

INDICATION AND IMPORTANT SAFETY INFORMATION

WHAT IS KEVZARA?

KEVZARA[®] (sarilumab) is an injectable prescription medicine called an interleukin-6 (IL-6) receptor blocker. KEVZARA is used to treat adult patients with moderately to severely active rheumatoid arthritis (RA) after at least one other medicine called a disease-modifying antirheumatic drug (DMARD) has been used and did not work well or could not be tolerated.

IMPORTANT SAFETY INFORMATION

KEVZARA can cause serious side effects including:

- **SERIOUS INFECTIONS: KEVZARA is a medicine that affects your immune system. KEVZARA can lower the ability of your immune system to fight infections. Some people have had serious infections while using KEVZARA, including tuberculosis (TB), and infections caused by bacteria, fungi, or viruses that can spread throughout the body. Some people have died from these infections. Your healthcare provider should test you for TB before starting KEVZARA. Your healthcare provider should monitor you closely for signs and symptoms of TB during treatment with KEVZARA.**
 - Before starting KEVZARA, tell your healthcare provider if you
 - think you have an infection or have symptoms of an infection, with or without a fever. Symptoms may include sweats or chills, muscle aches, a cough, shortness of breath, blood in your phlegm, weight loss, warm, red, or painful skin or sores on your body, diarrhea or stomach pain, burning when you urinate or urinating more often than normal, if you feel very tired, or if you are being treated for an infection, get a lot of infections or have repeated infections
 - have diabetes, HIV, or a weakened immune system
 - have TB, or have been in close contact with someone with TB
 - live or have lived, or have traveled to certain parts of the country (such as the Ohio and Mississippi River valleys and the Southwest) where there is an increased chance of getting certain fungal infections (histoplasmosis, coccidioidomycosis, or blastomycosis)
 - have or have had hepatitis
 - After starting KEVZARA, call your healthcare provider right away if you have any symptoms of an infection.
- **CHANGES IN CERTAIN LABORATORY TEST RESULTS:** Your healthcare provider should do blood tests before and after starting KEVZARA to check for low neutrophil (white blood cells that help the body fight off bacterial infections) counts, low platelet (blood cells that help with blood clotting and stop bleeding) counts, and an increase in certain liver function tests. Changes in test results are common with KEVZARA and can be severe. You may also have changes in other laboratory tests, such as your blood cholesterol levels. Your healthcare provider should do blood tests 4 to 8 weeks after starting KEVZARA and then every 6 months during treatment to check for an increase in blood cholesterol levels.

- **TEARS (PERFORATION) OF THE STOMACH OR INTESTINES:** Tell your healthcare provider if you have had a condition known as diverticulitis (inflammation in parts of the large intestine) or ulcers in your stomach or intestines. Some people using KEVZARA had tears in their stomach or intestine. This happens most often in people who also take nonsteroidal anti-inflammatory drugs (NSAIDs), corticosteroids, or methotrexate. Call your healthcare provider right away if you have fever and stomach (abdominal) pain that does not go away.
- **CANCER:** KEVZARA may increase your risk of certain cancers by changing the way your immune system works. Tell your healthcare provider if you have ever had any type of cancer.
- **SERIOUS ALLERGIC REACTIONS:** Serious allergic reactions can happen with KEVZARA. Get medical attention right away if you have any of the following signs: shortness of breath or trouble breathing; feeling dizzy or faint; swelling of your lips, tongue, or face; moderate or severe stomach (abdominal) pain or vomiting; or chest pain.
- Do not use KEVZARA if you are allergic to sarilumab or any of the ingredients of KEVZARA.
- Before using KEVZARA, tell your healthcare provider if you
 - have an infection
 - have liver problems
 - have had stomach (abdominal) pain or a condition known as diverticulitis (inflammation in parts of the large intestine) or ulcers in your stomach or intestines
 - recently received or are scheduled to receive a vaccine. People who take KEVZARA should not receive live vaccines
 - plan to have surgery or a medical procedure
 - are pregnant or plan to become pregnant. It is not known if KEVZARA will harm your unborn baby
 - are breastfeeding or plan to breastfeed. Talk to your healthcare provider about the best way to feed your baby if you use KEVZARA. It is not known if KEVZARA passes into your breast milk
 - take any prescription or nonprescription medicines, vitamins, or herbal supplements. It is especially important to tell your healthcare provider if you use
 - any other medicines to treat your RA. Using KEVZARA with these medicines may increase your risk of infection
 - medicines that affect the way certain liver enzymes work. Ask your healthcare provider if you are not sure if your medicine is one of these
- The most common side effects include:
 - injection site redness
 - upper respiratory tract infection
 - urinary tract infection
 - nasal congestion, sore throat, and runny nose

These are not all of the possible side effects of KEVZARA. Tell your doctor about any side effect that bothers you or does not go away. You are encouraged to report side effects of prescription drugs to the FDA at www.fda.gov/medwatch or call 1-800-FDA-1088 or to Sanofi-Aventis at 1-800-633-1610.

To learn more, talk about KEVZARA with your healthcare provider or pharmacist. The FDA-approved Medication Guide and Prescribing Information can be found below, or by calling **1-844-KEVZARA** (1-844-538-9272).

[Click here for full Prescribing Information including risk of SERIOUS SIDE EFFECTS and Medication Guide for KEVZARA.](#)

The health information contained herein is provided for general educational purposes only. Your healthcare provider is the single best source of information regarding your health. Please consult your healthcare provider if you have any questions about your health or treatment.