

Kineret[®] **(anakinra)**

Information for Patients

Kineret[®] (pronounced KIN-eh-ret)

Read these instructions carefully before you start taking Kineret[®]. You should read this leaflet each time you get your prescription refilled, in case something has changed. The information in this leaflet does not take the place of talking with your healthcare provider before you start taking this medication and at check ups. Talk to your healthcare provider if you have any questions about your treatment with Kineret[®].

What is Kineret[®]?

Kineret[®] is a medicine that is used to reduce the pain and swelling associated with moderate to severe active rheumatoid arthritis.

Kineret[®] is a man-made protein that is similar to a naturally occurring protein called interleukin-1 receptor antagonist (IL-1ra) found in the body.

How does Kineret[®] work?

In people with rheumatoid arthritis (RA), the body produces too much of certain proteins that lead to joint damage. One of these proteins is called interleukin-1 (IL-1). Too much IL-1 contributes to the pain, swelling, and stiffness associated with RA. Kineret[®] can block the action of IL-1.

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, some patients saw their arthritis symptoms improve in about 4 weeks after starting Kineret[®] treatment.

What important information do I need to know about taking Kineret[®]?

All medicines have side effects. The possible side effects of Kineret[®] include:

- **Serious Infections.** Patients taking Kineret[®] have a greater chance of developing a serious infection. If you have an infection, tell your healthcare provider **before** you start taking Kineret[®]. If you get an infection that does not go away while taking Kineret[®], tell your healthcare provider right away.

If you have asthma you could be at increased risk for getting a serious infection.

If you are using ENBREL[®] (etanercept), Humira[™] (adalimumab), or Remicade[®] (infliximab) you could also be at greater risk for getting a serious infection.

- **Malignancies.** The risk of developing cancer for patients taking Kineret[®] appears to be the same as that for patients not taking Kineret[®]. RA patients, particularly those with highly active RA, may be at higher risk for lymphoma (a type of cancer). There have been rare reports of lymphoma in patients taking Kineret[®] or other medicines that affect your immune system, occurring more often than expected for people in general. The role of Kineret[®] in the development of cancer is not known.
- **Blood problems.** Kineret[®] may cause the number of one type of white blood cell (neutrophil) to decrease. 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 checked every three months for up to one year.

What are other possible side effects of Kineret[®]?

- A reaction may occur at the site where Kineret[®] is injected. These reactions may include redness, swelling, bruising, itching and stinging. Most of the time the reactions are mild and last about 2 to 4 weeks. If you are having problems with your injection sites, call your healthcare provider.
- The Kineret[®] needle cover contains latex. If you know you are allergic to latex, talk to your healthcare provider before using Kineret[®].

Who should not take Kineret[®]?

Do not take Kineret[®] if you:

- have an infection that requires treatment with prescription antibiotics or an infection that is serious enough for you to be admitted to the hospital.
- have an allergy to proteins made from bacterial cells (*E coli*), or any of the ingredients in Kineret[®].
- are taking ENBREL[®] (etanercept), Humira[™] (adalimumab), or Remicade[®] (infliximab) unless your healthcare provider has told you to. When Kineret[®] is used with ENBREL[®], Humira[™], or Remicade[®] you may increase your risk of getting a serious infection.

Can I take Kineret[®] if I am pregnant or breast-feeding?

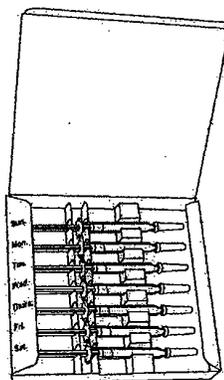
Kineret[®] has not been studied in pregnant women or nursing mothers. If you are pregnant or breast-feeding, talk to your healthcare provider before using Kineret[®].

How do I take Kineret®?

Kineret® is taken by injection under the skin. Your healthcare provider should instruct you on how to inject Kineret®, how often it should be injected, and the proper disposal of used syringes.

Kineret® should be administered once every 24 hours unless you have a kidney problem. If you have a kidney problem, talk to your healthcare provider about your Kineret® dose. You should inject Kineret® at the same time of day on a schedule that works best for you.

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.

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

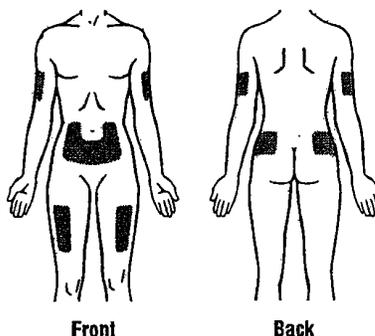
Setting up for an Injection

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. Do not use a prefilled syringe if the contents appear discolored or cloudy, or if there are any particles in the syringe. Call your healthcare provider or pharmacist if you have any questions about the way the solution looks.
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



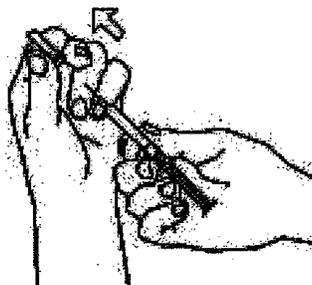
Choose a new site each time you use Kineret[®]. Choosing a new site can help avoid soreness at any one site. Do not inject Kineret[®] into an area that is tender, red, bruised, or hard. Avoid areas with scars or stretch marks. Do not inject close

to a vein that you can see under the surface of your skin.

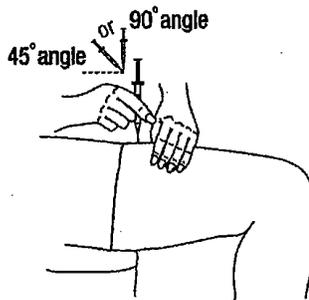
2. Clean the injection site with an alcohol swab. Let the area dry completely. Injecting through a site that is still moist from an alcohol swab may cause stinging.

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.

How should I store Kineret®?

Store Kineret® in its original carton in the refrigerator at 2° to 8°C (36° to 46°F). **DO NOT FREEZE OR SHAKE.** Contact your healthcare provider with any questions about storage. If you are traveling, make sure you store Kineret® at the correct temperature. For a complimentary travel cooler, call 1-866-Kineret (1-866-546-3738).

A healthcare provider familiar with Kineret® should answer all questions. You can also call the **Kineret® Customer Call Center toll-free at 1-866-Kineret (1-866-546-3738).**

AMGEN®

Manufactured by:
Amgen Manufacturing, Limited,
a subsidiary of Amgen Inc
One Amgen Center Drive

This label may not be the latest approved by FDA.
For current labeling information, please visit <https://www.fda.gov/drugsatfda>

Thousand Oaks, CA 91320-1799

© 2001-200X Amgen. All rights reserved.

3XXXXXX – vXX

Issue Date: XX/XX/XXXX