

**Package leaflet:**  
**Information for the patient**  
**Kezvara®**  
**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**  
**SONOFI**

**What Kezvara is used for**  
Kezvara 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. Kezvara 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.
- Kezvara 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). Kezvara can be used alone or together with a medicine called corticosteroid.

**How Kezvara works**

- Kezvara 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 Kezvara**

- Do not use Kezvara:**
- 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. Kezvara 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 Kezvara, your doctor will check you for TB.
- you have had viral hepatitis or other liver disease. Before you use Kezvara, your doctor will do a blood test to check your liver function.

- you have had diverticulitis (a condition of your lower bowel) or ulcers in your stomach or intestines, or develop symptoms such as fever and stomach (abdominal) pain that does not go away.
- if 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 or pharmacist.  
**Pregnancy and breast-feeding**  
Talk to your doctor before using Kezvara if you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby.

- Do not take Kezvara if you are pregnant unless your doctor specifically recommends it.
- The effects of Kezvara on an unborn baby are not known.
- You and your doctor should decide if you should use Kezvara if you are breast-feeding.

**Driving and using machines**

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

**Kezvara 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 Kezvara**

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.

Kezvara 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 Kezvara. Following these instructions, Kezvara can be self-injected or administered by a care-giver after proper training.

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- 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 Kezvara than you should**

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

**If you miss a dose of Kezvara**

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 Kezvara**

Do not stop using Kezvara 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
- 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 Kezvara**

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 Kezvara 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.

**Marketing Authorisation Holder**






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RG6 1PT  
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uk-medicalinformation@sanofi.com

**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 November 2024**

Packaging Administration Sanofi Winthrop Industrie - Le Trait - France				sanofi						
Brand name	KEZVARA	Article	Leaflet PFS	Date of creation	26/11/2024	Tech. specifi.	TRA-P041399a	Datamatrix	929783	
Dosage	200 mg	Item code	929783	By	L Wasserman	Tech. area	TRA-P041399-1c	Font size	10 pt	
Quantity	2 vrs	Based on	926131	Date of modification	06/12/2024	Size (mm)	420 x 296 mm			
Manuf. site	Le Trait		mockup	By	L Wasserman	folded	52,5 x 148 mm			
Country	UK			Proof n°	3					
<b>This artwork proof indicates colour position only.</b> Please refer to Pantone Colour Formula Guide 1000 for exact references				Colours used:	4					

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 Kezvara contains**

- The active substance is sarilumab. Each pre-filled syringe contains 200 mg sarilumab in 1.14 mL solution.
- The other ingredients are arginine, histidine, polysorbate 20 (E432), sucrose, and water for injections.

**What Kezvara looks like and contents of the pack**

Kezvara 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. Kezvara 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.

Packaging Administration				Sanofi Winthrop Industrie - Le Trait - France		sanofi	
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Quantity	2 srg	Based on	926131	Date of modification	06/12/2024	Size (mm)	420 x 296 mm
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Country	UK			Proof n°	3		
This artwork proof indicates colour position only. Please refer to Pantone Colour Formula Guide 1000 for exact references				Colours used:	4	Cyan	Magenta
						Yellow	Black
							Plan

### Step A: Get ready for an injection

- 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.
- 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.
- 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.
- Lay the syringe on a flat surface and allow it to warm up to room temperature (<math><25^{\circ}\text{C}</math>) 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.
- 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.
- Prepare the injection site.**
  - Wash your hands.
  - Clean skin with an alcohol wipe.
  - Do not touch the injection site again before the injection.

### 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.

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

Instructions for use

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

- 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.
- Pinch the skin.**
  - Use your thumb and first (index) finger to pinch a fold of skin at the injection site.
- Insert the needle into the fold of skin at roughly a 45° angle.**
- Push the plunger down.**
  - Slowly push the plunger down as far as it will go until the syringe is empty.
- 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.
- 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.

Packaging Administration				sanofi	
Sanofi Winthrop Industrie - Le Trait - France					
Brand name	KEVZARA	Article	Leaflet PFS	Date of creation	26/11/2024
Dosage	200 mg	Item code	929783	Tech. specifi.	TRA-P041399a
Quantity	2 syz	Based on	926131	Tech. area	TRA-P041399-1c
Manuf. site	Le Trait	Date of modification	06/12/2024	Size (mm)	420 x 296 mm
Country	UK	By	L Wasserman	folded	52,5 x 148 mm
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# Page 1 : RECTO / FRONT

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Datamatrix code

Identify Number  
Code resource

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Pliage  
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TRA-P041399-1b

05/09/2024

Modification position Datamatrix selon CC-010866 / Modification position Datamatrix according to CC-010866



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Area without text

**Package leaflet:**  
**Information for the patient**  
**Kevezara®**  
**200 mg**  
**sarilumab**  
**solution for injection in pre-filled syringe**

**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.

**What is in this leaflet**

- What Kevezara is and what it is used for
- What you need to know before you use Kevezara
- How to use Kevezara
- Possible side effects
- How to store Kevezara
- Contents of the pack and other information

**1. What Kevezara is and what it is used for**

**What Kevezara is**

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

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 Kevezara contains**

- The active substance is sarilumab. Each pre-filled syringe contains 200 mg sarilumab in 1.14 ml solution.
- The other ingredients are arginine, histidine, polysorbate 20 (E432), sucrose, and water for injections.

**What Kevezara looks like and contents of the pack**

Kevezara 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. Kevezara 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**

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

FRONT FACE

BACK FACE

Top and Bottom

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Packaging Administration				sanofi	
Sanofi Winthrop Industrie - Le Trait - France					
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Manuf. site	Le Trait	mockup		By	L Wasserman
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# Page 2 : VERSO / BACK

4

### Step A: Get ready for an injection

- 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.
- 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.
- 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.
- Lay the syringe on a flat surface and allow it to warm up to room temperature (<math>\leq 25^{\circ}\text{C}</math>) 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.
- 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.
- Prepare the injection site.**
  - Wash your hands.
  - Clean skin with an alcohol wipe.
  - Do not touch the injection site again before the injection.

### Important information

This device is a single-dose pre-filled syringe (called "syringe" in these instructions). It contains 200 mg of Kezvara 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.

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

Kezvara 200 mg solution for injection in pre-filled syringe

Instructions for use

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

- 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.
- Pinch the skin.**
  - Use your thumb and first (index) finger to pinch a fold of skin at the injection site.
- Insert the needle into the fold of skin at roughly a 45° angle.**
- Push the plunger down.**
  - Slowly push the plunger down as far as it will go until the syringe is empty.
- 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.
- 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.

4

Pliage Folding

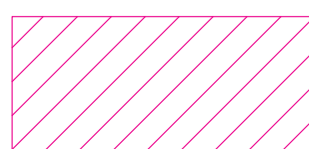
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TRA-P041399-1b

05/09/2024

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**Package leaflet:**  
**Information for the patient**  
**Kezvara®**  
**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**  
**SCNTOFI**

**What Kezvara is used for**  
Kezvara 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. Kezvara 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.
- Kezvara 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). Kezvara can be used alone or together with a medicine called corticosteroid.

**How Kezvara works**

- Kezvara 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 Kezvara**  
**Do not use Kezvara:**

- 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. Kezvara 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 Kezvara, your doctor will check you for TB.
- you have had viral hepatitis or other liver disease. Before you use Kezvara, your doctor will do a blood test to check your liver function.

- you have had diverticulitis (a condition of your stomach) or ulcers in your stomach
  - oral contraceptive or intrauterine devices (IUDs) or other 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 Kezvara if you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, because:

- Do not take Kezvara if you are pregnant unless your doctor specifically recommends it.
- The effects of Kezvara on an unborn baby are not known.
- You and your doctor should decide if you should use Kezvara if you are breast-feeding.

**Driving and using machines**

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

**Children and adolescents**

The Kezvara pre-filled syringe 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. Kezvara is not recommended in children under 2 years of age. Kezvara must not be given to children with pJIA weighing less than 10 kg.

**3. How to use Kezvara**

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.

Kezvara 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 Kezvara. Following these instructions, Kezvara can be self-injected or administered by a care-giver after proper training.

- statins, used to reduce cholesterol levels
  - 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.

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The Kezvara pre-filled syringe 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. Kezvara is not recommended in children under 2 years of age. Kezvara must not be given to children with pJIA weighing less than 10 kg.

**3. How to use Kezvara**

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.

Kezvara 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 Kezvara. Following these instructions, Kezvara 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 syringe exactly as described in the "Instructions for Use".
- If you use more Kezvara than you should**  
If you have used more Kezvara than you should, talk to your doctor, pharmacist or nurse.

**If you miss a dose of Kezvara**

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 Kezvara**

Do not stop using Kezvara 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
- **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
- 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.

**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](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple App Store.

**5. How to store Kezvara**

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 Kezvara 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 Kezvara contains**

- The active substance is sarilumab. Each pre-filled syringe contains 200 mg sarilumab in 1.14 ml solution.
- The other ingredients are arginine, histidine, polysorbate 20 (E432), sucrose, and water for injections.

**What Kezvara looks like and contents of the pack**  
Kezvara 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. Kezvara 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**

Sanofi  
410 Thames Valley Park Drive  
Reading  
Berkshire  
RG6 1PT  
UK  
Tel: 0800 035 2525  
Email:  
[uk-medicalinformation@sanofi.com](mailto:uk-medicalinformation@sanofi.com)

**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 November 2024**



Kezara 200 mg solution for injection in pre-filled syringe  
 sarlumab  
 Instructions for use

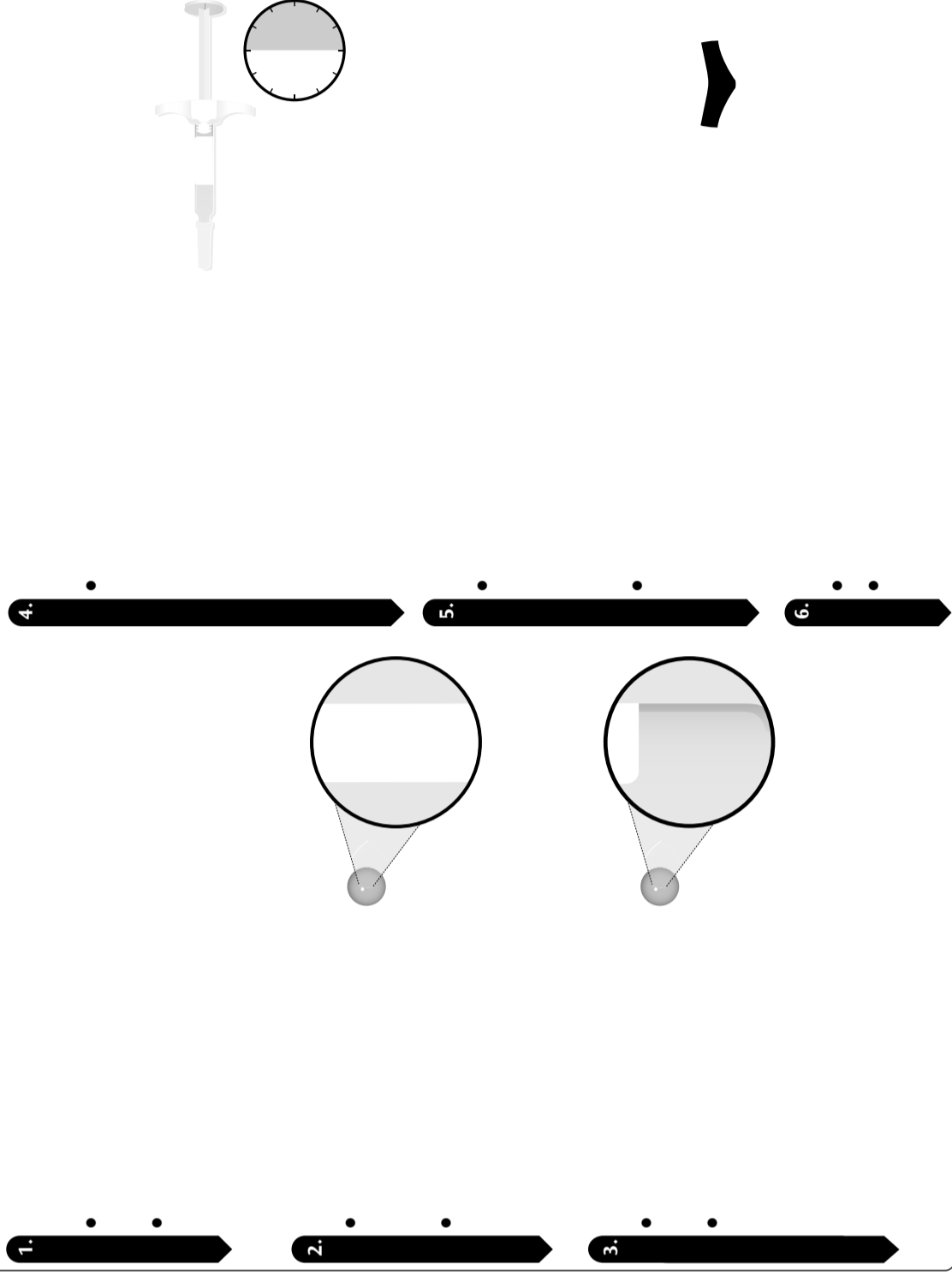


**Important information**

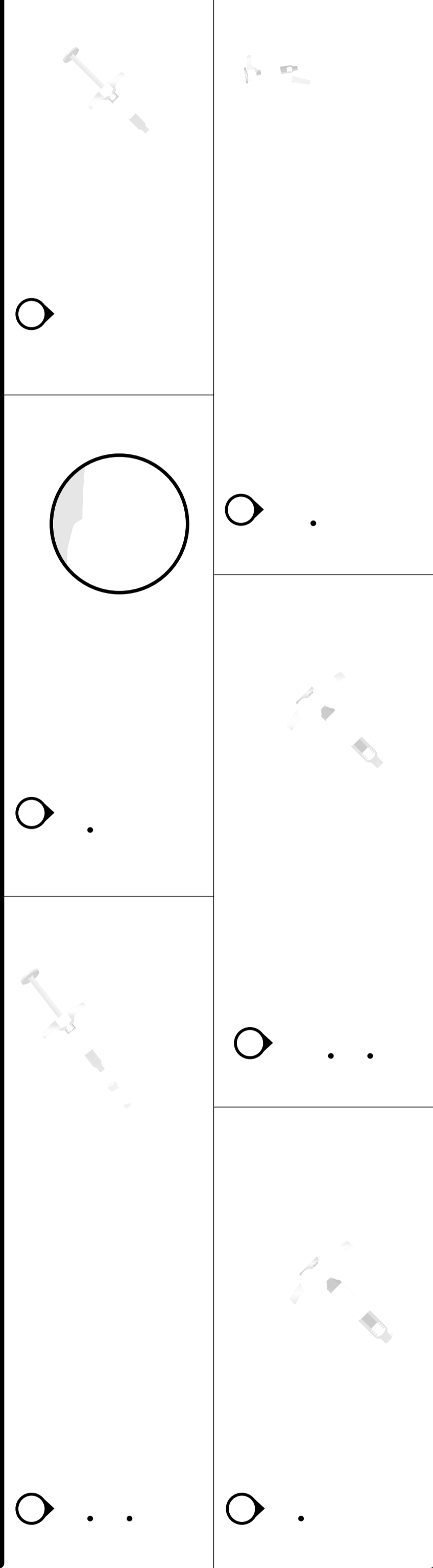
**Do**

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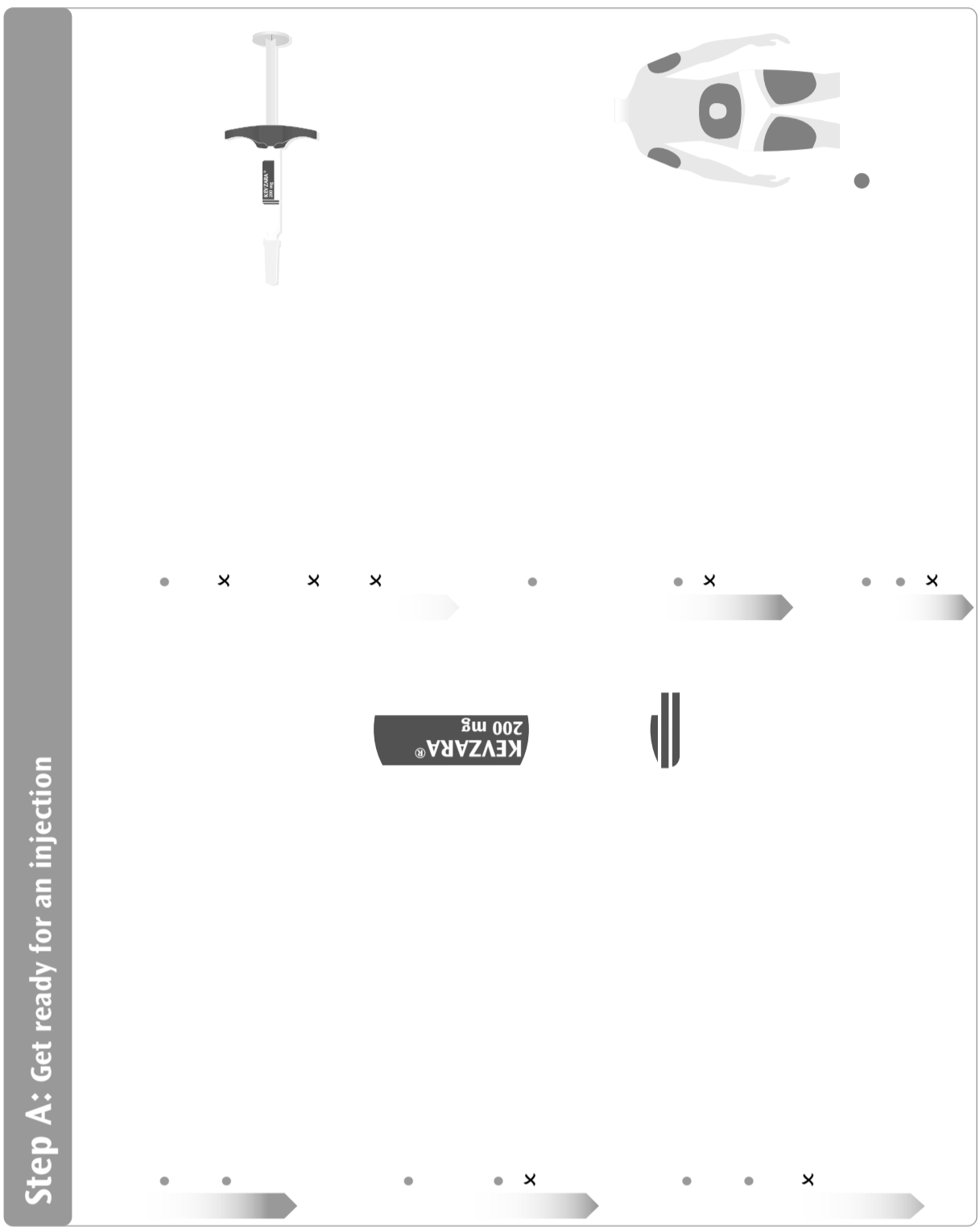
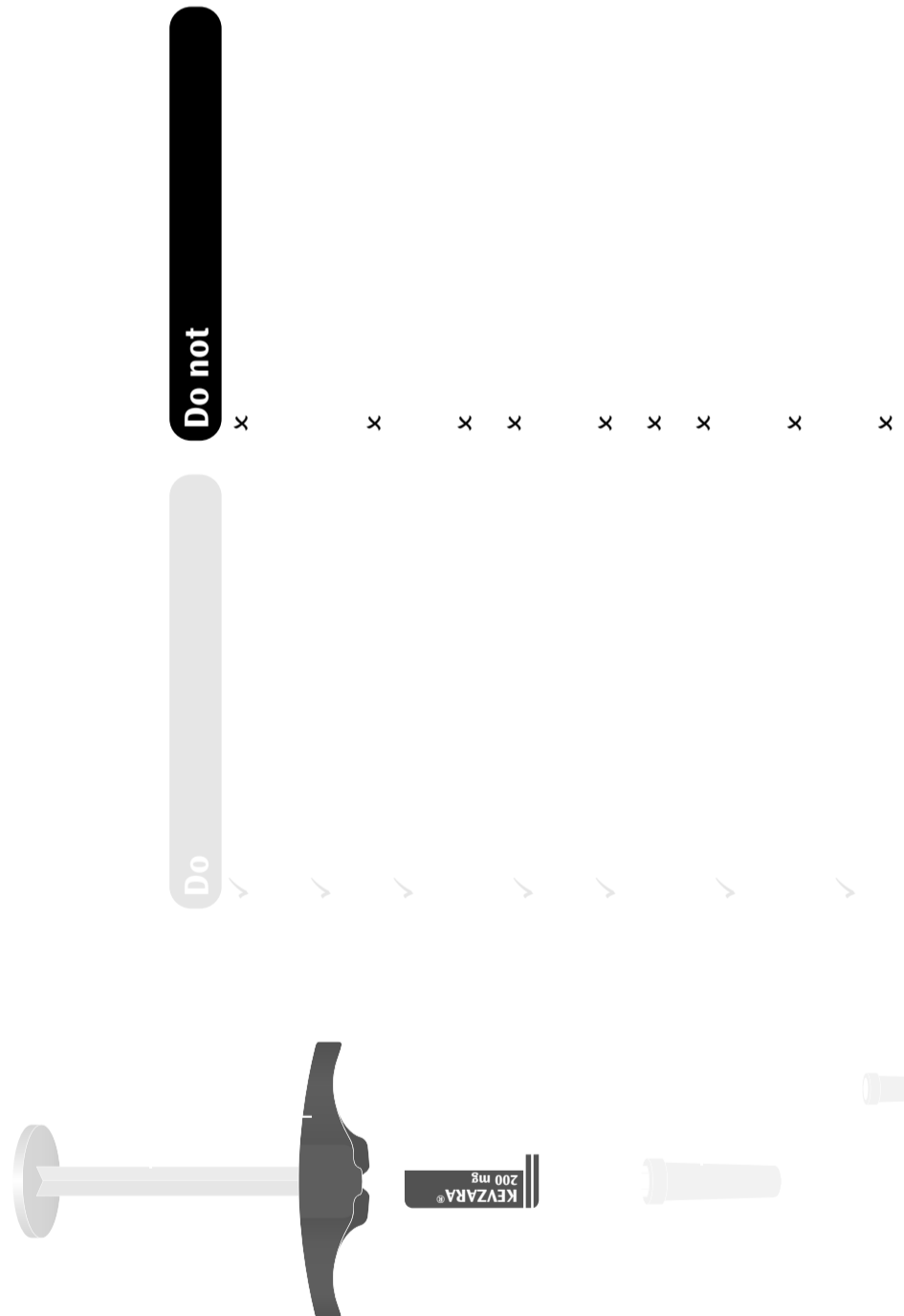
**Step A: Get ready for an injection**



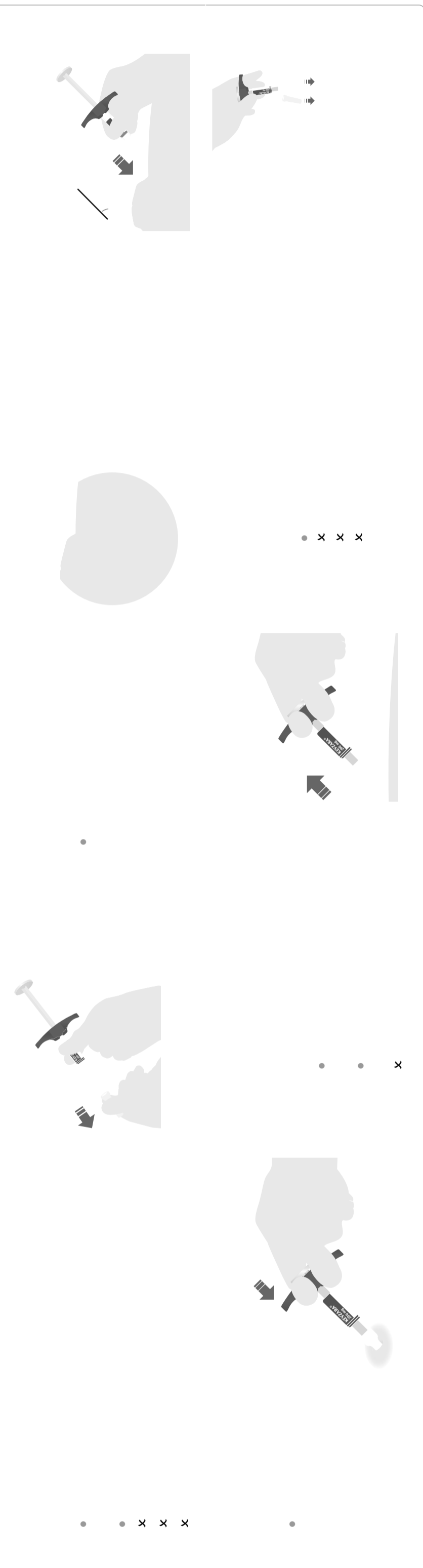
**Step B: Perform the injection – Perform Step B only after completing Step A “Get ready for an injection”**



Kezara 200 mg solution for injection in pre-filled syringe

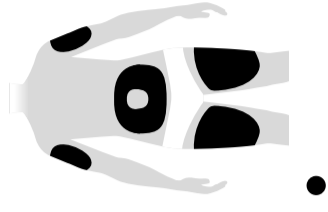


Step B: Perform the injection – Perform Step B only after completing Step A “Get ready for an injection”

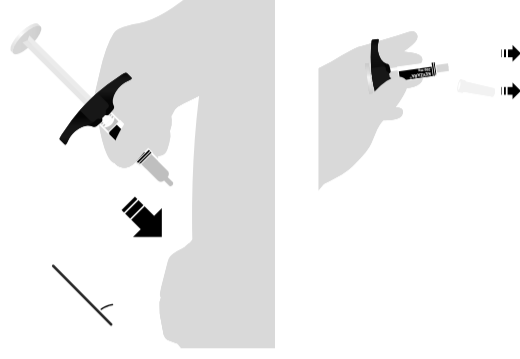




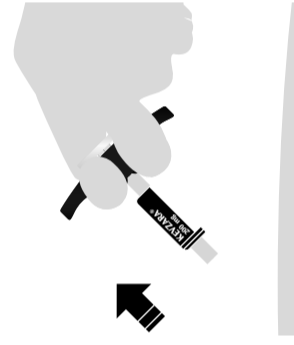
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x x



x x x



x

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Do not

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x

Do

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✓

✓

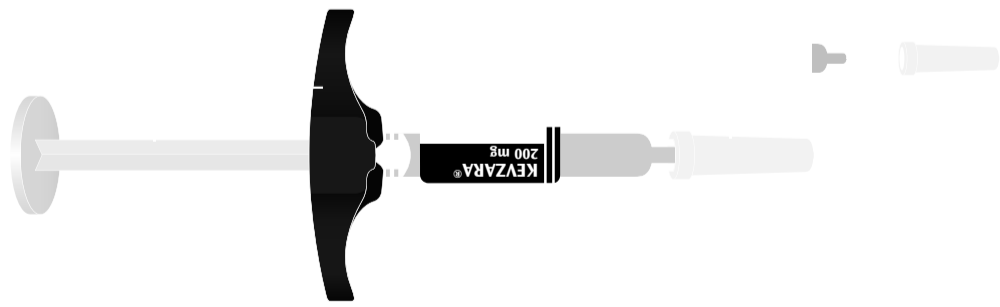
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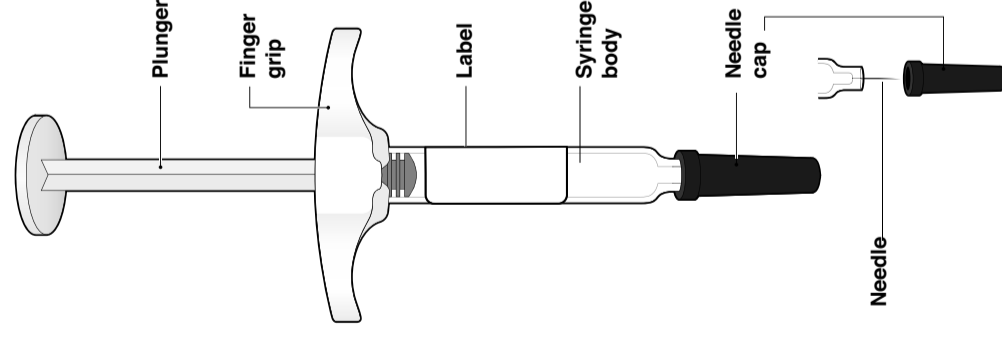
✓



x x x



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



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.

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 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.

**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.

**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.

**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.

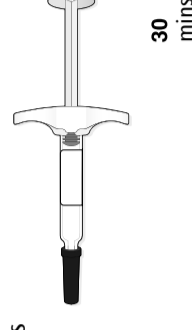
**Lay the syringe on a flat surface and allow it to warm up to room temperature (<math><25^{\circ}\text{C}</math>) for at least 30 minutes.**

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.

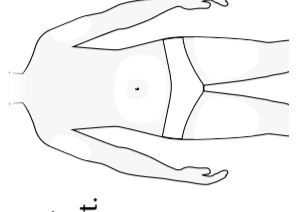


**Select the injection site.**

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

**Prepare the injection site.**

Wash your hands.

Clean skin with an alcohol wipe.

Do not touch the injection site again before the injection.

**1**

**Pull off the needle cap.**

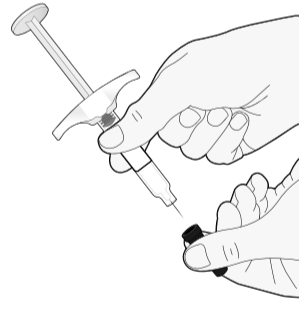
Hold the syringe in the middle of the syringe body with the needle pointing away from you.

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.**

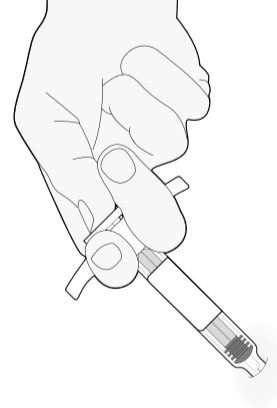
Use your thumb and first (index) finger to pinch a fold of skin at the injection site.



**4**

**Push the plunger down.**

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



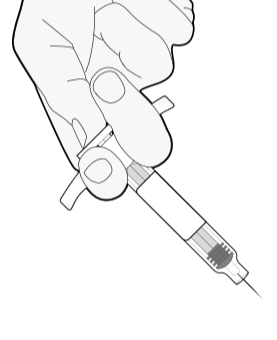
**5**

**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**

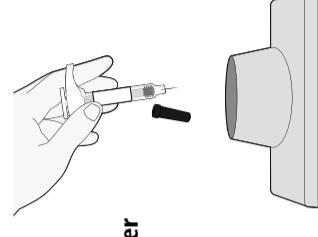
**Put your used syringe and the cap into a puncture-resistant container right away after use.**

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.



**3**

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

