Package leaflet:
Information for the patient

Kevzara® 150 mg

solution for injection in pre-filled pen

Kevzara® 200 mg

solution for injection in pre-filled pen

sarilumab

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

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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 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 (RA) if previous therapy did not work well enough or was not tolerated. Kevzara can be used alone or together with a medicine called methotrexate (MTX).
It may help you by:
- slowing down damage to joints
- improving your ability to perform daily activities.

Kevzara is used to treat adults with polymyalgia rheumatica after corticosteroids have been used and did not work well or if you experience a relapse while decreasing the dose of corticosteroids (taper). Kevzara can be used alone or together with a medicine called corticosteroid.

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 RA 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 and 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 if you have a low blood cell count, liver problems, or changes in your cholesterol levels.

Every time you get a new pack of Kevzara, it is important you note down the name of the medicine, the date of the administration and the batch number (which is on the packaging after "Lot") and keep this information in a safe place.

Children and adolescents
The Kevzara pre-filled pen has not been studied in children 2 years of age and older with polyarticular juvenile idiopathic arthritis (pJIA) and is not intended for use in children. Kevzara is not recommended in children under 2 years of age. Kevzara must not be given to children with pJIA weighing less than 10 kg.

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 RA.

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.

Kevzara contains polysorbate 20
This medicine contains 2.28 mg of polysorbate 20 in each 1.14 mL of solution for injection which is equivalent to 2 mg/mL. Polysorbates may cause allergic reactions. Tell your doctor if you have any known allergies.

3. How to use Kevzara

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

Adult Patients
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 pen
- 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 after proper training.
- Carefully follow the "Instructions for Use" provided in the carton.
- Use the pre-filled pen 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.

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:

Adults
Very common (may affect more than 1 in 10 people):
- Low white blood cell counts shown by blood tests

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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)
- inflammation of the deep skin tissue
- infection of the lungs

Uncommon (may affect up to 1 in 100 people):
- 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 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 pen within 14 days after taking it out of the refrigerator or the insulated bag.
- Keep the pen in the original carton in order to protect from light.

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

After use, put the pen 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. Each pre-filled pen contains 150 mg or 200 mg sarilumab in 1.14 ml solution.
- The other ingredients are arginine, histidine, polysorbate 20 (E432), 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 pen.

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

Not all pack sizes may be marketed.

Kevzara is available as 150 mg or 200 mg pre-filled pens.

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65926 Frankfurt am Main
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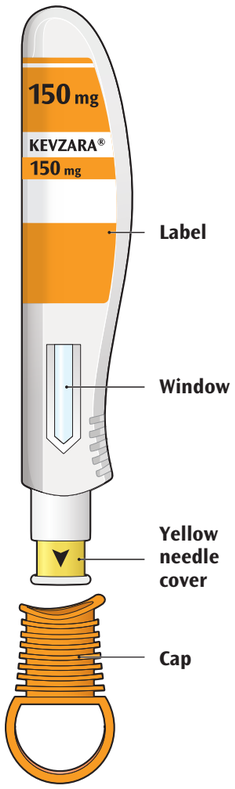
This leaflet does not contain all the information about your medicine. If you have any questions or are not sure about anything, ask your doctor or pharmacist.

This leaflet was last revised in November 2024.

Kevzara 150 mg solution for injection in pre-filled pen
sarilumab
Instructions for use

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



Important information

This device is a single-dose pre-filled pen (called "pen" in these instructions). It contains 150 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 pen before your first injection.

Do

- ✓ Read all of the instructions carefully before using a pen.
- ✓ Check that you have the correct medicine and the correct dose.
- ✓ Keep unused pens 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 pen warm up to room temperature for at least 60 minutes before using.
- ✓ Use the pen within 14 days after taking it out of the refrigerator or insulated bag.
- ✓ Use the pen within 14 days after taking it out of the refrigerator or insulated bag.
- ✓ Keep the pen out of the sight and reach of children.

Do not

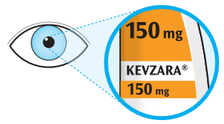
- ✗ Do not use a pen if it has been damaged or the cap is missing or not attached.
- ✗ Do not remove the cap until just before you are ready to inject.
- ✗ Do not press or touch the yellow needle cover with your fingers.
- ✗ Do not try to put the cap back on a pen.
- ✗ Do not re-use the pen.
- ✗ Do not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

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

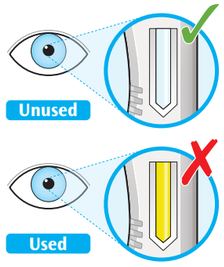
Step A: Get ready for an injection

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 pen out of the packaging by holding the middle of the pen body. Keep the remaining pen 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), this is shown on the side of the pens.
- ✗ **Do not** use the pen if the date has passed.



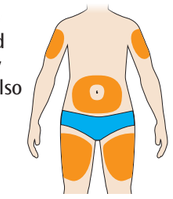
3 Look at the window.
- Check that the liquid is clear and colourless to pale yellow.
- You may see an air bubble, this is normal.
- ✗ **Do not** inject if the liquid is cloudy, discoloured or contains particles.
- ✗ **Do not** use if the window is solid yellow.



4 Lay the pen on a flat surface and allow it to warm up to room temperature (<25 °C) for at least 60 minutes.

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

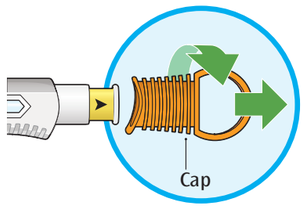


6 Prepare the injection site.
- Wash your hands.
- Clean skin with an alcohol wipe.
- ✗ **Do not** touch the injection site again before the injection.

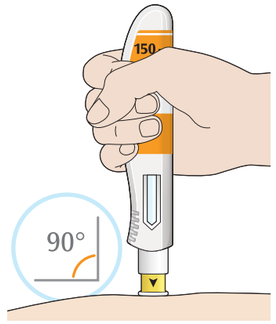
Step B: Perform the injection – Perform Step B only after completing Step A "Get ready for an injection"

1 Twist or pull off the orange cap.

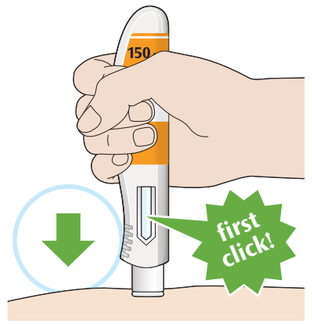
- ✗ **Do not** remove the cap until you are ready to inject.
- ✗ **Do not** press or touch the yellow needle cover with your fingers.
- ✗ **Do not** put the cap back on.



2 Put the yellow needle cover on your skin at roughly a 90° angle.
- Make sure you can see the window.

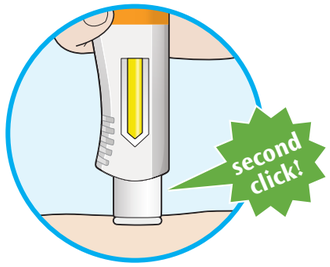


3 Press down and hold the pen firmly against your skin.
- There will be a "click" when the injection starts.

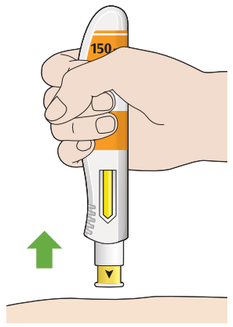
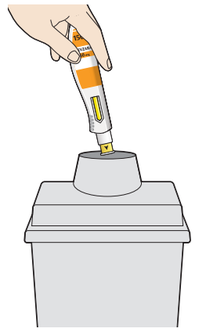


4 Keep holding the pen firmly against your skin.
- The window will start to turn yellow.
- The injection can take up to 15 seconds.

5 There will be a second click. Check to see if the entire window has turned yellow before you remove the pen.
- If you do not hear the second click, you should still check to see if the window has turned fully yellow.
- ✗ If the window does not turn fully yellow, **do not** give yourself a second dose without speaking to your healthcare provider.



6 Pull the pen away from your skin.
- If you see any blood, press a cotton ball or gauze on the site.
- ✗ **Do not** rub your skin after the injection.



7 Put your used pen 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 cap back on.
- ✗ **Do not** throw the used pens 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.