פברואר 2025

Kevzara 150mg
Kevzara 200mg

SOLUTION FOR INJECTION

חומר פעיל:

Kevzara 150mg - SARILUMAB 131.6 MG / 1 ML
Kevzara 200mg - SARILUMAB 175 MG / 1 ML

ההתוויה המאושרת:

Kevzara 150mg & 200mg:
Kevzara in combination with methotrexate (MTX) is indicated for the treatment of moderately to severely active rheumatoid arthritis (RA) in adult patients who have responded inadequately to, or who are intolerant to one or more disease modifying anti rheumatic drugs (DMARDs). Kevzara can be given as monotherapy in case of intolerance to MTX or when treatment with MTX is inappropriate.

Kevzara 200mg:
KEVZARA is indicated for treatment of adult patients with polymyalgia rheumatica who cannot tolerate corticosteroid taper.

חברת סאנופי ישראל בע"מ מבקשת להודיע על עדכון העלונים לרופא ולצרכן.

העדכונים העיקריים הינם:

בעלון לרופא:

בסעיף משטר מינון חלו עדכוני נוסח:

4.2 Posology and method of administration

Treatment should be initiated and supervised by healthcare professionals experienced in the diagnosis and treatment of the condition for which this medicinal product is intended (see section 4.1).
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Table 1: Recommended dose modifications in case of neutropenia, thrombocytopenia, or liver enzyme elevations for rheumatoid arthritis (see sections 4.4 and 4.8):
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Low Platelet Count	
Lab Value (cells x $10^3/\mu L$)	**Recommendation**
50 to 100	Treatment with ~~Sarilumab~~ sarilumab should be withheld until >100 x $10^3/\mu L$. Sarilumab can then be resumed at 150 mg every 2 weeks and increased to 200 mg every 2 weeks as clinically appropriate.
Less than 50	If confirmed by repeat testing, treatment with sarilumab should be discontinued.

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Paediatric population

The safety and efficacy of sarilumab pre-filled syringe and pre-filled pen in children ~~up to~~less than 18 years of age have not been established. No data are available.

Method of administration

Subcutaneous use.

Injection sites (abdomen, thigh and upper arm) should be rotated with each injection. Sarilumab should not be injected into skin that is tender, damaged, or has bruises or scars.

Pre-filled syringe and pre-filled pen

The total content (1.14 ml) of the pre-filled syringe/pre-filled pen should be administered as a subcutaneous injection. ~~Injection sites (abdomen, thigh and upper arm) should be rotated with each injection. Sarilumab should not be injected into skin that is tender, damaged, or has bruises or scars.~~

For the pre-filled syringe/pre-filled pen, a~~A~~ patient may self-inject sarilumab or the patient's caregiver may administer sarilumab if their healthcare professional determines that it is appropriate. Proper training should be provided to patients and/or caregivers on the preparation and administration of sarilumab prior to use.

The pre-filled syringe or pen has not been studied in paediatric patients.

Comprehensive instructions for administration of this medicinal product are given in the package leaflet.

4.4 Special warnings and precautions for use

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Serious infections

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Treatment with sarilumab should be withheld if a patient develops a serious infection or an opportunistic infection. Once the infection is controlled, treatment with sarilumab may be re-initiated at the discretion of the healthcare professional.

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Serious and sometimes fatal infections due to bacterial, mycobacterial, invasive fungal, viral, or other opportunistic pathogens have been reported in patients receiving immunosuppressive agents. The most frequently observed serious infections with sarilumab in RA patients included pneumonia and cellulitis (see section 4.8). Among opportunistic infections, tuberculosis, candidiasis, and pneumocystis were reported with sarilumab in RA. In some patients with RA with concomitant tuberculosis, disseminated rather than localised infections were observed, most of whom were taking concomitant immunosuppressants such as MTX or corticosteroids, which may increase the risk of infection.

Tuberculosis
Patients should be evaluated for tuberculosis risk factors and tested for latent infection prior to initiating treatment with sarilumab. Patients with latent or active tuberculosis should be treated with standard antimycobacterial therapy before initiating treatment. Anti-tuberculosis therapy should be considered prior to initiation of treatment in patients with a past medical history of latent or active tuberculosis in whom an adequate course of treatment cannot be confirmed, and for patients with a negative test for latent tuberculosis but having risk factors for tuberculosis infection. Healthcare professionals 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. When considering anti-tuberculosis therapy, consultation with a physician with expertise in tuberculosis may be appropriate.
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Gastrointestinal perforation and diverticulitis
Cases of gastrointestinal perforation and diverticulitis have been reported in association with sarilumab. Gastrointestinal perforation has been reported in patients with and without diverticulitis. Patients presenting with symptoms potentially indicative of diverticulitis, such as abdominal pain, gastrointestinal haemorrhage and/or unexplained change in bowel habits with fever should be evaluated promptly for early identification of diverticulitis which can be associated with gastrointestinal perforation. Sarilumab should be used with caution in patients with previous history of intestinal ulceration or diverticulitis~~. Patients presenting with new-onset abdominal symptoms such as persistent pain with fever should be evaluated promptly~~ (see section 4.8).
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4.8 Undesirable effects

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Tabulated list of adverse reactions

Adverse reactions listed in the table have been reported in controlled clinical studies. The frequency of adverse reactions listed below is defined using 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); very rare (< 1/10,000); not known (cannot be estimated from the available data). Within each frequency grouping, adverse reactions~~undesirable effects~~ are presented in order of decreasing seriousness.
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Paediatric population

The safety and efficacy of sarilumab pre-filled syringe and pre-filled pen in children less than 18 years of age have not been established. No data are available.

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5.2 Pharmacokinetic properties

Rheumatoid arthritis
The pharmacokinetics of sarilumab were characterised in 2186 adult patients with RA treated with sarilumab which included 751 patients treated with 150 mg and 891 patients treated with 200 mg subcutaneous doses every two weeks for up to 52 weeks.
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Special populations

Age, gender, ethnicity and body weight
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Body weight influenced the pharmacokinetics of sarilumab in adult patients. In patients with higher body weight (>100 ~~Kg~~kg) both 150 mg and 200 mg doses demonstrated efficacy; however, patients weighing >100 ~~Kg~~ kg had greater therapeutic benefit with the 200 mg dose.
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בעלונים לצרכן:

בסעיף 3 "כיצד תשתמש בתרופה" חל עדכון נוסח:

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כיצד להשתמש בעט או במזרק המוכן לשימוש
- הרופא, הרוקח או האחות יראו לך כיצד להזריק קבזרה. לאחר קבלת ההנחיות הללו, קבזרה יכולה להיות מוזרקת באופן עצמאי או באמצעות מטפל לאחר הדרכה מספקת.
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העלונים המעודכנים נשלחו לפרסום במאגר התרופות שבאתר משרד הבריאות וניתן לקבלם מודפסים על ידי פנייה לבעל הרישום - סאנופי ישראל בע"מ, Greenwork Park, מתחם העסקים בקיבוץ יקום, בניין E (קומה 1), 6097600, יקום או בטלפון: 09-8633081.

להלן הקישור לאתר משרד הבריאות: https://www.gov.il/he/service/israeli-drug-index

בברכה,
חברת סאנופי ישראל בע"מ