהותי ולא שינויים במיקום הטקסט.