אוגוסט 2023

Actemra® 20 mg/ml I.V.
אקטמרה 20 מ"ג/מ"ל I.V.
tocilizumab
Concentrate for solution for infusion

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 (tocilizumab) is indicated for reducing signs and symptoms in adult patients with moderately to severely active rheumatoid arthritis who had an inadequate response to one or more DMARDs (Disease Modifying Anti-Rheumatic Drugs) or TNF antagonists or in whom DMARDs cannot be used. Actemra can be used alone or in combination with methotrexate or other DMARDs.

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 is indicated for the treatment of active systemic juvenile idiopathic arthritis in patients 2 years of age and older.

Actemra in combination with methotrexate (MTX) is indicated for the treatment of juvenile idiopathic polyarthritis (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 in combination with methotrexate (MTX) in indicated for the treatment of severe, active and progressive rheumatoid arthritis (RA) in adults not previously treated with MTX.

Actemra is indicated for the treatment of chimeric antigen receptor (CAR) T cell-induced severe or life-threatening cytokine release syndrome (CRS) in adults and paediatric patients 3 years of age and older.

הסבר:

<u>טקסט עם קו תחתי</u> מציין טקסט שהוסף לעלון.
~~טקסט עם קו חוצה~~ מציין טקסט שהוסר מן העלון.

למידע נוסף יש לעיין בעלון לרופא כפי שנשלח למשרד הבריאות.

העלון המעודכן נשלח לפרסום במאגר התרופות שבאתר משרד הבריאות, וניתן לקבלו מודפסים ע"י 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,

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לביא עמי-עד
רוקח ממונה

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אביטל ויסברוט
מחלקת רישום

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עדכונים מהותיים בעלון לרופא

בסעיף 5.2 Pharmacokinetic properties עודכן המידע הבא:

Elimination
Following intravenous administration, tocilizumab undergoes ~~biphasic~~ a dual elimination from the circulation. ~~The total ,~~ one following a linear clearance ~~of tocilizumab was~~ and one following a concentration-dependent ~~and is the sum of the linear and~~ non linear clearance. ~~The~~ In RA patients, the linear clearance was ~~estimated as a parameter in the population pharmacokinetic analysis and was~~ 9.5 mL/h .
The concentration-dependent non linear clearance plays a major role at low tocilizumab concentrations. Once the non linear clearance pathway is saturated, at higher tocilizumab concentrations, clearance is mainly determined by the linear clearance.

בסעיף 6.3 Shelf-life עודכן המידע הבא:

Diluted product: After dilution, the prepared solution for infusion is physically and chemically stable in sodium chloride 9 mg/mL (0.9%) solution for injection at ~~30ºC~~ . It can be stored for 24 hours at 30ºC and for up to 2 weeks (14 days) in a refrigerator at 2°C -8°C for polypropylene (PP) soft bag & hard bottle, polyethylene (PE) soft bags & hard bottle, polyvinyl chloride (PVC) soft bag and glass vial.