אפריל 2021

Actemra® 162 mg S.C. (tocilizumab)

Solution for Injection in Pre-filled Syringe

רופא/ה יקר/ה, רוקח/ת יקר/ה,

חברת רוש פרמצבטיקה (ישראל) בע"מ מבקשת להודיעכם על מספר עדכונים שבוצעו בעלון לרופא של התכשיר.

בהודעה זו מצוינים רק עדכונים מהותיים ועדכונים אשר מהווים החמרה.

ההתוויות הרשומות לתכשיר בישראל:

- Actemra, in combination with methotrexate (MTX), is indicated for the treatment of moderate to severe active rheumatoid arthritis (RA) in adult patients who have either responded inadequately to, or who were intolerant to, previous therapy with one or more disease-modifying anti-rheumatic drugs (DMARDs) or tumour necrosis factor (TNF) antagonists. In these patients, Actemra can be given as monotherapy in case of intolerance to MTX or where continued treatment with MTX is inappropriate
- Actemra has been shown to reduce the rate of progression of joint damage as measured by X-ray and to improve physical function when given in combination with methotrexate.
- Actemra in combination with methotrexate (MTX) is indicated for the treatment of severe, active and progressive rheumatoid arthritis (RA) in adults not previously treated with MTX.
- Actemra (tocilizumab) is indicated for the treatment of giant cell arteritis (GCA) in adult patients.
- Actemra in combination with methotrexate (MTX) is indicated for the treatment of juvenile idiopathic polyarthritis (pJIA; rheumatoid factor positive or negative and extended oligoarthritis) in patients 2 years of age and older, who have responded inadequately to previous therapy with MTX. Actemra can be given as monotherapy in case of intolerance to MTX or where continued treatment with MTX is inappropriate.
- Actemra is indicated for the treatment of active systemic juvenile idiopathic arthritis (sJIA) in patients 1 year of age and older, who have responded inadequately to previous therapy with NSAIDs and systemic corticosteroids. Actemra can be given as monotherapy (in case of intolerance to MTX or where treatment with MTX is inappropriate) or in combination with MTX.

העלונים המעודכנים נשלחו לפרסום במאגר התרופות שבאתר משרד הבריאות, וניתן לקבלם מודפסים על-ידי פנייה לבעל הרישום: רוש פרמצבטיקה (ישראל) בע"מ, ת.ד 6391 , הוד השרון 4524079 טלפון 09-9737777. כתובתנו באינטרנט: www.roche.co.il.

ב ב ר כ ה,

אביטל ויסברוט
מחלקת רישום

לביא עמי-עד
רוקח ממונה

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עדכונים מהותיים בעלון לרופא

בסעיף 4.2 Posology and method of administration עודכן המידע הבא:

Paediatric patients
The safety and efficacy of Actemra subcutaneous formulation in children from birth to less than 1 year have not been established. ~~There is no~~ No data are available.

בסעיף 4.4 Special warnings and precautions for use עודכן המידע הבא:

Patients and parents/guardians of sJIA or pJIA patients should be advised 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.

בסעיף 4.8 Undesirable Effects עודכן המידע הבא:

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorization of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product . Any suspected adverse events should be reported to the Ministry of Health according to the National Regulation by using an online form ~~/http://sideeffects.health.gov.il~~ https://sideeffects.health.gov.il/