

## READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

### PART III: PATIENT MEDICATION INFORMATION

#### **KEVZARA® sarilumab injection**

Read this carefully before you start using **KEVZARA** and each time you get a refill. This leaflet is a summary and will not tell you everything about this medication. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **KEVZARA**.

#### **Serious Warnings and Precautions**

##### **Risk of 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 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.

#### **What is KEVZARA used for?**

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 Anti-Rheumatic Drug (DMARD) has been used and did not work well or caused side effects that led you to stop taking the medicine.

#### **How does KEVZARA work?**

KEVZARA (also known as sarilumab) is an injectable prescription medicine which blocks a protein, Interleukin-6 (IL-6), that is found at high levels in people diagnosed with RA. IL-6 plays a major role in the signs and symptoms of rheumatoid arthritis (RA). KEVZARA is a medicine that helps keep the immune system from attacking healthy tissues in the body. A normal immune system leaves healthy body tissues alone. In people with rheumatoid arthritis, the immune system attacks normal body tissues causing damage and inflammation, especially in the tissues of your joints and possibly other organs (such as heart, liver and bones). KEVZARA interferes with an important step in this attack (blocks a cytokine called IL-6 which is found at high levels in the joints affected by rheumatoid arthritis).

#### **What are the ingredients in KEVZARA?**

Medicinal ingredients: sarilumab

Non-medicinal ingredients: arginine, histidine, polysorbate 20, sucrose, water for injection.

The components of the prefilled syringe are latex free (including the needle cap).

**KEVZARA comes in the following dosage forms:**

- Pre-filled syringes, each containing 150 mg of KEVZARA for subcutaneous injection
- Pre-filled syringes, each containing 200 mg of KEVZARA for subcutaneous injection
- Pre-filled pen, each containing 150 mg of KEVZARA for subcutaneous injection
- Pre-filled pen, each containing 200 mg of KEVZARA for subcutaneous injection

**Do not use KEVZARA if:**

- you are allergic to sarilumab or any of the ingredients in KEVZARA (see section titled ‘What are the ingredients in KEVZARA?’).

**To help avoid side effects and ensure proper use, talk to your healthcare professional before you use KEVZARA. Talk about any health conditions or problems you may have, including if you:**

- have had an allergic reaction to KEVZARA
- think you have an infection or have symptoms of an infection, with or without a fever, such as sweating or chills, muscle aches, cough, shortness of breath, blood in 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, feeling very tired
- are being treated for an infection, get a lot of infections or have repeated infections
- have diabetes, HIV, or a weak immune system. People with these conditions have a higher chance of getting infections.
- have tuberculosis (TB), or have been in close contact with someone with TB
- live or have lived, or have traveled to certain parts of the country where there is an increased chance for getting certain kinds of fungal infections (histoplasmosis, coccidiomycosis, or blastomycosis). These infections may happen more often or worsen if you use KEVZARA. Ask your healthcare provider, if you do not know if you have lived in an area where these infections are common.
- have or have had hepatitis B or hepatitis C or other liver problems
- have or have had diverticulitis (inflammation in parts of the large intestine) or ulcers in your stomach or intestines. Some people using KEVZARA get tears (perforations) in their stomach or intestine. This happens most often in people who also take medicines such as nonsteroidal anti-inflammatory drugs (NSAIDs), corticosteroids, or methotrexate.
- have or have had any type of cancer
- have recently received or are scheduled to receive a vaccine
- have a surgery or a medical procedure planned
- have any other medical conditions
- plan to become pregnant or are pregnant. It is not known if KEVZARA will harm your unborn baby.

Pregnancy Registry: Sanofi has a registry for pregnant women who use KEVZARA to gather information about the outcomes of pregnancies. If you are pregnant or become pregnant while using KEVZARA, talk to your healthcare provider about how you can join this pregnancy registry or call 1-877-311-8972 to enroll.

- plan to breast-feed or are breast-feeding. You and your healthcare provider should decide if you will use KEVZARA or breast-feed. You should not do both.

After starting KEVZARA, call your healthcare provider right away if you have any symptoms of an infection. KEVZARA may make you more likely to get an infection or worsen any infection you have.

Tell your healthcare provider right away if you have fever and stomach-area pain that does not go away.

KEVZARA may decrease the activity of your immune system. Medicines that affect the immune system may increase your risk of certain cancers. Tell your healthcare provider if you have ever had any type of cancer.

**Other warnings you should know about:**

- Changes to laboratory tests:

Your healthcare provider should do blood tests before you start KEVZARA, 4 to 8 weeks after starting KEVZARA, and then approximately every 3 months during treatment to check for the following:

- low neutrophil count. Neutrophils are white blood cells that help the body fight off bacterial infections.
- low platelet count. Platelets are blood cells that help with blood clotting and stop bleeding.
- increase in certain liver function tests.

Your healthcare provider may not prescribe KEVZARA if your neutrophil or platelet counts are too low or your liver function tests are too high.

Your healthcare provider may interrupt your KEVZARA treatment for a period of time and/or decrease your dose of medicine if needed because of changes in these blood test results.

You may also have changes in other laboratory tests, such as your blood cholesterol levels. Your healthcare provider may do blood tests to check your cholesterol levels while you are taking KEVZARA.

- Tears (perforations) 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 taking KEVZARA get tears in their stomach or intestine. This happens most often in people who also take medicines such as 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 decrease the activity of your immune system. Medicines that affect the immune system may increase your risk of certain cancers. Tell your healthcare provider if you have ever had any type of cancer.

See “What are the possible side effects from using KEVZARA?” for more information about side effects.

**Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.**

**The following may interact with KEVZARA:**

- any other medicines to treat your RA. You should not take rituximab (Rituxan<sup>®</sup>), etanercept (Enbrel<sup>®</sup>), infliximab (Remicade<sup>®</sup>), anakinra (Kineret<sup>®</sup>), adalimumab (Humira<sup>®</sup>), abatacept (Orencia<sup>®</sup>), certolizumab (Cimzia<sup>®</sup>), golimumab (Simponi<sup>®</sup>), tocilizumab (Actemra<sup>®</sup>), or tofacitinib (Xeljanz<sup>®</sup>) while you are taking KEVZARA. Using KEVZARA with these medicines may increase your risk of infection.
- medicines that affect the way your liver works. Ask your healthcare provider if you are not sure if your medicine is one of these.

**How to take KEVZARA:**

- **See the detailed Instructions for Use that comes with this Patient Medication Information for instructions about the right way to prepare and give your KEVZARA injections.**
- KEVZARA is given as an injection under the skin (subcutaneous injection).
- KEVZARA comes as a single-dose (1 time) pre-filled syringe or pen. Your healthcare provider will prescribe the dose that is best for you.
- If your healthcare provider decides that you or a caregiver can give the injections of KEVZARA, 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.

**Usual dose:**

KEVZARA should be injected every two weeks. The usual recommended dose is 200mg. Your healthcare provider may interrupt your KEVZARA treatment for a period of time and/or decrease your dose of KEVZARA to 150mg every two weeks.

**Overdose:**

If you think you have used too much KEVZARA, contact your healthcare professional, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

**Missed Dose:**

If you miss a dose of KEVZARA and it has been 3 days or less since the missed dose, take your

dose as soon as you can. Then take your next dose at your regularly scheduled time. If it has been 4 days or more, or you are unsure when to take your next dose of KEVZARA, call your healthcare provider for instructions.

**What are possible side effects from using KEVZARA?**

Like all medicines, KEVZARA, can cause unwanted effects. These are not all the possible side effects you may feel when using KEVZARA. If you experience any side effects not listed here, contact your healthcare professional.

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

<b>Serious side effects and what to do about them</b>			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
<b>COMMON</b> Upper respiratory tract infections such as coughs and cold, sore throat, runny nose, nasal congestion, sneezing, coughing	<b>X</b>		
Urinary tract infection: burning when you urinate or urinating more often than normal		<b>X</b>	

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to your healthcare professional.

### **Reporting Side Effects**

You can help improve the safe use of health products for Canadians by reporting serious and unexpected side effects to Health Canada. Your report may help to identify new side effects and change the product safety information.

#### **3 ways to report:**

- Report online at [www.healthcanada.gc.ca/medeffect](http://www.healthcanada.gc.ca/medeffect)
- Call toll-free at 1-866-234-2345
- Complete a Canada Vigilance Reporting Form and:
  - Fax toll-free to 1-866-678-6789 (toll-free), or
  - Mail to: Canada Vigilance Program  
Health Canada, Postal Locator 1908C  
Ottawa, ON  
K1A 0K9

*NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.*

### **Storage:**

Keep out of reach and sight of children.

Do not use this medicine after the expiry date which is stated on the label and carton.

Store in a refrigerator (2°C - 8°C). Do not freeze.

Keep the syringe or pen in the outer carton in order to protect from light.

Do not expose to intense heat.

The pre-filled syringe should be left at room temperature for 30 minutes prior to use. The pre-filled pen should be left at room temperature for 60 minutes prior to use. The syringe or pen should be used within 14 days after being taken out of the refrigerator. A puncture-resistant container for disposal of syringes or pens should be used and should be kept out of the reach of children. Instruct patients or caregivers in the technique as well as proper pre-filled syringe or pre-filled pen disposal, and caution against reuse of these items.

### **If you want more information about KEVZARA:**

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the [Health Canada website](#); the manufacturer's website [sanofigenzyme.ca](http://sanofigenzyme.ca), or by calling 1-800-589-6215.

This leaflet was prepared by Sanofi Canada Inc.

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Last Revised: August 8, 2019

## INSTRUCTIONS FOR USE

### KEVZARA® (sarilumab)

#### Injection, for Subcutaneous Injection Single-Dose Pre-Filled Syringe

#### Important information

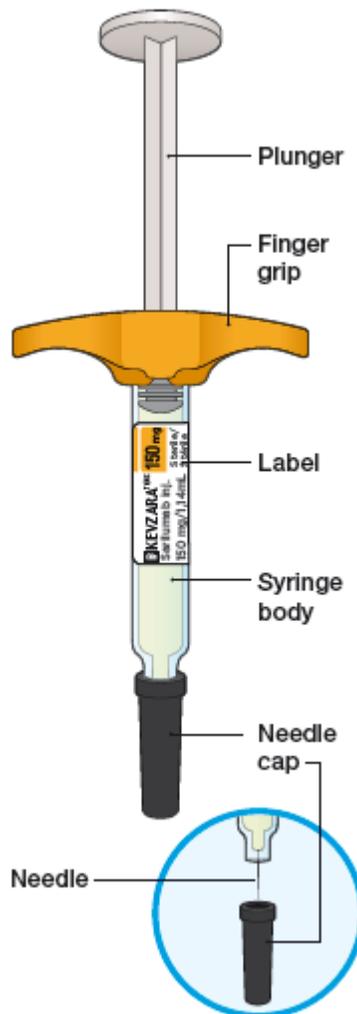
This device is a single-dose pre-filled syringe (called “syringe” in these instructions). It contains KEVZARA for injection under the skin (subcutaneous injection) once every two weeks.

Ask your healthcare provider to show you the right way to use the syringe before you inject for the first time.

<b>Do</b>	<b>Do not</b>
<ul style="list-style-type: none"><li>✓ Read all of the instructions carefully before using a syringe.</li><li>✓ Keep unused syringes in the original carton and store in the refrigerator between 2°C and 8°C (36°F and 46°F).</li><li>✓ Keep the carton in an insulated bag with an ice pack when traveling.</li><li>✓ Let the syringe warm up at room temperature for at least 30 minutes before using.</li><li>✓ Use the syringe within 14 days after taking it out of the refrigerator or insulated bag.</li><li>✓ Keep the syringe out of the reach of children.</li></ul>	<ul style="list-style-type: none"><li>✗ Do not use the syringe if it has been damaged or the needle cap is missing or not attached.</li><li>✗ Do not remove the needle cap until just before you are ready to inject.</li><li>✗ Do not touch the needle.</li><li>✗ Do not re-use or try to put the cap back on the syringe.</li><li>✗ Do not freeze or heat up the syringe.</li><li>✗ Do not expose the syringe to direct sunlight.</li><li>✗ Do not inject through your clothes.</li></ul>

Keep these instructions for future use.

If you have any further questions, ask your healthcare provider or call 1-800-589-6215.



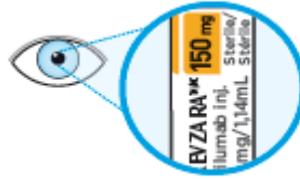
### Step A: Get ready for an injection

#### 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.

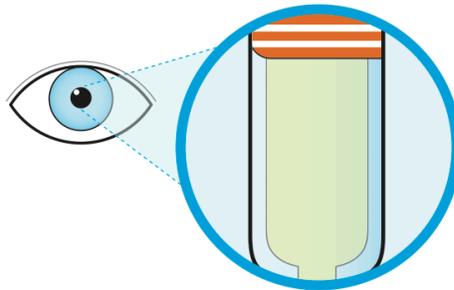
## 2. Look at the label.

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



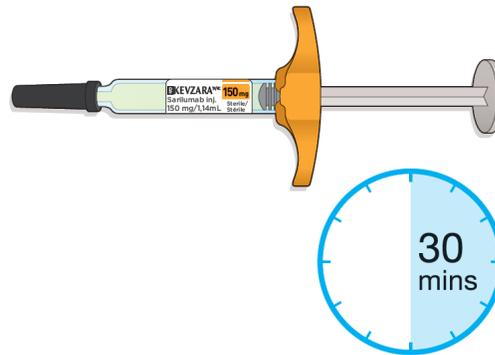
## 3. Look at the medicine.

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



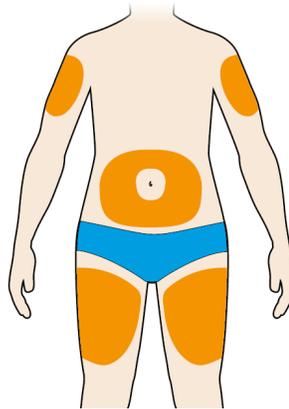
## 4. Lay the syringe on a flat surface and allow it to warm up at room temperature for at least 30 minutes.

- 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.



## 5. Select the injection site.

- You can inject into your thigh or belly (abdomen) – except for the 5 cm (2 inches) around your belly button (navel). If somebody else gives you the injection, you can also use 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

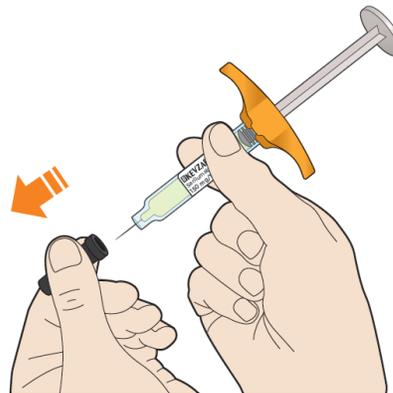
## 6. Prepare the injection site.

- 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”

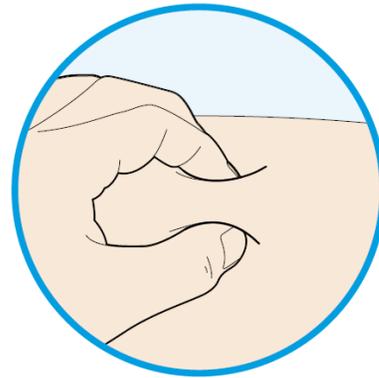
### 1. Pull off the needle cap.

- 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.

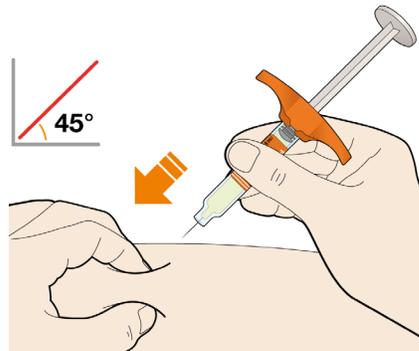


## 2. Pinch the skin.

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

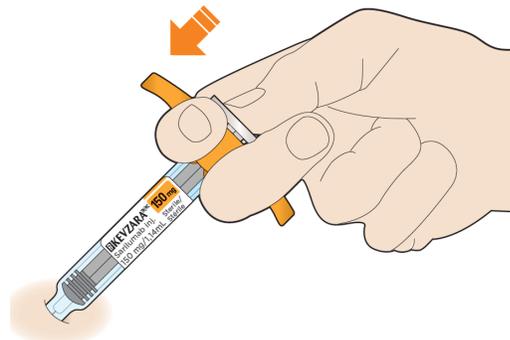


## 3. Insert the needle into the fold of skin at roughly a 45° angle.



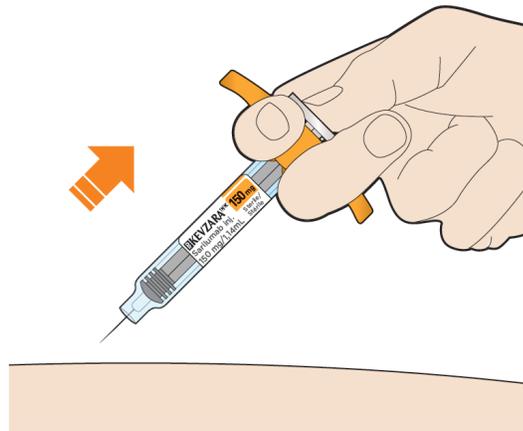
## 4. Push the plunger down.

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



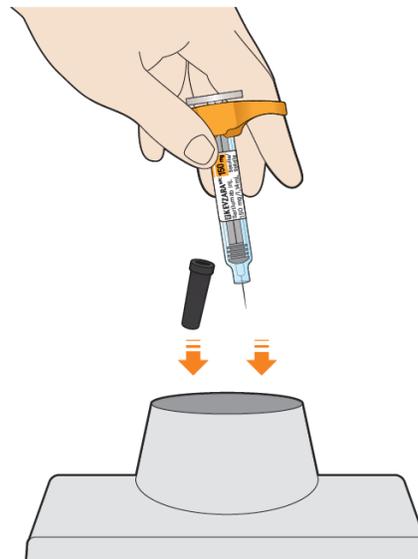
**5. Before you remove the needle, check that the syringe is empty.**

- 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.**

- Always keep the container out of reach of children.
- ✗ **Do not** put the needle cap back on.
- ✗ **Do not** throw away the used syringe in the household trash.



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## INSTRUCTIONS FOR USE

### KEVZARA® (sarilumab)

#### Injection, for Subcutaneous Injection Single-Dose Pre-Filled Pen

#### Important information

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

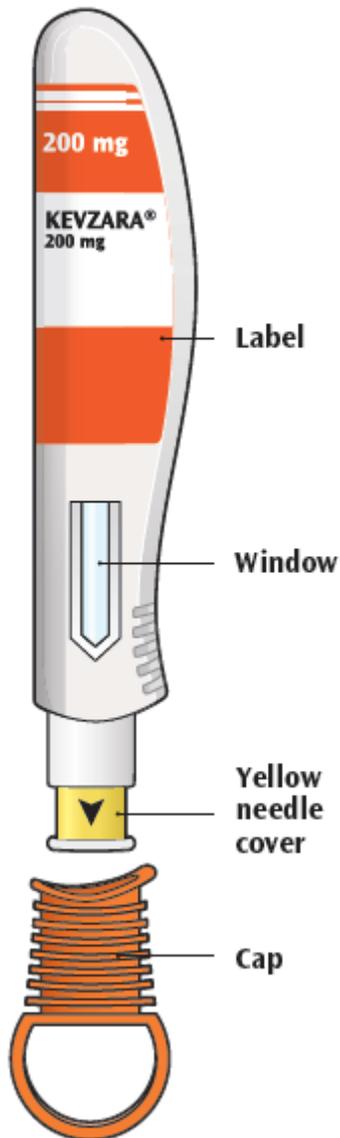
Ask your healthcare provider to show you the right way to use the pen before you inject for the first time.

<b>Do</b>	<b>Do not</b>
<ul style="list-style-type: none"><li>✓ Read all of the instructions carefully before using a pen.</li><li>✓ Keep unused pens in the original carton and store in the refrigerator between 2°C and 8°C (36°F and 46°F).</li><li>✓ Keep the carton in an insulated bag with an ice pack when traveling.</li><li>✓ Let the pen warm up at room temperature for at least 60 minutes before using.</li><li>✓ Use the pen within 14 days after taking it out of the refrigerator or insulated bag.</li><li>✓ Keep the pen out of the reach of children.</li></ul>	<ul style="list-style-type: none"><li>✗ Do not use the pen if it has been damaged or the needle cap is missing or not attached.</li><li>✗ Do not remove the needle cap until just before you are ready to inject.</li><li>✗ Do not press or touch the yellow needle cover with your fingers.</li><li>✗ Do not try to put the cap back on a pen.</li><li>✗ Do not re-use the pen.</li><li>✗ Do not freeze or heat up the pen.</li><li>✗ Once removed from the refrigerator, do not store the pen above 25°C</li><li>✗ Do not expose the pen to direct sunlight.</li><li>✗ Do not inject through your clothes.</li></ul>

Keep these instructions for future use.

If you have any further questions, ask your healthcare provider or call 1-800-589-6215.

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



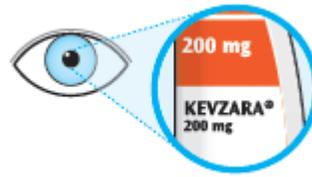
### Step A: Get ready for an injection

#### 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.

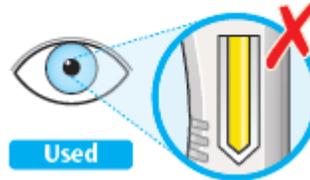
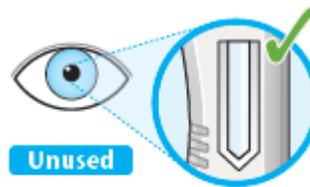
## 2. Look at the label.

- Check that you have the correct medicine and the correct dose.
- Check the expiration date (EXP), this is shown on the side of the pens.
- ✗ **Do not** use the syringe if the date has passed.



## 3. Look at the medicine.

- Check if 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.



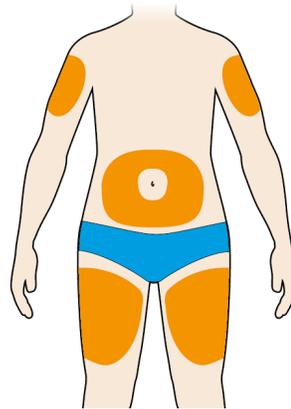
## 4. Lay the pen on a flat surface and allow it to warm up at room temperature for at least 60 minutes.

- 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 (2 inches) around your belly button (navel). If somebody else gives you the injection, you can also use 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

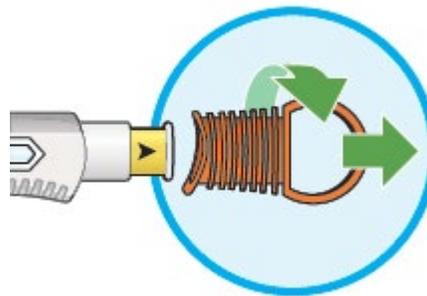
### 6. Prepare the injection site.

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

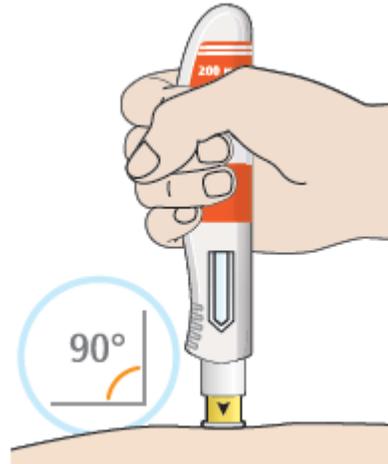
### Step B: Perform the injection – Perform Step B only after completing Step A “Get ready for an injection”

#### 1. 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.

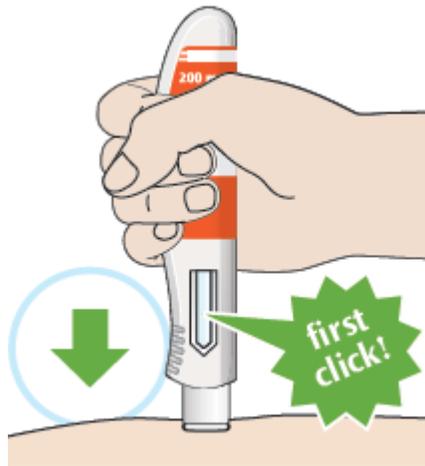


- 2. Put the yellow needle cover on your skin at roughly a 90° angle.**
- Make sure you can see the window.



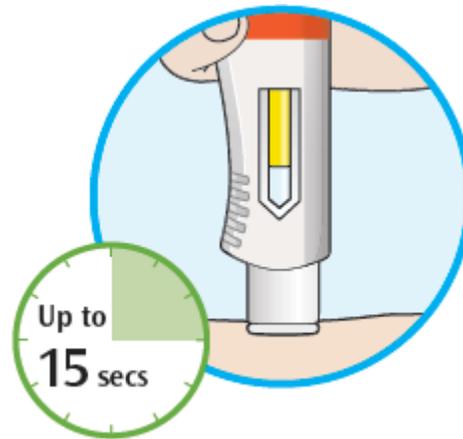
**3. Press down and hold the pen firmly against your skin.**

- There will be a “click” when the injection starts.



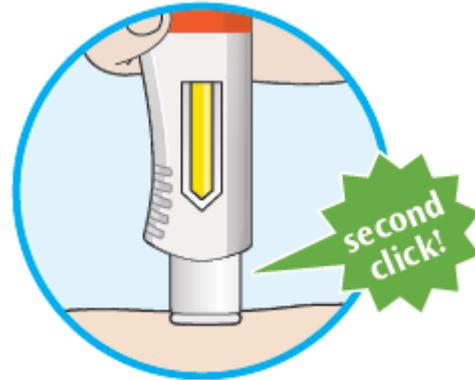
**4. Keep holding the pen firmly against your skin.**

- The window will start to turn yellow.
- The injection can take up to 15 seconds.



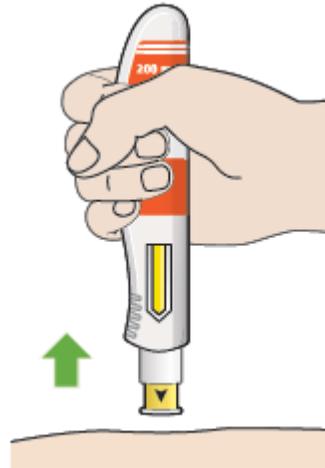
**5. There will be a second click. Check to see if the entire window has turned yellow before you remove the pen.**

- If you do not hear a 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



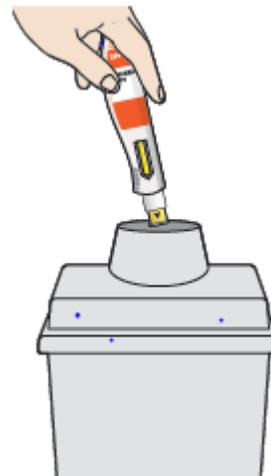
## 6. Pull the pen away from your skin.

- 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.

- Put your used pen and the cap in 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 away the used pens in the household waste.
- ✗ **Do not** recycle your used puncture-resistant container.
- ✗ **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.



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