מרץ 2019

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.

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,

אביטל ויסברוט
מחלקת רישום

בת אל מלכה כהן
רוקחת ממונה

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עדכונים מהותיים בעלון לרופא

בסעיף 4.2 Posology and method of administration עודכן המידע הבא:

sJIA Patients

[…]

The safety and efficacy of intravenous Actemra in children below 2 years of age has not been established.

~~No data are available.~~

[…]

pJIA Patients

[…]

The safety and efficacy of intravenous Actemra in children below 2 years of age has not been established.

~~No data are available.~~

[…]

בסעיף 4.8 Undesirable Effects עודכן המידע הבא:

~~The~~ ADRs from clinical trials and/or post marketing experience with Actemra based on spontaneous case reports, literature cases and cases from non-interventional study programs are listed in Table 1 and are presented by MedDRA system organ class ~~and~~. The corresponding frequency ~~categories defined using~~ category for each ADR is based on the following convention: very common (≥ 1/10); common (≥ 1/100 to < 1/10), uncommon (≥ 1/1,000 to < 1/100), rare (>1/10,000 to <1/1,000) or very rare (<1/10,000). Within each frequency grouping, undesirable effects are presented in order of decreasing seriousness.

Table 1. List of ADRs occurring in patients with RA receiving tocilizumab as monotherapy or in combination with MTX or other DMARDs in the double-blind controlled period or during postmarketing experience

MedDRA System Organ Class	Frequency categories with preferred terms		
	Very Common	**Common**	**Uncommon**
Blood and lymphatic system disorders		Leukopenia, Neutropenia, Hypofibrinogenaemia	

*For the full list of Adverse drug reactions, please see Actemra® 20 mg/ml I.V. prescribing information.

[…]

בסעיף 5.1 Pharmacodynamic Properties עודכן המידע הבא:

RA Patients

Pharmacodynamic effects

In clinical studies with tocilizumab, rapid decreases in CRP, erythrocyte sedimentation rate (ESR), serum amyloid A (SAA) and fibrinogen were observed.

[…]