הודעה על החמרה (מידע בטיחות) בעלון לרופא

תאריך:	**06.12.2012**
שם התכשיר באנגלית ומספר הרישום:	**Actemra 142.21.31931.00**
שם בעל הרישום:	**רוש פרמצבטיקה (ישראל) בע"מ**

טופס זה מיועד לפרוט ההחמרות בלבד!

ההחמרות המבוקשות		
טקסט חדש	**טקסט נוכחי**	**פרק בעלון**
Tuberculosis As recommended for other biological treatments, RA and sJIA patients should be screened for latent tuberculosis (TB) infection prior to starting Actemra therapy. Patients with latent TB should be treated with standard anti-mycobacterial therapy before initiating Actemra.-Prescribers are reminded of the risk of false negative tuberculin skin and interferon-gamma TB blood test results, especially in patients who are severely ill or immunocompromised. Patients should be instructed to seek medical advice if signs/symptoms (e.g., persistent cough, wasting/weight loss, low grade fever) suggestive of a tuberculosis infection occur during or after therapy with Actemra.	*Tuberculosis* As recommended for other biological treatments, RA and sJIA patients should be screened for latent tuberculosis (TB) infection prior to starting Actemra therapy. Patients with latent TB should be treated with standard anti-mycobacterial therapy before initiating Actemra	**4.4 Special warnings and precautions for use**