

Patient Information Kineret® (KIN-eh-ret) (anakinra)

Read the patient information that comes with Kineret before you start taking it and each time you get a refill. There may be new information. This leaflet does not take the place of talking with your healthcare provider about your medical condition or your treatment.

What is the most important information I should know about Kineret?

Kineret is a medicine that affects your immune system. Kineret can lower the ability of your immune system to fight infections. Serious infections have happened in patients taking Kineret. Taking Kineret may give you a higher chance for getting an infection or make any infection you have worse.

Before starting Kineret, tell your healthcare provider if you:

- think you have an infection
- are being treated for an infection
- have signs of infection such as fever, chills, or have any open sores on your body
- have asthma. Patients with asthma may have a higher chance of getting an infection if they take Kineret.
- get a lot of infections or have infections that keep coming back
- take other medicines that affect your immune system

If you take other medicines that affect the immune system, such as ENBREL® (etanercept), Humira® (adalimumab), or Remicade® (infliximab) while you are taking Kineret, you could also have an increased risk for getting a serious infection.

It is recommended that you do not take these medications (Tumor Necrosis Factor or TNF blocking agents) while taking Kineret.

What is Kineret?

Kineret is an interleukin-1 receptor antagonist (IL-1ra). Kineret is used to reduce the signs and symptoms, and slow down damage that happens in patients with moderate to severe active Rheumatoid Arthritis (RA), but it can also lead to serious side effects because of the affects on your immune system. See *“What is the most important information I should know about Kineret?”* and *“What are the possible side effects with Kineret?”*

Kineret is only for adults who have taken other medicines for their RA that have not worked. Kineret can be taken alone or along with other RA medicines except for TNF blocking agents.

Who should not take Kineret?

Do not take Kineret if you have an allergy to:

- proteins made from bacterial cells (*E coli*). Ask your healthcare provider if you are not sure.
- any of the ingredients in Kineret. See the end of this leaflet for a complete list of ingredients in Kineret.

What should I tell my healthcare provider before taking Kineret?

Kineret may not be right for you. 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 conditions that can increase your risk of infections.** See “What is the most important information I should know about Kineret?”
- **have an allergy to rubber or latex. The needle cover on the prefilled syringe contains latex. Do not handle the needle cover if you are allergic to latex.**
- **have kidney problems**
- **are scheduled to receive any vaccines.** Patients taking Kineret should not receive live vaccines.

Tell your healthcare provider if you are pregnant, plan to become pregnant, or breastfeeding. Kineret has not been studied in pregnant or nursing women. Kineret should be used during a pregnancy only if needed. It is not known if Kineret will pass into your breast milk. Discuss treatment options with your doctor if you plan on breastfeeding.

Tell your healthcare provider about all the medicines you take, including prescription and non-prescription medicines, vitamins, and herbal supplements. Tell your healthcare provider if you take other medicines that affect your immune system.

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 take Kineret?

- Kineret is taken by injection under the skin. Your healthcare provider should instruct you on how to inject, how often to inject Kineret, and the correct way to dispose of used syringes.
- Take Kineret exactly as your healthcare provider tells you to
- If you have a kidney problem your healthcare provider may need to change how often you take your Kineret injections
- Inject Kineret at about the same time each day, on a schedule that works best for you
- If you miss a dose of Kineret, contact your healthcare provider to find out when to take your next injection
- Only you and your healthcare provider can determine how well Kineret is working for you. The time it takes to see improvement in symptoms varies from person to person. In clinical studies, most patients saw their arthritis symptoms improve within 12

weeks of starting Kineret.

What are the possible side effects of Kineret?

Kineret may cause serious side effects, including:

- **Serious Infections.** See “What is the most important information I should know about Kineret?”
During treatment with Kineret, call your healthcare provider right away if you get an infection, any sign of an infection including a fever, chills, or have any open sores on your body.
- **Blood problems.** Kineret may cause certain white blood cells called neutrophils to decrease in number (neutropenia). Neutrophils are important in fighting infections. You will need to have blood tests before starting treatment with Kineret, then monthly for three months. After the first three months you will be asked to have your blood tested every three months for up to one year.

The most common side effect with Kineret is injection site reaction. These reactions may include redness, swelling, bruising, itching and stinging. Most injection site reactions are mild and last about 2 to 4 weeks.

Side effects that are rare include:

- **Malignancies.** Patients with rheumatoid arthritis (RA) may be at higher risk for lymphoma (a type of cancer).
- **Allergic reactions.** Allergic reactions rarely occur in patients taking Kineret. If you develop a severe rash, swollen face or difficulty breathing while taking Kineret, call your doctor right away or seek emergency care immediately. 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.

How should I store Kineret?

- Store Kineret in its original carton in the refrigerator at 36°F to 46°F (2°C to 8°C)
- **DO NOT FREEZE OR SHAKE Kineret**
- Keep Kineret away from light
- When traveling, make sure you store Kineret at the correct temperature
- Safely dispose of Kineret that is out of date or no longer needed

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

General Information about Kineret

Medicines are sometimes prescribed for conditions that are not mentioned in the patient 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.

This patient information leaflet summarizes the most important information about Kineret. If you would like more information about Kineret, talk with your healthcare

provider. You can ask your healthcare provider or pharmacist for information about Kineret that is written for health professionals. For more information go to www.kineretrx.com or call **1-866-546-3738**.

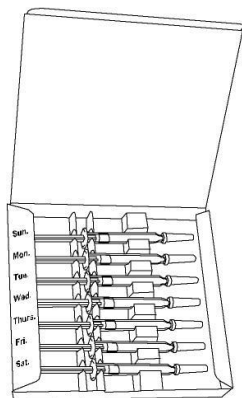
What are the ingredients in Kineret?

Active ingredients: anakinra

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

What do I need to know to prepare and give an injection of Kineret?

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



Use each Kineret prefilled syringe only once. Be sure to inject all of the solution in the syringe. If you notice some solution remaining in the syringe, do not re-inject. You should discard the syringe with any remaining solution in the puncture-resistant container. (See “Disposal of Syringes and Supplies”).

If you drop a syringe, **do not use the syringe**. This is for your safety in case the glass syringe is broken, or the needle is bent or dirty. Dispose of the syringe and replace it with a new one. Take the new 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 syringes in your current box, start your next box.

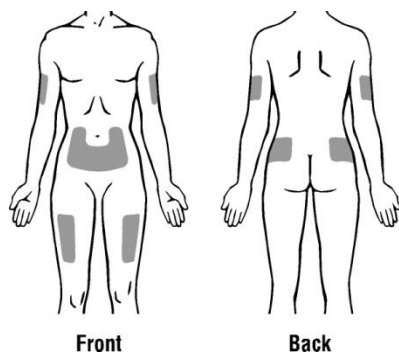
Setting up for an Injection

1. Find a clean, flat work surface, such as a table.
2. Assemble the supplies needed for an injection:
 - One alcohol swab
 - A dry gauze or cotton ball
 - Kineret prefilled syringe
 - A puncture-resistant container

3. 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. Return the carton containing the remaining prefilled syringes back into the refrigerator.
4. Check the expiration date on the syringe label. If the expiration date has passed, do not use the syringe. Contact your pharmacist or call 1-866-Kineret (1-866-546-3738) for assistance.
5. Let the Kineret solution warm to room temperature for 60 to 90 minutes prior to injection. **Do not remove the needle cover during this process.**
6. Do not shake the prefilled syringe. If the solution is foamy, allow the prefilled syringe to sit for a few minutes until it clears.
7. Make sure the solution in the prefilled syringe is clear and colorless. You may see a small amount of tiny particles that are white, or that you can see through. These particles come from the protein in Kineret[®] and are okay. Do not inject the solution if it is cloudy or discolored, or has large or colored particles. Call your healthcare provider or pharmacist if you have any questions about a Kineret prefilled syringe.
8. Wash your hands with soap and warm water.

Selecting and preparing the injection site

1. Choose an injection site. Recommended injection sites include:
 - The outer area of the upper arms
 - The abdomen (except the two-inch area around the navel)
 - The front of the middle thighs
 - The upper outer areas of the buttocks



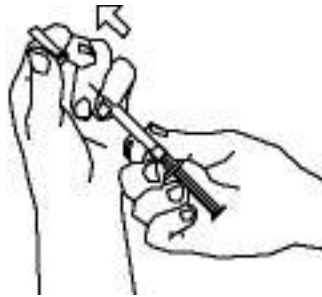
Choose a new site each time you use Kineret. Choosing a new site can help

avoid soreness at any one site. Do not inject Kineret into an area that is tender, red, bruised, or hard. Avoid areas with scars or stretch marks. Do not inject close to a vein that you can see under the surface of your skin.

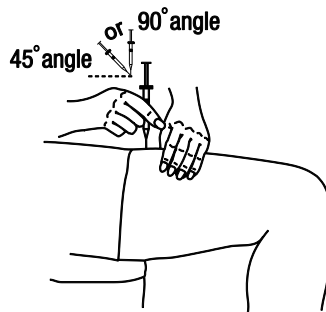
2. Clean the injection site with an alcohol swab. Let the area dry completely. Injecting through a site that is still moist from an alcohol swab may cause stinging.

Administering the subcutaneous injection

1. Pick up the prefilled syringe from your flat work surface. Hold the syringe in the hand you will use to inject Kineret. Remove the needle cover. Twisting the needle cover while pulling will help in the removal. Do not touch the needle or allow it to touch any surface. You may notice a small air bubble in the prefilled syringe. You do not have to remove the air bubble. Injecting the solution with the air bubble is harmless.



2. With your free hand, gently pinch a fold of skin at the cleaned injection site.
3. Hold the syringe (like a pencil) at a 45 to 90 degree angle to the skin. With a quick, dart-like motion insert the needle into the skin.



4. After the needle is inserted, gently let go of the skin. Pull the plunger back slightly. If no blood appears in the syringe, slowly push the plunger all the way down to inject Kineret.

If blood comes into the syringe, do not inject Kineret, because the needle has entered a blood vessel. Withdraw the needle. Dispose of the used prefilled

syringe in a puncture-resistant container. Prepare a new injection site and use a new prefilled syringe.

5. When the syringe is empty, pull the needle out of the skin, being careful to keep it at the same angle as inserted.
6. Place a cotton ball or gauze over the injection site and press for several seconds. 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.

Disposal of the syringe and supplies

- The syringes should **NEVER** be reused. **NEVER** recap a needle.
- Place the used syringe in a puncture-resistant container. A coffee can with a plastic lid or a hard plastic container with a screw-on top may be used. Puncture-resistant containers can also be purchased at your local pharmacy.
- Talk to your healthcare provider or pharmacist about how to properly dispose of your used syringes. There may be special local and state laws for disposing of used needles and syringes. **Do not throw the disposal container in the household trash. Do not recycle.**
- The needle cover, alcohol swabs, and other used supplies can be placed in the trash.
- Always keep all syringes, injection supplies, and disposal containers out of the reach of children.

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