Get to know KEVZARA



Please see Indication and Important Safety Information throughout, and full Prescribing Information and Medication Guide, including risk of SERIOUS SIDE EFFECTS.



What is **KEVZARA®?**

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.

KEVZARA is a treatment for adults with moderate to severe rheumatoid arthritis (RA).

Your doctor may prescribe a biologic known as a tumor necrosis factor inhibitor (TNFi), like Enbrel® (etanercept) or Humira® (adalimumab), followed by a Janus kinase inhibitor (JAKi), like Xeljanz® (tofacitinib) or Rinvoq® (upadacitinib).

If these treatments stop working, don't work as well as they used to, or if your body can't tolerate them, a different type of biologic may help.

KEVZARA comes in a pre-filled pen or syringe, and is injected under the skin once every 2 weeks.

KEVZARA can be used with or without a conventional disease-modifying antirheumatic drug (DMARD) like methotrexate.

You should take KEVZARA and other medications exactly as your doctor has told you.



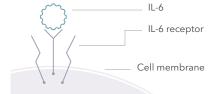
What makes KEVZARA® different than **most other biologics?**

IMPORTANT SAFETY INFORMATION (cont'd)

- 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

KEVZARA targets the interleukin-6 (IL-6) receptor.

IL-6 is an immune system protein produced by the white cells in your blood. IL-6 is believed to play a role in the symptoms of RA.



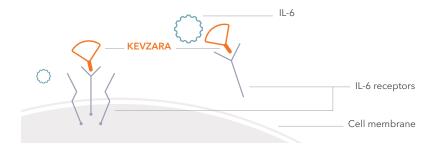
IL-6 and its effect on RA.

IL-6 leads a dual life. In a healthy body, it helps create inflammation that can act as a defense against infections and some injuries. But for people with RA, higher levels of IL-6 can actually work against the best interests of the body, because they create inflammation where it's not needed.

This inflammation day after day can lead to joint damage.

How KEVZARA works.

KEVZARA blocks the IL-6 protein from attaching to the receptor, potentially helping to reduce the amount of inflammation in your body, and helping to slow the damage that RA may cause.





What do you need to know before getting started?

KEVZARA, taken with methotrexate, has been proven to*:

- Reduce pain after only 2 weeks (although for some, it may take up to 3 months)
- Help improve the ability to do everyday activities
- Make joints less sore and swollen
- Slow the progression of RA and help protect the joints from further damage

*Individual results may vary.

IMPORTANT SAFETY INFORMATION (cont'd)

- Before starting KEVZARA, tell your healthcare provider if you (cont'd)
 - have diabetes, HIV, or a weakened immune system
 - have TB, or have been in close contact with someone with TB

Please see additional IMPORTANT SAFETY INFORMATION on pages <u>15-18</u>.



The KEVZARA pre-filled syringe and pen received an **Ease of Use Commendation** from the Arthritis Foundation after independent testing by experts and evaluation by patients with arthritis.



Sticking to your schedule is important.



To help make sure that your treatment is working as it should, it's important to follow the dosing and treatment schedule set by your doctor. And remember to keep at it, even if you don't feel a change right away. You should always tell your doctor how you've been feeling, especially if you have any signs of infection.

To help stay on schedule, think about keeping a special "injection calendar," and mark the dates and time of your injections so you don't forget.



Caregiver Corner

If you're taking care of someone with RA, it may be helpful to tie his or her injection schedule to another routine event, like a trip to the supermarket together, or lunch out with friends.

IMPORTANT SAFETY INFORMATION (cont'd)

- Before starting KEVZARA, tell your healthcare provider if you (cont'd)
 - 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)

Please see additional IMPORTANT SAFETY

INFORMATION on pages 15-18.

- have or have had hepatitis

Take note of any changes you might be feeling.

When you start a new treatment such as KEVZARA, it's especially important to note how it's affecting your health and things like your activity level. Tracking these changes will help you keep your doctor better informed about whether KEVZARA is working for you. And it allows both of you to determine the right balance of relief versus side effects.

If you experience any side effects or have other concerns, tell your doctor immediately.



Like other biologics, there may be side effects.

Common side effects of KEVZARA include:

- Injection site redness
- Upper respiratory tract infection
- Urinary tract infection
- Nasal congestion, sore throat, and runny nose

These are the most common side effects, but there may be some others. Even if they're not listed in this guide, you should always tell your doctor about any changes or side effects.



After starting KEVZARA, call your doctor right away if you have any symptoms of an infection.

Infection is a serious side effect.

Like most biologics, KEVZARA can lower the ability of your immune system to fight infections, making it easier to get one, or worsen one you already have.

Some people get serious infections while taking 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 doctor should test you for TB before starting KEVZARA and continue to monitor you closely for signs and symptoms of TB during treatment.

Tell your doctor if you think you have an infection or symptoms of an infection, with or without a fever, before starting KEVZARA. **Don't start treatment unless your doctor says it's okay.**

Signs of an infection may include:

• Fever	• Weight loss
Sweating or chills	• Warm, red, or painful skin or sores
Muscle aches	Diarrhea or stomach pain
• Cough	Burning when you urinate
• Shortness of breath	Urinating more often than normal
Blood in your phlegm	Feeling very tired



Treatment may also increase your risk of cancer.

KEVZARA may increase your risk of certain cancers by changing the way your immune system works. Tell your doctor if you've ever had any type of cancer.

You may see changes in your blood tests.

You've probably been given quite a few blood tests to keep track of your moderate to severe RA, but do you know what your doctor is tracking?

With KEVZARA, your doctor should give you blood tests before you start treatment, 4 to 8 weeks after starting treatment, and then every 3 months to check for:

- Low white blood cell counts
- Low platelet counts
- An increase in certain liver function tests

Your doctor should also do blood tests 4 to 8 weeks after starting treatment and then every 6 months to check for:

• An increase in blood cholesterol levels

Once you start treatment, if there's a change in any of your blood test results, your doctor may interrupt your treatment for a period of time and/or decrease your dose if necessary.

You may get tears in your stomach or intestines.

When taken with medicines like aspirin or ibuprofen, corticosteroids, or disease-modifying antirheumatic drugs (DMARDs) like methotrexate, some people taking KEVZARA get tears or small holes known as perforations in their stomach or intestine. This happens most often in people who also take nonsteroidal anti-inflammatory drugs (NSAIDs), corticosteroids, or methotrexate.



Call your doctor right away if you have a fever and stomach (abdominal) pain that doesn't go away.



What does your doctor **need to know?**

Tell your doctor about all of your medicines.

That means prescription and nonprescription medicines, vitamins, and herbal supplements. It's especially important to tell your doctor about any medications you're using to treat your moderate to severe RA.

What else should you tell your doctor?

Before you start KEVZARA, make sure your doctor knows about any other medical conditions you currently have or have had in the past, including:

An allergic reaction to sarilumab

An infection or any history of infections

Liver problems

Stomach area pain, ulcers in your stomach or intestines, or inflammation in parts of your intestines (diverticulitis)

Vaccines you've recently received or are scheduled to receive

Surgery or planned medical procedures

Diabetes, HIV, or a weakened immune system

TB, or if you've been in close contact with someone with TB

Plan to become pregnant or are pregnant

Plan to breastfeed or are currently breastfeeding

If you've ever lived or traveled to areas in the US, like the Southwest or the Ohio and Mississippi River valleys, where there's an increased chance of getting certain fungal infections. These infections may happen more often or worsen if you use KEVZARA. Ask your doctor if you're unsure whether you've lived where these infections are common.



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 - 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.



IMPORTANT SAFETY INFORMATION (cont'd)

- 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.

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

Another great resource available to you, 24/7

KEVZARA.com was created to provide you with information you can use, whether you're learning more about KEVZARA, just starting your medication, or are looking for lifestyle tips and ideas to help you in your day-to-day life.





Please see full <u>Prescribing Information</u> and <u>Medication Guide</u>, including risk of SERIOUS SIDE EFFECTS.

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