Kevzara (sarilumab)

NEW PRODUCT SLIDESHOW

MPR

Introduction

- **Brand name:** Kevzara
- **Generic name:** Sarilumab
- **Pharmacological class:** Interleukin-6 antagonist
- **Strength and Formulation:** 150mg/1.14mL, 200mg/1.14mL; soln for SC inj; preservative-free
- **Manufacturer:** Sanofi US and Regeneron
- **How supplied:** Single-dose prefilled syringes—2
- **Legal Classification:** Rx

KEVZARA


NDC 0024-5910-01
℞ Only
KEVZARA®
(sarilumab)
injection
200 mg/1.14 mL (175.4 mg/mL)
2 Single-Dose Pre-filled Syringes
For Subcutaneous Injection Use Only
REGENERON
SANOFI GENZYME
Store in a refrigerator at 36°F to 46°F (2°C to 8°C) in the original carton to protect from light. Do NOT freeze. Do NOT shake.
If needed, patients/caregivers may store KEVZARA at room temperature up to 77°F (25°C) up to 14 days in the outer carton.
Do not store above 77°F (25°C). After removal from the refrigerator, use KEVZARA within 14 days or discard.
Date removed from the refrigerator ___/___/____
ATTENTION: Enclosed Medication Guide is required for each patient.
200mg/1.14mL
KEVZARA®
(sarilumab)
injection
OPEN HERE
200mg/1.14mL

Indications

- Moderately-to-severely active **rheumatoid arthritis** (RA) in adults who have had an inadequate response or intolerance to ≥1 DMARDs
- May be used as monotherapy or in combination with methotrexate or other DMARDs

Dosage & Administration

- Rotate inj sites; do not inj into tender, damaged, bruised, or scarred skin
- Give 200mg SC inj once every 2 weeks
- **Do not initiate** if ANC <2000/mm^3, platelets <150000/mm^3, or ALT/AST >1.5xULN
- **Dose modifications** for neutropenia, thrombocytopenia, and elevated liver enzymes: see full labeling

Considerations for Special Populations

- **Pregnancy:** Limited data to inform drug-associated risk
- **Nursing mothers:** Consider benefits and adverse effects
- **Pediatric:** Not established
- **Elderly:** Use caution
- **Hepatic impairment:** Active disease or impairment: not recommended
- **Renal impairment:** No adjustment required

Warnings/Precautions

- Increased risk of **serious or fatal infections** (eg, TB, bacterial, invasive fungal, viral, and other opportunistic infections); if develop, interrupt until controlled
- **Active infections**: do not give therapy
- Monitor closely for signs/symptoms of infection during and after therapy; interrupt if serious or opportunistic infection develops

Warnings/Precautions

- Consider r**isks/benefits** prior to initiating: chronic or recurrent, or history of opportunistic infections, exposed to TB, travel to, or residence in, areas with endemic TB or mycoses, conditions that predispose to infection
- Test for and treat **latent TB** prior to starting therapy

Warnings/Precautions

- **Monitor** neutrophils, platelets, ALT/AST 4–8 weeks after initiation, then every 3 months
- **Monitor** lipids 4–8 weeks after initiation, then every 6 months
- Increased risk of GI perforation with concurrent **diverticulitis**

Warnings/Precautions

- Immunosuppression
- Malignancies
- **Discontinue immediately** if anaphylaxis or other hypersensitivity reactions occur

Interactions

- Avoid **concomitant live vaccines**
- **Increased risk** of infection and immunosuppression with concomitant biological DMARDs (eg, TNF antagonists, IL-1R antagonists, anti-CD20 monoclonal antibodies, selective co-stimulation modulators); avoid

Interactions

- Increased risk of **GI perforation** with concomitant NSAIDs, corticosteroids
- Monitor warfarin, cyclosporine, theophylline, other CYP450 substrates with narrow therapeutic indices
- Caution with **CYP3A4 substrate** drugs (eg, oral contraceptives, lovastatin, atorvastatin, others)

Adverse Reactions

- Neutropenia
- Increased ALT
- Inj site erythema
- Upper respiratory infection
- Urinary tract infections
- Hypersensitivity reactions (may be severe)
- Thrombocytopenia
- GI perforation
- Increased lipids
- Immunosuppression

Mechanism of Action

- **Sarilumab** is an interleukin-6 (IL-6) antagonist that inhibits IL-6 mediated signaling
- IL-6 is pro-inflammatory cytokine produced by synovial and endothelial cells in joints affected by RA

Clinical Studies

- Kevzara was studied in 2 randomized, double-blind, placebo-controlled multicenter studies **(Study 1 and Study 2)**
- Enrolled patients (ages ≥18) had moderately to severely active RA with ≥8 tender and 6 swollen joints at baseline with inadequate clinical response to either methotrexate (MTX) or DMARD(s)

Clinical Studies

- Kevzara 150mg, Kevzara 200mg, or placebo was given subcutaneously every 2 weeks
- The **primary endpoint** was the proportion of patients who achieved an ACR20 response at Week 24

Clinical Studies

- In **Study 1**, patients were randomized to Kevzara 200mg + MTX (n=399), Kevzara 150mg + MTX (n=400), or placebo + MTX (n=398)
- Kevzara 150mg and 200mg were superior in achieving ACR20 at Week 24 (**58.0%** and **66.4%**) vs. placebo (33.4%)

Clinical Studies

- In **Study 1**, more significant major clinical response was seen in Kevzara 150mg and Kevzara 200mg (**12.8%** and **14.8%**) vs. placebo (3.0%) by Week 52
- There was a greater change in tender and swollen joints with Kevzara 150mg (**-14.42, -9.03**) and Kevzara 200mg (**-14.94, -10.12**) vs. placebo (-10.51, -7.02)

Clinical Studies

- In **Study 2**, patients were randomized to Kevzara 200mg + DMARD(s) (n=184), Kevzara 150mg + DMARD(s) (n=181), or placebo + DMARD(s) (n=181)
- Kevzara 150mg and 200mg arms were superior in achieving ACR20 at Week 24 (**55.8%** and **60.9%**) vs. placebo (33.7%)

Clinical Studies

- In **Study 2**, there was a greater change in tender and swollen joints in Kevzara 150mg (**-14.11, -10.77**) and Kevzara 200mg (**-15.92, -10.89**) vs. placebo (-9.79, -7.25)
- Major clinical response was not applicable in Study 2

Clinical Studies

- Both **Study 1 and Study 2** assessed physical function and disability by the Health Assessment Questionnaire Disability Index (HAQ-DI)
- Patients receiving Kevzara150mg or 200mg showed greater improvement from baseline in physical function vs. placebo

Clinical Studies

- In both **Study 1 and 2**, physical and mental health status was measured by the Short Form health survey (SF-36)
- Kevzara 200mg demonstrated greater improvement in **physical component** summary; no difference was seen in mental component summary
- For more clinical trial data, see full labeling

New Product Monograph

- For more information view the product monograph available at:

  http://www.empr.com/kevzara/drug/34685/