

# Your guide to treatment

# WITH KEVZARA FOR PMR

(polymyalgia rheumatica)

For adults with PMR after corticosteroids have been used and did not work well or when a slow decrease in the dose of corticosteroids (taper) cannot be tolerated.



### What is PMR?



Polymyalgia rheumatica (PMR) is an inflammatory rheumatic disease. These are types of diseases that cause your body to attack your joints, muscles, bones, and organs. Pain and stiffness in the hips and shoulders on both sides of the body are the most common symptoms of PMR.

PMR inflammation happens when **the immune system isn't working like it should** and attacks healthy cells in the body. There are many proteins that cause PMR inflammation. Interleukin-6, or IL-6, is one of the most common proteins in the body. People with PMR who experience pain and stiffness have high levels of IL-6.

# IMPORTANT SAFETY INFORMATION KEVZARA can cause serious side effects

### **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

### What is KEVZARA?

KEVZARA is an injectable prescription medicine called an 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.



IL-6 Blocker

 polymyalgia rheumatica (PMR) after corticosteroids have been used and did not work well or when a slow decrease in the dose of corticosteroids (taper) cannot be tolerated.

It is not known if KEVZARA is safe and effective in children.

#### Who should not use KEVZARA?

- Do not use KEVZARA if you are allergic to sarilumab or any of the ingredients in KEVZARA.
- See the <u>Medication Guide</u> for a complete list of ingredients in KEVZARA.

## IMPORTANT SAFETY INFORMATION (cont'd)

- 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



### **Using KEVZARA**

#### How should I use KEVZARA?

- KEVZARA is given as an **injection under the skin** (subcutaneous injection).
- KEVZARA is available as a single-use pre-filled syringe or single-use pre-filled pen. Your healthcare provider will prescribe the dose and type of KEVZARA that is best for you.
- If your healthcare provider decides that you or a caregiver can give the injections of KEVZARA at home, you or your caregiver should receive training on the right way to prepare and inject KEVZARA.
   Do not try to inject KEVZARA until you have been shown the right way to give the injections by your healthcare provider.
- Inject 1 dose of KEVZARA every 2 weeks.

See the detailed Instructions for Use within the <u>Medication Guide</u> found in the pocket of this brochure for instructions about the right way to prepare and inject your KEVZARA at home.

#### How should I store KEVZARA?

- Store KEVZARA in the refrigerator at 36°F to 46°F (2°C to 8°C). Store KEVZARA in the original carton until use to protect it from light.
- Do not freeze KEVZARA.
- Do not shake KEVZARA.
- KEVZARA may be stored at room temperature up to 77°F (25°C) for up to 14 days in the original outer carton.
- Throw away KEVZARA if it has been kept at room temperature and not been used within 14 days.

Keep KEVZARA and all medicines out of the reach of children.



### Savings on copays

With the
KevzaraConnect®
Copay Card, eligible
patients may pay as
little as a \$0 copay
per month.\*



Maximum copay assistance of \$15,000 per calendar year. Subject to program terms and conditions.

Call **1-844-KEVZARA** (1-844-538-9272) or visit **KEVZARA.com** to learn more and find out if you're eligible.

\*Subject to an annual maximum copay assistance amount of \$15,000. This program is not valid for prescriptions covered, in whole or in part, by Medicaid, Medicare, VA, DOD, TRICARE, or similar federal or state programs, including any state pharmaceutical assistance program. This program is not valid where prohibited by law, taxed, or restricted. KevzaraConnect reserves the right to rescind, revoke, terminate, or amend this offer, eligibility, and terms of use at any time without notice. Any savings provided by the Copay program may vary depending on patients' out-of-pocket costs. See full program terms and conditions at KEVZARA.com.

# IMPORTANT SAFETY INFORMATION (cont'd)

- 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.



# Building a support system

Tell your friends, family, and loved ones how PMR is affecting you. It's important to have a support system of people there to help when you're struggling with your diagnosis.

Many people with PMR require a caregiver. The role of caregiver begins with trust. Choose a friend or loved one to help with things like:

- Taking you to doctor visits
- Keeping you company
- Helping you with daily activities when you're in pain
- · Listening when you need someone to talk to



# IMPORTANT SAFETY INFORMATION (cont'd)

- 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 get 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.

### IMPORTANT SAFETY INFORMATION (cont'd)

- 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 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 or PMR.
       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
  - · injection site itching
  - · upper respiratory tract infection
  - urinary tract infection
  - nasal congestion, sore throat, and runny nose



Talk to your doctor and ask any questions you may have about your treatment with KEVZARA.

### IMPORTANT SAFETY INFORMATION (cont'd)

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 <a href="https://www.fda.gov/medwatch">www.fda.gov/medwatch</a> 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 <a href="https://www.KEVZARA.com">www.KEVZARA.com</a> or by calling 1-844-KEVZARA.

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

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