

Patient Information
Kineret® (KIN-eh-ret)
(anakinra)
injection, for subcutaneous use

What is Kineret?

Kineret is a prescription medicine called an interleukin-1 receptor antagonist (IL-1Ra) used to:

- Reduce the signs and symptoms and slow the damage of moderate to severe active rheumatoid arthritis (RA) in people age 18 years and older when 1 or more other medicines for RA have not worked.
- Treat people with a form of Cryopyrin-Associated Periodic Syndromes (CAPS) called Neonatal-Onset Multisystem Inflammatory Disease (NOMID).
- Treat people with Deficiency of Interleukin-1 Receptor Antagonist (DIRA).

Kineret is not for children with Juvenile Rheumatoid Arthritis.

Do not use Kineret if you are allergic to:

- proteins made from bacteria called E.Coli. Ask your healthcare provider if you are not sure.
- anakinra or any of the ingredients in Kineret. See the end of this leaflet for a complete list of ingredients in Kineret.

Before you use Kineret, tell your healthcare provider about all of your medical conditions, including if you:

- have an infection, a history of infections that keep coming back or other problems that can increase your risk of infections.
- are scheduled to receive any vaccines. People using Kineret should not receive live vaccines.
- have kidney problems.
- are pregnant or plan to become pregnant. It is not known if Kineret will harm your unborn baby.
- are breastfeeding or plan to breastfeed. It is not known if Kineret passes into your breast milk. You and your healthcare provider should decide if you will use Kineret or breastfeed.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

Kineret and other medicines may affect each other and cause serious side effects.

Especially, tell your healthcare provider if you take certain other medicines that:

- affect your immune system called Tumor Necrosis Factor (TNF) blockers

Ask your healthcare provider for a list of these medicines if you are not sure.

Know the medicines you take. Keep a list of your medicines and show it to your healthcare provider and pharmacist when you get a new prescription.

How should I use Kineret?

- Read the **Instructions for Use** at the end of this Patient Information for information about the right way to use Kineret.
- Use Kineret exactly as your healthcare provider tells you to.
- You may not have to use all of the liquid medicine in the prefilled syringe. Your healthcare provider will show you how to find the correct dose of Kineret for you or your child.
- Kineret is given by injection under your skin.
- Inject Kineret at about the same time each day.
- If you have a kidney problem your healthcare provider may need to change how often you use your Kineret injections.
- If you miss a dose of Kineret, talk to your healthcare provider to find out when you should use your next injection.

What are the possible side effects of Kineret?

Kineret may cause serious side effects, including:

- **serious infections.** Kineret may lower your ability to fight infections. During your treatment with Kineret, call your healthcare provider right away if you:
 - get an infection.
 - have any sign of an infection including a fever or chills.
 - have any open sores on your body.You may get an infection if you receive live vaccines while you use Kineret. You should not receive live vaccines while you use Kineret.
- **allergic reactions.** Stop using Kineret and call your healthcare provider or get emergency help right away if you have any of these symptoms of an allergic reaction:
 - swelling of your face, lips, mouth or tongue
 - trouble breathing
 - wheezing
 - severe itching
 - skin rash, hives, redness, or swelling outside of the injection site area
 - dizziness or fainting
 - fast heartbeat or pounding in your chest (tachycardia)
 - sweating

People with DIRA may have an increased risk of allergic reactions, especially in the first several weeks.

- **decreased ability of your body to fight infections (immunosuppression).** It is not known if treatment with medicines that cause immunosuppression, like Kineret, affect your risk of getting cancer.
- **low white blood cell count (neutropenia).** Kineret may cause you to have a lower number of certain white blood cells (neutrophils). Neutrophils are important in fighting infections. You should have blood tests before starting treatment with Kineret, then monthly for 3 months. After the first 3 months you should have your blood tested every 3 months for up to 1 year.

The most common side effects of Kineret include:

- injection site skin reactions. The symptoms of injection site skin reactions may include:
 - redness
 - swelling
 - bruising
 - itching
 - stinging

Most injection site reactions are mild, happen early during treatment, and last about 14 to 28 days. Injection site reactions have been observed less frequently in people with NOMID.

- rheumatoid arthritis (RA) gets worse even with treatment, if you already have RA
- headache
- nausea and vomiting
- diarrhea
- joint pain
- fever
- feeling like you have the flu
- sore throat or runny nose
- sinus infection
- pain in your stomach area

Tell your healthcare provider if you have any side effect that bothers you or that does not go away.

These are not all of the possible side effects of Kineret. For more information, ask your healthcare provider or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store KINERET?

- Store Kineret in the refrigerator between 36°F to 46°F (2°C to 8°C).
- **Do not freeze or shake Kineret.**
- Keep Kineret in its original carton and away from light.

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

General information about the safe and effective use of KINERET.

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information Leaflet. Do not use Kineret for a condition for which it was not prescribed. Do not give Kineret to other people, even if they have the same symptoms that you have. It may harm them. You can ask your pharmacist or healthcare provider for information about Kineret that is written for health professionals.

What are the ingredients in KINERET?

Active ingredient: anakinra

Inactive ingredients: anhydrous citric acid, disodium EDTA, polysorbate 80, and sodium chloride in Water for Injection, USP

Manufactured by:
Swedish Orphan Biovitrum AB (publ)
SE-112 76 Stockholm, Sweden
License No. 1859

© Swedish Orphan Biovitrum AB (publ). All rights reserved.

For more information, go to www.kineretrx.com or call 1-866-547-0644.

This Patient Information has been approved by the U.S. Food and Drug Administration

Revised: December 2020

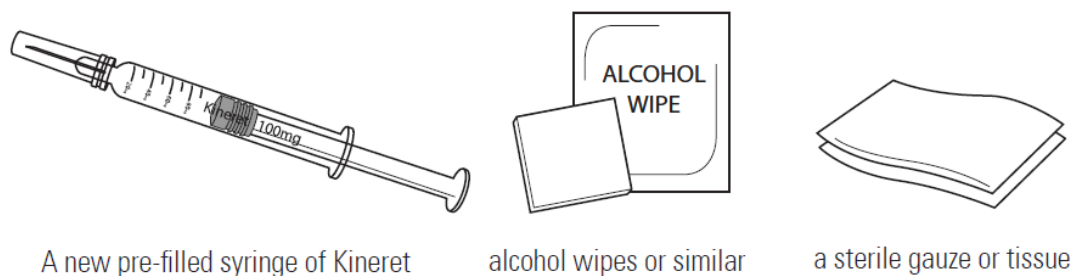
Instructions for Use
Kineret® (KIN-eh-ret)
(anakinra)
injection, for subcutaneous use

Read this Instructions for Use before you start using Kineret and each time you get a refill. There may be new information. This information does not take the place of talking to your healthcare provider about your medical condition or your treatment.

Supplies you will need to give your Kineret injection: See Figure A.

- 1 Kineret prefilled syringe
- 1 alcohol wipe
- 1 dry sterile gauze or tissue
- 1 puncture-resistant sharps disposal container

EQUIPMENT: To give yourself a subcutaneous injection you will need:



A new pre-filled syringe of Kineret

alcohol wipes or similar

a sterile gauze or tissue

Figure A

Each Kineret dose comes in a prefilled glass syringe. There are 7 syringes in each new Kineret box, 1 for each day of the week. Use a new Kineret syringe each day. Use the Kineret prefilled syringe that matches the day of the week until all 7 syringes are used.

Setting up for your injection:

Step 1. Take the carton containing the prefilled syringes of Kineret out of the refrigerator. Remove the prefilled syringe from the box that matches the day of the week. Put the carton containing the remaining prefilled syringes back in the refrigerator.

Step 2. Find a clean, flat work surface, such as a table.

Step 3. Check the expiration date (EXP) on the syringe label. **See Figure B.**

If the expiration date has passed, **do not** use the syringe. Call your pharmacist or call 1-866-773-5274 for assistance.

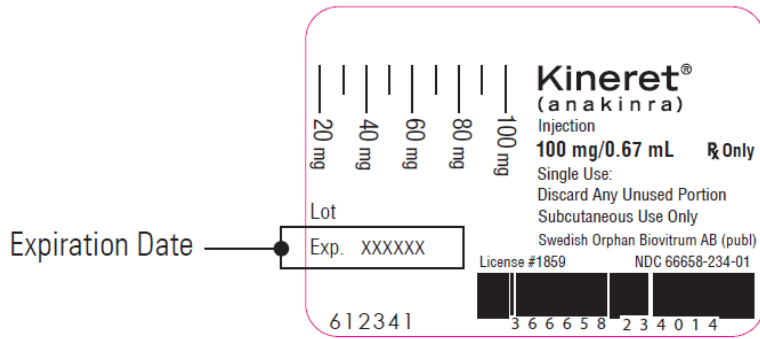


Figure B

Step 4. Take the Kineret prefilled syringe out of the refrigerator and leave it in room temperature for 30 minutes before your injection.

Make sure the liquid medicine in the prefilled syringe is clear and colorless. It is normal to see a small amount of tiny particles that are white, or that you can see through. **Do not** inject the medicine if it is cloudy or discolored, or has large or colored particles. Call your healthcare provider or pharmacist if you have any questions about your Kineret prefilled syringe.

Step 5. Gather all the supplies you will need for your injection.

Step 6. Wash your hands with soap and warm water.

Preparing your correct dose of Kineret:

- **Preparing a 100mg dose of Kineret:**
 - Hold the syringe barrel and pull the cover straight off the needle. **See Figure C.** Do not touch the needle or push the plunger. Throw away the needle cover.

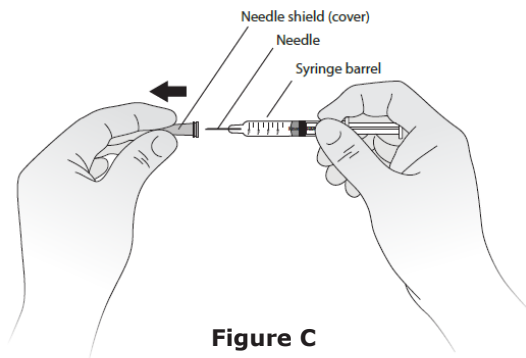


Figure C

- You may notice small air bubbles in the prefilled syringe. You do not have to remove the air bubbles before injecting. Injecting the solution with the air bubbles is harmless.
- Carefully place the barrel of the syringe on the table until you are ready to inject. **Do not let the needle touch the table. Do not recap the needle.**

- **How to prepare a dose of Kineret less than 100 mg:**

- Hold the syringe in 1 hand with the needle pointing straight upwards. **See Figure D.** Put your thumb on the plunger rod and push slowly until you see a tiny liquid drop at the tip of the needle.

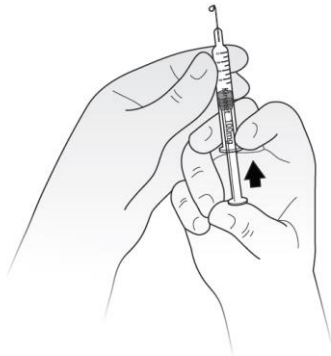


Figure D

- Turn the syringe so that the needle is now pointing downwards. Place a sterile gauze or tissue on a flat surface and hold the syringe above it with the needle pointing towards the gauze or tissue. **See Figure E.** Make sure the needle does not touch the gauze or tissue.

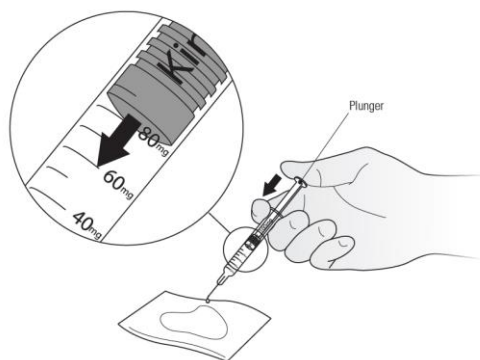


Figure E

- Put your thumb on the plunger rod and push slowly until you can see that the top of the plunger has reached the correct number for your Kineret dose your healthcare provider has prescribed. The liquid that was pushed out of the needle will be absorbed by the gauze or tissue. **See Figure E.**
- If you are not able to select the correct dose of Kineret, throw away the syringe and use a new one.
- Carefully place the barrel of the syringe on the table until you are ready to inject. **Do not let the needle touch the table. Do not recap the needle.**

Selecting and preparing the injection site:

Step 7. Choose an injection site. **See Figure F.**

Recommended injection sites for adults and children include:

- outer area of the upper arms
- abdomen (except the 2-inch area around the belly button)
- front of the middle thighs
- upper outer areas of the buttocks

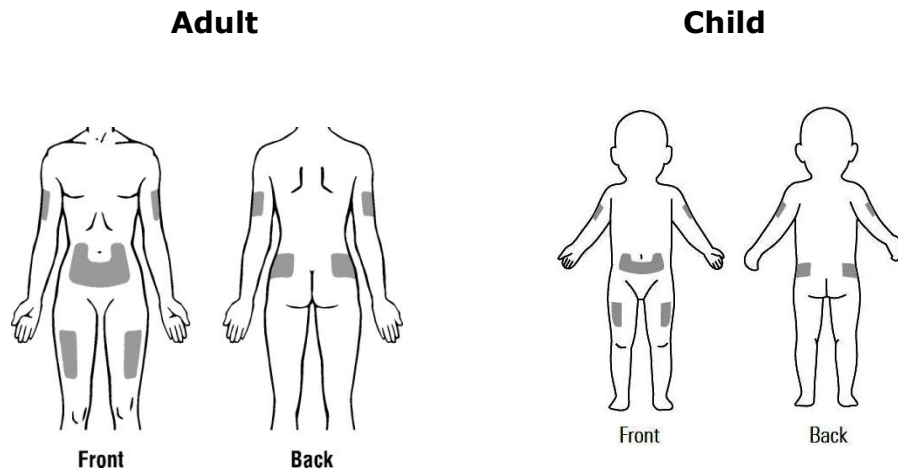


Figure F

Choose a new site each time you use Kineret. Choosing a new site may help avoid soreness at 1 site. Do not inject Kineret into an area of skin that is tender, red, bruised, swollen, or hard. Avoid areas of skin with scars or stretch marks. Do not inject Kineret close to a vein that you can see under the surface of your skin.

- Clean your injection site with an alcohol swab. Let the area dry completely.

Giving your injection:

Step 8. Gently pinch a fold of skin at the cleaned injection site.

Step 9. With your other hand, hold the syringe like a pencil at a 45 degree to 90 degree angle to the skin. With a quick, dart-like motion insert the needle into the skin. **See Figure G.**

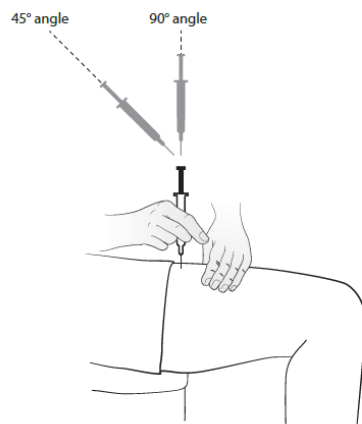


Figure G

Step 10. After the needle is inserted into the skin, slowly push the plunger all the way down to inject Kineret. **See Figure H.**

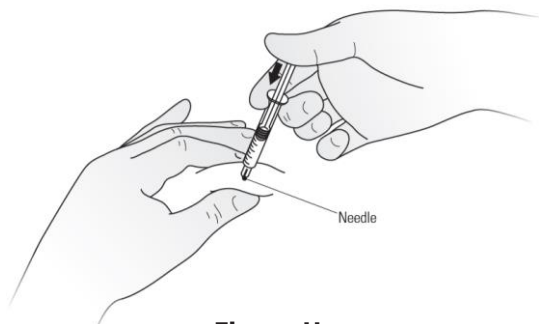


Figure H

Step 11. When the syringe is empty, pull the needle out of the skin while carefully keeping the needle at the same angle as inserted. **See Figure I.**

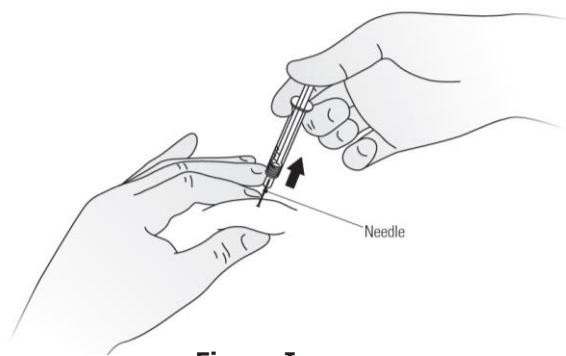


Figure I

Step 12. Place a dry cotton ball or gauze pad over the injection site and press for several seconds. **See Figure J.** Do not use an alcohol swab as it may cause stinging. If there is a little bleeding, you may cover the injection site with a small bandage.

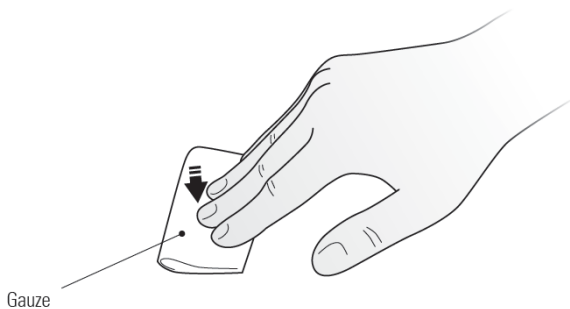


Figure J

Important Information about your Kineret prefilled syringe:

- Use each Kineret prefilled syringe only 1 time. **Do not** use a syringe more than 1 time. **Do not** recap a needle.
- You may not have to use all of the liquid medicine in the prefilled syringe. Your healthcare provider will show you how to find the correct dose of Kineret for you or your child.
- If you notice that some medicine is left in the prefilled syringe, do not inject again with the same prefilled syringe.
- **If you drop a prefilled syringe, do not use it.** The glass syringe may be broken, or the

needle may be bent or dirty. Throw away the prefilled syringe and replace it with a new one. Take a new prefilled syringe from what would be the last day of the week in your current box. For example, if you start on Wednesday, the last day of the week in your series is Tuesday. After using all the remaining prefilled syringes in your current box, start your next box of Kineret prefilled syringes.

Disposal of your Kineret syringes:

- Put your used syringes in a FDA-cleared sharps disposal container right away after use. **Do not throw away (dispose of) loose syringes in your household trash.**
- If you do not have a FDA-cleared sharps disposal container, you may use a household container that is:
 - made of a heavy-duty plastic
 - can be closed with a tight-fitting, puncture-resistant lid, without sharps being able to come out
 - upright and stable during use
 - leak-resistant
 - properly labeled to warn of hazardous waste inside the container
- When your sharps disposal container is almost full, you will need to follow your community guidelines for the right way to dispose of your sharps disposal container. There may be state or local laws about how you should throw away used needles and syringes. For more information about safe sharps disposal, and for specific information about sharps disposal in the state that you live in, go to the FDA's website at: <http://www.fda.gov/safesharpsdisposal>.
- Do not dispose of your used sharps disposal container in your household trash unless your community guidelines permit this. Do not recycle your used sharps disposal container.
- Throw away the wet gauze or tissue with your syringe and clean the table surface with a fresh swab.

This Patient Information and Instructions for Use has been approved by the U.S. Food and Drug Administration.



Manufactured by:

Swedish Orphan Biovitrum AB (publ)
SE-112 76 Stockholm, Sweden
License No. 1859