

Package leaflet:
Information for the patient

Kevzara[®] 200 mg

solution for injection in
pre-filled syringe

sarilumab

Is this leaflet hard to see or
read? Phone 0800 035 2525
for help

**REGENERON
sanofi**

Read all of this leaflet carefully
before you start using this
medicine because it contains
important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist, or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist, or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

In addition to this leaflet, you will be given a patient alert card, which contains important safety information that you need before and during treatment with Kevzara.

What is in this leaflet

1. What Kevzara is and what it is used for
2. What you need to know before you use Kevzara
3. How to use Kevzara
4. Possible side effects
5. How to store Kevzara
6. Contents of the pack and other information

1. What Kevzara is and what it is used for

What Kevzara is

Kevzara contains the active substance sarilumab. It is a type of protein called a monoclonal antibody.

What Kevzara is used for

Kevzara is used to treat adults with moderately to severely active rheumatoid arthritis if previous therapy did not work well enough or was not tolerated. Kevzara can be used alone or together with a medicine called methotrexate.

It may help you by:

- slowing down damage to joints
- improving your ability to perform daily activities.

How Kevzara works

- Kevzara attaches to another protein called interleukin-6 (IL-6) receptor and blocks its action.
- IL-6 plays a major role in the symptoms of rheumatoid arthritis such as pain, swollen joints, morning stiffness, and fatigue.

2. What you need to know before you use Kevzara

Do not use Kevzara:

- if you are allergic to sarilumab or any of the other ingredients of this medicine (listed in section 6).
- if you have an active severe infection.

Warnings and precautions

Talk to your doctor, pharmacist, or nurse if:

- you have any infection or you get a lot of infections. Kevzara can lower your body's ability to fight infection: this means it can make you more likely to get infections or make your infection worse.
- you have tuberculosis (TB), symptoms of TB (persistent cough, weight loss, listlessness, mild fever), or have been in close contact with someone with TB. Before you are given Kevzara, your doctor will check you for TB.
- you have had viral hepatitis or other liver disease. Before you use Kevzara, your doctor will do a blood test to check your liver function.
- you have had diverticulitis (a condition of the lower bowel) or ulcers in your stomach or intestines, or develop symptoms such as fever and stomach (abdominal) pain that does not go away.
- you have ever had any type of cancer.

- you have recently had any vaccination or are going to have a vaccination.

If any of the above apply to you (or you are not sure), talk to your doctor, pharmacist or nurse before using Kevzara.

You will have blood tests before you are given Kevzara. You will also have the tests during your treatment. This is to check for low blood cell count, liver problems, or changes in your cholesterol levels.

Children and adolescents

Do not give this medicine to children and adolescents under 18 years of age.

Other medicines and Kevzara

Tell your doctor or pharmacist if you are using, have recently used, or might use any other medicines. This is because Kevzara can affect the way some other medicines work. Also some other medicines can affect the way Kevzara works.

In particular, do not use Kevzara and tell your doctor or pharmacist if you are using:

- a group of medicines called “Janus kinase (JAK) inhibitors” (used for diseases like rheumatoid arthritis and cancer)
- other biological medicines used in the treatment of rheumatoid arthritis

If any of the above apply to you (or you are not sure), talk to your doctor or pharmacist.

Kevzara can affect the way some medicines work: this means the dose of other medicines may need changing. If you are using any of the following medicines, tell your doctor or pharmacist before using Kevzara:

- statins, used to reduce cholesterol level
- oral contraceptives
- theophylline, used to treat asthma
- warfarin, used to prevent blood clots.

If any of the above apply to you (or you are not sure), talk to your doctor or pharmacist.

Pregnancy and breast-feeding

Talk to your doctor before using Kevzara if you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby.

- Do not take Kevzara if you are pregnant unless your doctor specifically recommends it.

- The effects of Kevzara on an unborn baby are not known.
- You and your doctor should decide if you should use Kevzara if you are breast-feeding.

Driving and using machines

The use of Kevzara is not expected to affect your ability to drive or use machines. However, if you are feeling tired or unwell after you use Kevzara, you should not drive or use machines.

3. How to use Kevzara

Treatment should be started by a doctor experienced in the diagnosis and treatment of rheumatoid arthritis. Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose is one 200 mg injection every two weeks.

- Your doctor may adjust the dose of your medicine based on results of blood tests.

Kevzara is given as an injection under the skin (called "subcutaneous" injection).

Learning how to use the pre-filled syringe

- Your doctor, pharmacist, or nurse will show you how to inject Kevzara. Following these instructions, Kevzara can be self-injected or administered by a care-giver.
- Carefully follow the “Instructions for Use” provided in the carton.
- Use the pre-filled syringe exactly as described in the “Instructions for Use”.

If you use more Kevzara than you should

If you have used more Kevzara than you should, talk to your doctor, pharmacist or nurse.

If you miss a dose of Kevzara

If it has been 3 days or less since the missed dose:

- inject your missed dose as soon as you can.
- then inject your next dose at your regular time.

If it has been 4 days or more, inject the next dose at your regular time. Do not inject a double dose to make up for a forgotten injection.

If you are unsure when to inject your next dose ask your doctor, pharmacist or nurse for instructions.

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If you stop using Kevzara

Do not stop using Kevzara without talking to your doctor.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist, or nurse.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Serious side effect

Tell your doctor straight away if you think you have an **infection** (which may affect up to 1 in every 10 people). The symptoms may include fever, sweats, or chills.

Other side effects

Tell your doctor, pharmacist, or nurse if you notice any of the following side effects:

Very common (may affect more than 1 in 10 people)

- Low white blood cell counts shown by blood tests

Common (may affect up to 1 in 10 people)

- infections in your sinuses or throat, blocked or runny nose and sore throat (upper respiratory tract infection)
- urinary tract infection
- cold sores (oral herpes)
- low platelet counts shown by blood tests
- high cholesterol, high triglycerides shown by blood tests
- abnormal liver function tests
- injection-site reactions (including redness and itching).

Uncommon (may affect up to 1 in 100 people)

- infection of the lungs
- inflammation of the deep skin tissue
- diverticulitis (a disease affecting the gut often with stomach (abdominal) pain, nausea and vomiting, fever, and constipation, or less commonly diarrhoea)

Rare (may affect up to 1 in 1000 people)

- perforation in stomach or intestines (a hole that develops in the wall of the gut)

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist, or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Kevzara

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the label and carton after EXP. The expiry date refers to the last day of that month.

Store in a refrigerator (2°C to 8°C).

- Do not freeze.
- Once taken out of the refrigerator, do not store Kevzara above 25 °C.
- Write down the date of removal from the refrigerator in the space provided on the outer carton.
- Use the syringe within 14 days after taking it out of the refrigerator or the insulated bag.
- Keep the syringe in the original carton in order to protect from light.

Do not use this medicine if the solution in the syringe is cloudy, discoloured or contains particles, or if any part of the pre-filled syringe looks damaged.

After use, put the syringe into a puncture-resistant container. Always keep the container out of the sight and reach of children. Ask your doctor, pharmacist, or nurse how to throw away the container.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Kevzara contains

- The active substance is sarilumab.
- The other ingredients are arginine, histidine, polysorbate 20, sucrose, and water for injections.

What Kevzara looks like and contents of the pack

Kevzara is a clear, colourless to pale yellow solution for injection that comes in a pre-filled syringe.

Each pre-filled syringe contains 1.14 ml of solution delivering one single dose. Kevzara is available in packs containing 1 or 2 pre-filled syringes and in multipacks comprising 3 cartons, each containing 2 pre-filled syringes.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

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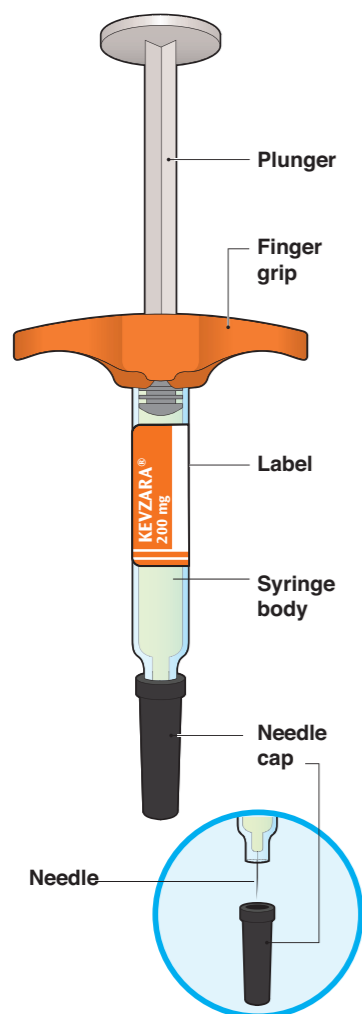
Manufacturer

Sanofi Winthrop Industrie
1051 Boulevard Industriel
76580 Le Trait
France

This leaflet does not contain all the information about your medicine. If you have any questions or are not sure about anything, ask your doctor or pharmacist.

**This leaflet was last revised in
January 2024**

The parts of the Kevzara pre-filled syringe are shown in this picture.



Important information

This device is a single-dose pre-filled syringe (called “syringe” in these instructions). It contains 200 mg of Kevzara for injection under the skin (subcutaneous injection) once every two weeks.

Ask your healthcare professional to show you the right way to use the syringe before your first injection.

Do

- ✓ Read all of the instructions carefully before using a syringe.
- ✓ Check that you have the correct medicine and the correct dose.
- ✓ Keep unused syringes in the original carton and store in the refrigerator between 2°C and 8°C.
- ✓ Keep the carton in an insulated bag with an ice pack when travelling.
- ✓ Let the syringe warm up to room temperature for at least 30 minutes before using.
- ✓ Use the syringe within 14 days after taking it out of the refrigerator or insulated bag.
- ✓ Keep the syringe out of the sight and reach of children.

Do not

- ✗ Do not use the syringe if it has been damaged or the needle cap is missing or not attached.
- ✗ Do not remove the needle cap until just before you are ready to inject.
- ✗ Do not touch the needle.
- ✗ Do not try to put the cap back on the syringe.
- ✗ Do not re-use the syringe.
- ✗ Do not freeze or heat the syringe.
- ✗ Once removed from the refrigerator, do not store the syringe above 25°C.
- ✗ Do not expose the syringe to direct sunlight.
- ✗ Do not inject through your clothes.

If you have any further questions, ask your doctor, pharmacist or nurse.

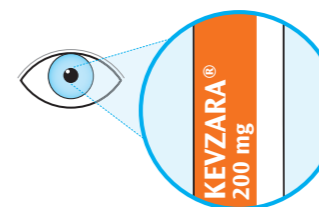
Step A: Get ready for an injection

1. Prepare all the equipment you will need on a clean, flat working surface.

- You will need an alcohol wipe, a cotton ball or gauze, and a puncture-resistant container.
- Take one syringe out of the packaging by holding the middle of the syringe body. Keep the remaining syringe in the carton in the refrigerator.

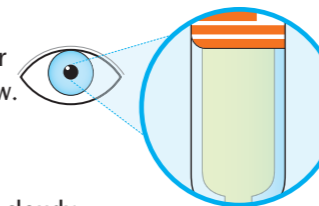
2. Look at the label.

- Check that you have the correct medicine and the correct dose.
- Check the expiry date (EXP).
- ✗ **Do not** use the syringe if the date has passed.



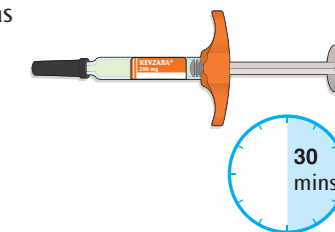
3. Look at the medicine.

- Check that the liquid is clear and colourless to pale yellow.
- You may see an air bubble, this is normal
- ✗ **Do not** inject if the liquid is cloudy, discoloured or contains particles.



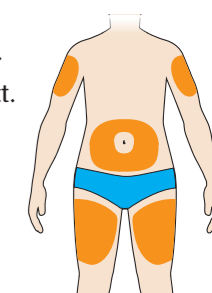
4. Lay the syringe on a flat surface and allow it to warm up to room temperature (<25°C) for at least 30 minutes.

- Using the syringe at room temperature may make the injection more comfortable.
- ✗ **Do not** use the syringe if it has been out of the refrigerator for more than 14 days.
- ✗ **Do not** heat the syringe; let it warm up on its own.
- ✗ **Do not** expose the syringe to direct sunlight.



5. Select the injection site.

- You can inject into your thigh or belly (abdomen) except for the 5 cm around your belly button (navel). If somebody else gives you the injection, you can also use the outer area of the upper arm.
- Change injection site each time you inject.
- ✗ **Do not** inject into skin that is tender, damaged or has bruises or scars.



● Injection sites

6. Prepare the injection site.

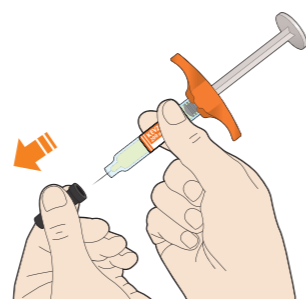
- Wash your hands.
- Clean skin with an alcohol wipe.
- ✗ **Do not** touch the injection site again before the injection.

Step B: Perform the injection – Perform Step B only after completing Step A “Get ready for an injection”

1

Pull off the needle cap.

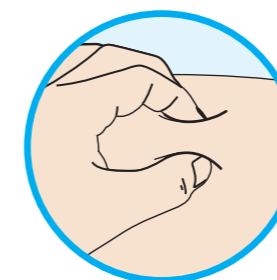
- Hold the syringe in the middle of the syringe body with the needle pointing away from you.
- Keep your hand away from the plunger.
- ✗ **Do not** get rid of any air bubbles in the syringe.
- ✗ **Do not** pull off the needle cap until you are ready to inject.
- ✗ **Do not** put the needle cap back on.



2

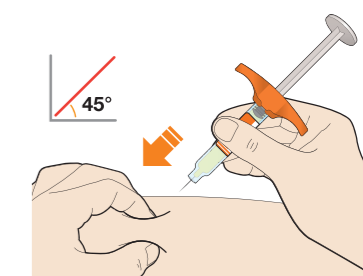
Pinch the skin.

- Use your thumb and first (index) finger to pinch a fold of skin at the injection site.



3

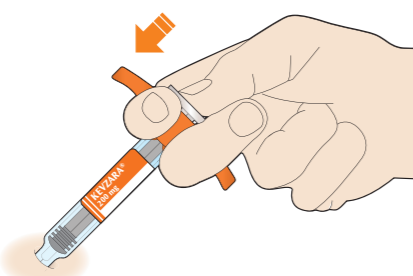
Insert the needle into the fold of skin at roughly a 45° angle.



4

Push the plunger down.

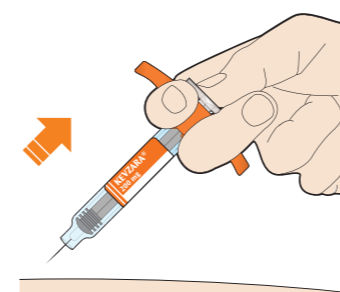
- Slowly push the plunger down as far as it will go until the syringe is empty.



5

Before you remove the needle, check that the syringe is empty.

- Pull the needle out at the same angle it was injected.
- If you see any blood, press a cotton ball or gauze on the site.
- ✗ **Do not** rub your skin after the injection.



6

Put your used syringe and the cap into a puncture-resistant container right away after use.

- Always keep the container out of the sight and reach of children.
- ✗ **Do not** put the needle cap back on.
- ✗ **Do not** throw the used syringe in household waste.
- ✗ **Do not** dispose of your used puncture-resistant container in your household waste unless your local guidelines permit this. Ask your doctor, pharmacist or nurse how to throw away the container.

