

KINERET[®]

anakinra

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about KINERET. It does not contain all the available information. It does not take the place of talking to your doctor, nurse or pharmacist.

This leaflet was last updated on the date at the end of this leaflet.

Speak to your pharmacist or doctor to obtain the most up to date information on this medicine.

You can also download the most up to date leaflet from www.menarini.com.au/cmi

All medicines have risks and benefits. Your doctor has weighed the risks of you using KINERET against the benefits they expect it will have for you.

If you have any concerns about using this medicine, ask your doctor, nurse or pharmacist.

Read this leaflet carefully before you start using KINERET and keep it with the medicine.

You may need to read it again.

What KINERET is used for

This medicine is used to treat the signs and symptoms associated with active rheumatoid arthritis (RA), such as pain and swelling, in adults and to treat the signs and symptoms of inflammation associated with Cryopyrin-Associated Periodic Syndromes (CAPS), such as rash, joint pain, fever, headache and fatigue in adults and children (age 8 months and older).

It is also used to treat patients with Systemic Juvenile Idiopathic Arthritis (SJIA).

KINERET is a man-made protein that is similar to a naturally occurring protein found in the body called interleukin-1 receptor antagonist (IL-1Ra). In people with RA and CAPS, the body produces too much of a certain protein called interleukin-1 (IL-1). Too much IL-1 causes inflammation contributing to the symptoms of the diseases. KINERET can block the action of IL-1.

Only you and your doctor can determine how well KINERET is working for you. The time it takes to see improvement in symptoms varies from person to person.

In people with RA, KINERET is given in combination with methotrexate if methotrexate alone is not enough.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

Before you use KINERET

When you must not use it

Do not use KINERET if you are using a medicine known as tumour necrosis factor (TNF) antagonist.

Do not use KINERET if you have an allergy to:

- any medicine containing anakinra
- any of the ingredients listed at the end of this leaflet
- any other medicines made using *E.coli*-derived proteins

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing

- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin

Do not give this medicine to a child with RA and to a child younger than 8 months of age with CAPS.

Do not use this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

Do not use KINERET if the syringe has been left out of the refrigerator for more than 12 hours.

Do not use KINERET if the syringe has been dropped.

This is for your safety in case the syringe is broken or the needle is bent or dirty.

KINERET is not recommended for use in patients with severe renal impairment.

KINERET is not recommended for use in patients with pre-existing malignancy.

KINERET should not be used in patients with neutropenia (low white blood cell count).

If you are not sure whether you should start taking this medicine, talk to your doctor, nurse or pharmacist.

Before you start to use it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have or have had any of the following medical conditions:

- kidney disease
- cancer
- infections (on-going or recent)
- diseases that affect your immune response
- asthma

Tell your doctor if you have had a recent vaccination.

Tell your doctor if you have a history of increased levels of liver enzymes.

Tell your doctor if you are using any other medicines to treat rheumatoid arthritis.

Tell your doctor if you are pregnant or plan to become pregnant or are breast-feeding.

Your doctor can discuss with you the risks and benefits involved.

KINERET has not been tested in pregnant women. Use of KINERET is not recommended during pregnancy and adequate contraception must be used by women of childbearing potential when using KINERET.

You must not breast-feed if you use KINERET.

It is not known whether KINERET passes into breast milk.

If you have not told your doctor about any of the above, tell them before you start using KINERET.

Taking other medicines

Tell your doctor if you are taking warfarin or phenytoin.

Your doctor may need to adjust the dose of your medication.

Tell your doctor or pharmacist if you are taking any other medicines, including any that you buy without a prescription from your pharmacy, supermarket or health food shop.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

How to use KINERET

KINERET is given by daily injection under your skin; this is called a subcutaneous injection.

Follow all directions given to you by your doctor, nurse or pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions in this leaflet, ask your doctor, nurse or pharmacist for help.

Your doctor, nurse or pharmacist may suggest that you or your carer be taught how to give a subcutaneous injection.

This will allow you to administer your KINERET at home.

Do not try to give yourself the injection unless you have received special training from your doctor or nurse.

If you are not sure about giving the injection or you have any questions, ask your doctor or nurse for help.

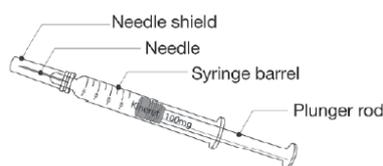
How much to use

Always use this medicine exactly as your doctor has told you.

Your doctor will decide what dose you or your child needs.

Check with your doctor or pharmacist if you are not sure.

Each KINERET dose comes in a 1 mL graduated pre-filled syringe.



Use each KINERET graduated pre-filled syringe only once.

If you notice some solution remaining in the syringe, do not re-inject.

You should discard the syringe with any remaining solution in a puncture-proof sharps container.

If you drop the syringe, do not use the syringe.

This is for your safety in case the syringe is broken or the needle is bent or dirty.

How to prepare your injection

Do not try to give yourself the injection if you or your carer have not been trained.

1. Set up the materials needed for the injection:
 - A new graduated pre-filled syringe of KINERET with attached needle
 - Alcohol swab
 - A cotton ball

2. Take the box out of the refrigerator, and take one KINERET graduated pre-filled syringe from the box and put the remaining graduated pre-filled syringes back in the refrigerator.

3. **Do not shake the graduated pre-filled syringe.** If the solution is foamy, allow the graduated pre-filled syringe to sit for a few minutes until it clears.

4. Check the expiry date (Exp.) on the graduated pre-filled syringe label.

Do not use it if the date has passed the last day of the month shown.

5. Check the appearance of KINERET. It must be a clear, colourless-to-white solution. If there are clumps or particles in it, you must not use it. Use a new graduated pre-filled syringe.

6. For a more comfortable injection, take the graduated pre-filled syringe out of the fridge 30 minutes before you intend to use it or hold the graduated pre-filled syringe gently in your hand, warming it for a few minutes.

Do not warm KINERET in any other way (for example, do not warm it in a microwave or in hot water).

7. **Do not remove the needle cover from the graduated pre-filled syringe until you are ready to inject.**

8. Wash your hands thoroughly with soap and water.

Selecting and preparing the injection site

9. Find a comfortable, well-lit, clean surface and put everything you need within reach. Make sure you know what KINERET dose your doctor has prescribed; 20 to 90 mg, 100 mg, or higher.

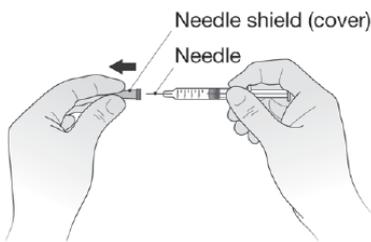
- If your doctor has prescribed a 100 mg dose you should follow the “**How to prepare a 100 mg dose**” section;
- If your doctor has prescribed a lower dose you should follow the “**How to prepare a 20 to 90 mg dose**” section.

Administering the KINERET injection

How to prepare a 100 mg dose

Before you inject KINERET you must do the following:

Figure A



1. Hold the syringe barrel and gently remove the cover from the needle without twisting. Pull straight as shown in **Figure A**. Do not touch the needle or push the plunger. Discard the needle cover straight away.
2. You may notice a small air bubble in the graduated pre-filled syringe. You don't have to remove the air bubble before injecting. Injecting the solution with the air bubble is harmless.
3. You can now use the pre-filled syringe as described in the “**Where should you give your injection?**” section and “**How do you give your injection?**” section.

How to prepare a 20 to 90 mg dose

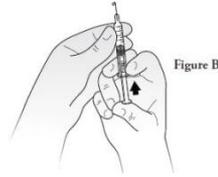
Before you inject Kineret you must do the following:

1. Hold the syringe barrel and gently remove the cover from the needle without twisting. Pull straight as shown in **Figure A**. Do not touch the needle or push the plunger. Discard the needle cover straight away.
2. Turn the graduated pre-filled syringe so that the needle is

now pointing straight upwards as shown in **Figure B**.

Put your thumb on the plunger rod and push slowly until you see a tiny liquid drop at the tip of the needle.

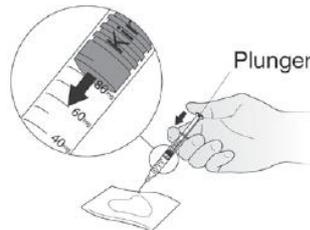
Figure B



3. 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, as shown in **Figure C**.

Make sure the needle does not touch the gauze or tissue.

Figure C



4. Put your thumb on the plunger rod and push slowly until the front end of the plunger has reached the mark on the graduated scale of the recommended dose. The extra liquid will be absorbed by the gauze or tissue as shown in **Figure C**.
5. If you are not able to set the correct dose or if you drop the syringe, dispose of the syringe and use a new one.
6. You can now use the graduated pre-filled syringe as described in the “**Where should you give your injection?**” section and the “**How do you give your injection?**” section.

Where should you give your injection?

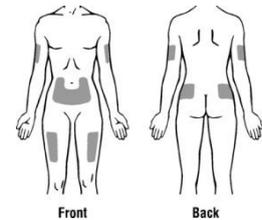
The most suitable places to inject yourself or your child are (see **Figure D**):

- the abdomen (except for the area around the navel);

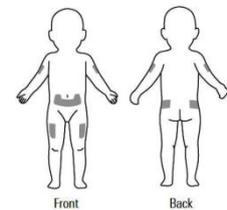
- the top of the thighs (this is especially good for infants under a year if they have slightly chubby legs);
- the upper outer areas of the buttocks; and
- the outer area of the upper arms

Figure D

Adult



Child



If someone is injecting for you, they can also use the back of your arms.

Change the place that you inject each time so you don't become sore in one area.

Do not inject into skin that is tender, red, bruised, or hard.

Avoid scars or stretch marks.

Don't inject close to a vein.

How do you give the injection

1. Disinfect the skin with the alcohol wipe and let it dry off naturally in the air (this only takes a few seconds). Then pinch the skin between your thumb and forefinger, without squeezing.
2. Put the needle fully into the skin as shown by your nurse or doctor.
3. Inject the liquid slowly and evenly, always keeping the skin pinched as in **Figure E**.

Figure E



4. After injecting the liquid, remove the needle and let go of the skin.

Only use each syringe for one injection. Do not reuse a syringe as this can cause infection. Any unused medicine must be discarded.

When to use it

Try to inject KINERET at approximately the same time each day on a schedule that works best for you.

Taking it at the same time each day will have the best effect. It will also help you remember when to use it.

Schedule your KINERET injections with another task you do each day, such as getting dressed in the morning.

If you forget to use it

If you have forgotten to use a dose of KINERET you should contact your doctor or nurse to discuss when you should use the next dose.

If you use too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) for advice, or go to Emergency at the nearest hospital, if you think that you or anyone else may have used too much KINERET. Do this even if there are no signs of discomfort or poisoning.

While you are using KINERET

Things you must do

Always follow your doctor's instructions carefully.

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking KINERET.

Tell any other doctors, dentists, and pharmacists who treat you that you are taking this medicine.

If you become pregnant while taking this medicine, tell your doctor immediately.

Keep all of your doctor's appointments so that your progress can be checked.

KINERET may cause a small change in certain blood cells. Your doctor will arrange for blood tests before treatment and then periodically during treatment to monitor these changes.

Things you must not do

Do not use KINERET to treat any other complaints unless your doctor tells you to.

Do not give your medicine to anyone else, even if they have the same condition as you.

Do not use the KINERET graduated pre-filled syringe if you think it has been frozen.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using KINERET, even if you do not think the problems are connected with the medicine or are not listed in this leaflet.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects. Other side effects are minor and are likely to be temporary.

Do not be alarmed by the following list of side effects. You may not experience any of them.

Ask your doctor, nurse or pharmacist to answer any questions you may have.

Tell your doctor, nurse or pharmacist if you notice any of the following and they worry you:

- Headaches
- Injection Site Reactions (ISRs)

Most ISRs occur at the site where KINERET is injected. These reactions include redness, swelling, bruising or itching at the injection site. It is not unusual to experience mild to moderate stinging or injection site reactions, especially when you are beginning therapy.

The symptoms usually disappear about a month after continued use.

Helpful hints to manage injection site reactions:

- Swelling - Apply a cold pack to the injection site immediately after injection.
- Itching - Talk to your doctor.
- Bruising – Apply a cold pack to the injection site immediately after injection.
- Pain during and/or after injection – Try different injection locations. The stomach may be the best site due to the low number of nerve endings.
 - Let the KINERET syringe warm to room temperature before injecting (30 minutes).
 - Allow the alcohol at the injection site to dry before injecting KINERET.

These are mild side effects of KINERET.

If any of the following happen, tell your doctor immediately or go to Emergency at your nearest hospital:

- A fever, a cough or redness and tenderness of the skin or other signs of infection
- Swelling of the face, tongue or throat
- Itchy skin or rash
- Shortness of breath
- Wheezing
- Suddenly feeling fast pulse or sweating.

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation.

Tell your doctor or pharmacist if you notice anything that is making you feel unwell or worries you. Other side effects not listed above may also occur in some people.

After using KINERET

Storage

Keep your KINERET graduated pre-filled syringes in the box until it is time to use them.

Keep your graduated pre-filled syringes in the refrigerator where the temperature stays between 2°C and 8°C.

You can leave KINERET out of the refrigerator but for no longer than a total of 12 hours at room temperature (up to 25°C).

Do not store KINERET in the freezer.

Do not let KINERET freeze.

The expiry date (Exp.) for KINERET is stamped on the box and on the syringe label. Do not use KINERET after this date, the last day of the month shown.

Keep it where children cannot reach it.

Disposal

Do not put the cover back on used needles.

Put used syringes into a puncture-proof sharps container and keep it out of the reach and sight of children.

Dispose of the full puncture-proof sharps container as instructed by your doctor, nurse or pharmacist.

Never put the used syringes into your normal household rubbish bin.

If you had a dose lower than 100 mg you will have been told to eject liquid from the syringe onto a gauze or tissue. After your injection discard the wet gauze or tissue with your syringe and clean the surface with a fresh tissue.

The needle cover, alcohol swabs and other used supplies can be thrown out with your normal household rubbish.

Product description

What it looks like

KINERET is supplied in single use graduated pre-filled syringes as a sterile, clear, colourless-to-white, preservative-free solution for subcutaneous (SC) administration.

The solution may contain some small translucent-to-white particles of protein.

Ingredients

Each KINERET syringe contains 100 mg of the active ingredient anakinra (100 mg/0.67 mL).

Other ingredients:

- Anhydrous citric acid,
- sodium chloride,
- disodium EDTA,
- polysorbate 80,
- sodium hydroxide,
- Water for Injections.

Supplier

KINERET is supplied in Australia by:

A. Menarini Australia Pty. Ltd.,
Level 8, 67 Albert Ave,
Chatswood, NSW, 2067

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For medical information queries please contact 1800 644 542.

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