

## Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

### 1. Why am I using KINERET?

KINERET contains the active ingredient anakinra. KINERET is used to treat the signs and symptoms associated with Rheumatoid Arthritis (RA), Cryopyrin Associated Periodic Syndromes (CAPS), and Systemic Juvenile Idiopathic Arthritis (SJIA).

For more information, see Section [1. Why am I using KINERET?](#) in the full CMI.

### 2. What should I know before I use KINERET?

Do not use if you have ever had an allergic reaction to anakinra or any of the ingredients listed at the end of the CMI.

**Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.**

For more information, see Section [2. What should I know before I use KINERET?](#) in the full CMI.

### 3. What if I am taking other medicines?

Some medicines may interfere with KINERET and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

### 4. How do I use KINERET?

- KINERET is usually given by daily injection under your skin; this is called a subcutaneous injection.
- Your doctor will decide what dose you or your child needs and how often to give it.

More instructions can be found in Section [4. How do I use KINERET?](#) in the full CMI.

### 5. What should I know while using KINERET?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>• Remind any doctor, dentist or pharmacist you visit that you are using KINERET.</li><li>• If you become pregnant while using KINERET, tell your doctor immediately.</li><li>• Attend your scheduled appointments so that your doctor can monitor any changes in certain blood cells and discuss appropriate precautions with you.</li></ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"><li>• Do not try to inject yourself if you have not been trained.</li><li>• Do not stop using this medicine suddenly or change the dose unless your doctor tells you to.</li><li>• Do not use KINERET if you think it has been frozen.</li></ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"><li>• Be careful before you drive or use any machines or tools until you know how KINERET affects you.</li></ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"><li>• Store KINERET in a refrigerator (2 °C to 8 °C). Do not freeze. Keep the graduated pre-filled syringe in the original carton in order to protect from light.</li><li>• Once a syringe has been removed from the refrigerator and has reached room temperature (up to 25°C) it must either be used within 72 hours or discarded. Do not place it back in the refrigerator if it has been stored at room temperature.</li></ul>

For more information, see Section [5. What should I know while using KINERET?](#) in the full CMI.

### 6. Are there any side effects?

Common side effects include headaches, rash and injection site reactions (ISRs). Serious side effects that require urgent medical attention include serious infections, serious allergic reactions and signs and symptoms of a serious drug reaction.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

# KINERET®

Active ingredient(s): *anakinra*

## Consumer Medicine Information (CMI)

This leaflet provides important information about using KINERET. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using KINERET.**

Where to find information in this leaflet:

- [1. Why am I using KINERET?](#)
- [2. What should I know before I use KINERET?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use KINERET?](#)
- [5. What should I know while using KINERET?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

## 1. Why am I using KINERET?

KINERET contains the active ingredient **anakinra**. KINERET is a type of cytokine (an immunosuppressive agent).

KINERET is used to treat the signs and symptoms associated with:

- **active Rheumatoid Arthritis (RA) in adults**
- **Cryopyrin-Associated Periodic Syndromes (CAPS), including Neonatal-Onset Multisystem Inflammatory Disease (NOMID) / Chronic Infantile Neurological, Cutaneous, Articular Syndrome (CINCA), Muckle-Wells Syndrome (MWS), and Familial Cold Autoinflammatory Syndrome (FCAS) in adults and children (aged 8 months and older)**
- **active Systemic Juvenile Idiopathic Arthritis (SJIA) in patients aged 2 years and above.**

Cytokines are proteins made by your body that co-ordinate communication between cells and help control cell activity. In people with RA, CAPS and SJIA, your body produces too much of the protein interleukin-1. Too much interleukin-1 causes inflammation contributing to the symptoms of the diseases. Normally, your body blocks this inflammation by producing an interleukin-1-receptor antagonist (IL-1Ra). The active substance of KINERET is anakinra, this works in the same way as your natural interleukin-1 blocking protein.

The time it takes to see an improvement in symptoms varies from person to person; your doctor will monitor your response to KINERET.

In people with RA, KINERET is given in combination with methotrexate.

## 2. What should I know before I use KINERET?

### Warnings

**Do not use KINERET if:**

- you are allergic to anakinra, or any of the ingredients listed at the end of this leaflet.  
Always check the ingredients to make sure you can use this medicine.
- you are allergic to any other medicines made using *E. coli*-derived proteins.
- you are using medicines called tumour necrosis factor (TNF- $\alpha$ ) inhibitors, such as etanercept.  
Ask your doctor or pharmacist if you are not sure whether you are taking such a medicine.
- you have neutropenia (low white blood cell count) determined after a blood test.

**Check with your doctor if you:**

- have or have had any of the following medical conditions:
  - history of increased levels of liver enzymes
  - kidney disease
  - cancer
  - infections (ongoing or recent) or a history of frequent infections or any problems that increase your risk of infections
  - diseases that affect your immune response
  - asthma.
- have had a recent vaccination or require vaccinations. Your doctor may ask you to complete all vaccinations before starting KINERET.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

### Pregnancy and breastfeeding

**Check with your doctor if you are pregnant or intend to become pregnant.** 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.

**Talk to your doctor if you are breastfeeding or intend to breastfeed.** You must not breastfeed if you use KINERET. It is not known whether KINERET passes into breast milk.

## Children and adolescents

Do not give this medicine to a child with RA or to a child younger than 8 months of age or body weight less than 10 kg with CAPS.

Do not give this medicine to a child younger than 2 years with SJIA.

## 3. What if I am taking other medicines?

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

**Medicines called tumour necrosis factor (TNF- $\alpha$ ) inhibitors, such as etanercept should not be used with KINERET because this may increase the risk of infections.**

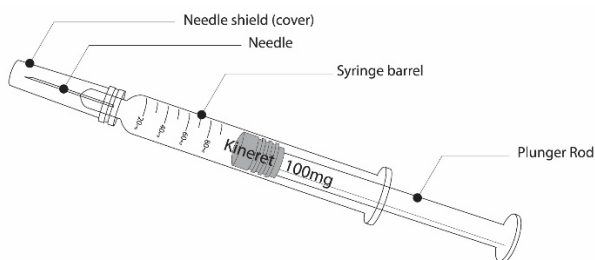
**Tell your doctor if you are taking warfarin or phenytoin.** Your doctor may need to adjust the dose of your medication.

**Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect KINERET.**

## 4. How do I use KINERET?

### How much to use

- The recommended dose is either 20 to 90 mg or 100 mg given as an injection under your skin (subcutaneous injection). Your doctor will tell you the dose that you need or whether you need a dose higher than 100 mg.
- Each KINERET dose comes in a 1 mL graduated pre-filled syringe containing 100 mg KINERET. The graduations are in milligrams (mg) to help you select and inject the right dose.



### When to use KINERET

- KINERET should be used daily. You should try to have the injection at the same time each day.
- Continue using your medicine for as long as your doctor tells you. KINERET helps control your condition, but it does not cure it. It is important to keep using KINERET even if you feel well.

### How to use KINERET

Your doctor may decide that it would be more convenient for you to inject KINERET yourself. Your doctor or nurse will show you how to inject yourself. **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.**
5. Check the appearance of KINERET. It must be a clear, colourless-to-white solution. It may contain some small translucent-to-white particles of protein. This is expected.  
  
The solution should not be used if discoloured or cloudy or if there are clumps, large or coloured particles present.  
  
**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 a microwave or in hot water or any other way.**
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

Find a comfortable, well-lit, clean, flat, hard surface and put everything you need within reach. Make sure you know what KINERET dose your doctor has prescribed.

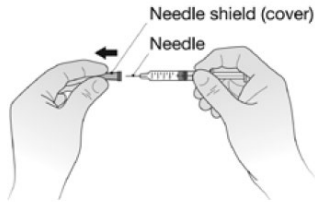
- If your doctor has prescribed a 100 mg dose, you should follow the "[How to prepare a 100 mg dose](#)" section.
- If your doctor has prescribed a lower dose, you should follow the "[How to prepare a 20 to 90 mg dose](#)" section.

### How to prepare a 100 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.

Figure A



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.

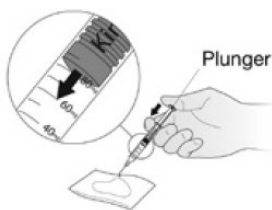
Figure B



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.

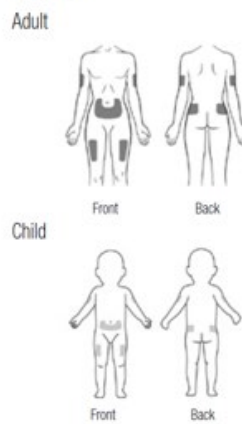
5. If you are not able to set the correct dose or if you drop the syringe, dispose of the syringe and use a new one.
6. You can now use the graduated pre-filled syringe as described in the "[Where should you give your injection?](#)" section and the "[How do you give your injection?](#)" section.

### 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



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

### It is important that you:

- **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.**
- **do not inject close to a vein.**

### How do you give your 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. Push 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.**

### **If you forget to use KINERET**

KINERET should be used regularly at the same time each day. If you miss your dose at the usual time, you should contact your doctor or nurse to discuss when you should use the next dose.

### **If you use too much KINERET**

If you think that you or anyone else have used too much KINERET, you may need urgent medical attention.

#### **You should immediately:**

- phone the Poisons Information Centre (in Australia telephone **13 11 26**. In New Zealand telephone **0800 POISON** or **0800 764 766**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

**You should do this even if there are no signs of discomfort or poisoning.**

## **5. What should I know while using KINERET?**

### **Things you should 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 using KINERET.
- Tell any other doctors, dentists, and pharmacists who treat you that you are taking this medicine.
- If you become pregnant while using this medicine, tell your doctor immediately.
- Keep all of your doctor's appointments so that your progress can be checked. KINERET may cause a 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 should not do**

- Do not try to inject yourself if you have not been trained.  
For instructions on how to inject yourself or your child with KINERET, please read the "[How to use KINERET](#)" section of this leaflet.
- 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 it has been frozen.

### **Helpful hints to manage injection site reactions**

- **swelling** - apply a cold pack to the injection site before and after injection
- **itching** - talk to your doctor or pharmacist. They may recommend a corticosteroid cream or antihistamine
- **bruising** - apply a cold pack to the injection site immediately after injection
- pain during and/or after injection:
  - Try different injection locations, see '[Where should you give your injection?](#)'. 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.

### **Driving or using machines**

**Be careful before you drive or use any machines or tools until you know how KINERET affects you.**

KINERET may cause dizziness in some people.

### **Looking after your medicine**

- 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 72 hours at room temperature (up to 25°C).
- Do not place it back in the refrigerator if it has been stored at room temperature.
- Do not store KINERET in the freezer.
- Do not let KINERET freeze.
- Do not shake KINERET.

Follow the instructions in the carton on how to take care of your medicine properly.

**Keep it where young children cannot reach it.**

**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.

### **Getting rid of any unwanted medicine**

After injecting KINERET, do not put the cover back on used needles. You should discard the used syringe with any remaining solution immediately into a sharps container. Do not put the used syringe into your normal household or recycling waste.

If you had a dose lower than 100 mg, you will have ejected liquid from the syringe onto a gauze or tissue. Discard the wet gauze or tissue into the sharps container 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.

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

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

## 6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

### Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none"> <li>headaches</li> <li>rash</li> <li>injection site reactions (ISRs).</li> </ul> <p>ISRs are reactions that occur at the site where KINERET is injected. These reactions include redness, swelling, bruising, itching and pain at the injection site. It is not unusual to experience mild to moderate stinging or injection site reactions, especially when you are beginning therapy. Most ISRs happen in the first 4 weeks of starting KINERET and usually resolve after about a month during continued use. See "<a href="#">Helpful hints to manage injection site reactions</a>".</p>	<p><b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b></p>

### Serious side effects

Serious side effects	What to do
<p><b>Serious infections:</b></p> <ul style="list-style-type: none"> <li>a persistent fever, shivers, cough or redness and tenderness of the skin or other signs of infection.</li> </ul> <p><b>Serious allergic reactions:</b></p> <ul style="list-style-type: none"> <li>swelling of the face, tongue or throat</li> <li>trouble swallowing</li> <li>itchy skin or rash</li> <li>wheezing, shortness of breath or difficulty breathing</li> <li>suddenly feeling fast pulse or sweating.</li> </ul> <p><b>Serious skin reaction:</b></p> <ul style="list-style-type: none"> <li>atypical, widespread rash, which may occur in conjunction with high body temperature and enlarged lymph nodes.</li> </ul> <p>Serious skin reaction, DRESS (drug reaction with eosinophilia</p>	<p><b>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</b></p>

and systemic symptoms), has rarely been reported in association with KINERET treatment, predominantly in patients with systemic juvenile idiopathic arthritis (SJIA).	
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**Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.**

Other side effects not listed here may occur in some people.

### Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems). By reporting side effects, you can help provide more information on the safety of this medicine.

**Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.**

## 7. Product details

This medicine is only available with a doctor's prescription.

### What KINERET contains

<b>Active ingredient (main ingredient)</b>	anakinra
<b>Other ingredients (inactive ingredients)</b>	<ul style="list-style-type: none"> <li>sodium citrate dihydrate</li> <li>sodium chloride</li> <li>disodium edetate</li> <li>polysorbate 80</li> <li>water for injections</li> </ul>

**Do not take this medicine if you are allergic to any of these ingredients.**

### What KINERET looks like

KINERET is a clear, colourless-to-white solution for injection and is supplied ready for use in a pre-filled syringe. It may contain some translucent-to-white particles of protein. The presence of these particles does not affect the quality of the product.

KINERET is available in packs of 28 syringes. AUST R 82872

### Who distributes KINERET

Swedish Orphan Biovitrum Pty Ltd  
Suite 3, Level 2, Building D,  
12-24 Talavera Road,  
Macquarie Park, NSW 2113

<https://au.sobi.com>

Medical enquiries: 1800 570 605

This leaflet was prepared in May 2025.