USING KINERET®(anakinra)

A guide for Healthcare Professionals (HCPs)

Please communicate the information outlined in this booklet to the patient/ caregiver, to ensure correct patient dosing and use of the graduated syringe including the correct injection technique when prescribing Kineret (anakinra) in Cryopyrin- Associated Periodic Syndromes (CAPS), Systemic Juvenile Idiopathic Arthritis (SJIA), and rheumatoid arthritis (RA).

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What the Kineret patient or carer will need:

1 Subcutaneous (SC) injection training by an appropriate healthcare professional

Although patients and caregivers can become confident in injecting at home, it can be daunting to begin with. The right education on SC injection technique when Kineret (anakinra) is initiated may ensure correct use. It is important to tell the patient/caregiver that injecting Kineret can sometimes make the skin react (see page 11).

2 Specific instruction on the graduated syringe

To ensure the correct dose is administered, careful guidance will need to be communicated on the use of the graduated syringe (see page 7).

3 Approved education material for patients

Sobi has produced a comprehensive booklet, *An Introduction to Kineret*, that should be given to all who use Kineret for CAPS, SJIA or RA to ensure appropriate use. This booklet, requested and approved by the regulatory authorities, should be handed to the patient and/or their caregiver when they start using Kineret.

Request printed copies

Download digital copy

What patients and caregivers need to know

Once you have discussed Kineret (anakinra) with the patient or caregiver and agreed that it should be prescribed, the following practical information should be covered.

How to inject Kineret

The patient or caregiver will need to receive appropriate instruction on how to give a subcutaneous injection, either to themselves or to the patient in their care.

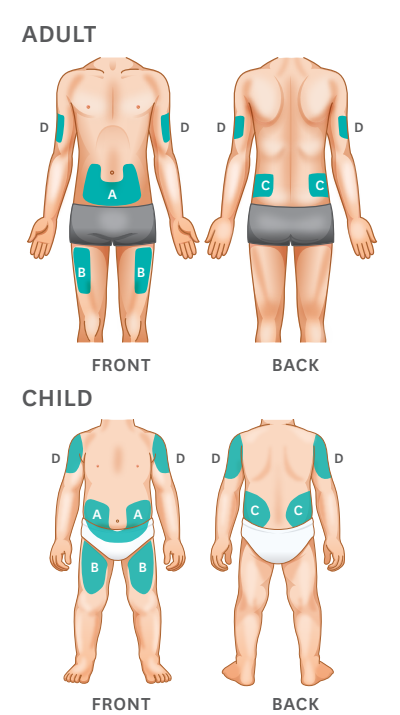
Where to inject Kineret

The most suitable places to inject are:

- **A** the abdomen (except for the area around the navel)
- **B** the top of the thighs (this is especially good for infants under a year if they have slightly chubby legs)
- **C** the upper outer areas of the buttocks*; and
- **D** the outer area of the upper arms*

*Only suitable if a caregiver is giving the injection

- Do not inject into skin that is tender, red, bruised, or hard
- Avoid scars or stretch marks
- Do not inject close to a vein



It is helpful to advise the patient/caregiver to change the injection site each time, so that the area does not become sore.

Dosing for CAPS and SJIA[1]

The dose of Kineret (anakinra) should be calculated and adjusted in line with the recommended dosage in the Australian approved Product Information (PI). It is vital that the patient or caregiver fully understands the dose in milligrams and graduations on the syringe.

See below for further instructions on delivering the appropriate dose.

Kineret CAPS and SJIA Initiation Dose	
All CAPS Subtypes	SJIA
1-2 mg/kg/day	2 mg/kg/day up to 100 mg/day

Kineret Maintenance Dose		
Mild CAPS (FCAS/mild disease)	Severe CAPS (MWS, NOMID/CINCA)	SJIA
1-2 mg/kg/day (Often not necessary to increase the dose)	3-4 mg/kg/day up to 8 mg/kg/day	2 mg/kg/day up to 100 mg/day

For SJIA

The recommended dose in SJIA (in patients aged 2 years or more) is 2 mg/kg/day up to a maximum of 100 mg/day by SC injection. See the Australian approved PI for full dosage and follow-up details, including different patient populations.

For CAPS, dose by severity[1]

Starting dose:

The recommended starting dose in all CAPS subtypes is 1-2 mg/kg/day by subcutaneous injection.

Maintenance dose in mild CAPS (FCAS, mild MWS):

Patients are usually well-controlled by maintaining the recommended starting dose (1-2 mg/kg/day).

Maintenance dose in severe CAPS (MWS and NOMID/CINCA):

Dose increases may become necessary within 1-2 months based on therapeutic response. The usual maintenance dose in severe CAPS is 3-4 mg/kg/day, which can be adjusted to a maximum of 8 mg/kg/day.

In addition to the evaluation of clinical symptoms and inflammatory markers in severe CAPS, assessments of inflammation of the CNS, including the inner ear (by MRI or CT, lumbar puncture, and audiology) and eyes (ophthalmological assessments) are recommended after an initial 3 months of treatment, and thereafter every 6 months, until effective treatment doses have been identified. When patients are clinically well-controlled, CNS and ophthalmological monitoring may be conducted yearly.

See Product Information for full dosage and follow-up details, including different patient populations. Scan the QR code or visit www.mbclink.com.au/kineretPI.

Ensure the appropriate dose is given

Kineret (anakinra) is supplied ready for use in a graduated pre-filled syringe. The marks on the side of the syringe indicate the milligrams.

The syringe allows for doses between 20 and 100 mg. As the minimum dose is 20 mg, Kineret is not approved for use in paediatric patients with a body weight below 10 kg. If less than 100 mg is to be administered, some of the liquid will need to be discarded. Instructions for the patient on how to do this appear in the Kineret patient booklet.

Do not transfer Kineret to another syringe and do not store any unused portion of the injection solution for later use.

As a healthcare professional, you will need to calculate the dose to be used, based initially on the weight of the patient. This dose may be adjusted later based on therapeutic response. In addition, the dose will need to be adjusted to the nearest dose which can be delivered from one or more graduated syringes.

As Kineret can only be administered as 20 to 100 mg per injection in 10 mg increments, it is important that the prescribed dose allows for this administration.

Dose calculation examples

CAPS

Harry

Harry suffers from severe Muckle-Wells Syndrome and needs a dose of 4-5 mg/kg/day.
Harry's weight is 45 kg.
Daily dose = 45 kg x 4-5 mg/kg/day = 180-225 mg/day
Here, it is most practical to prescribe 200 mg per day to be given at suitable times, approximately the same every day.

Lucy

Lucy is recently diagnosed with NOMID/CINCA syndrome and has ceased responding to her initial dose of 1-2 mg/kg/day. She now needs a dose increase to 2-3 mg/kg/day.
Lucy's weight is 12 kg.
New daily dose = 12 kg x 2-3 mg/kg/day = 24-36 mg/day
You could prescribe 30 mg of Kineret® (anakinra) once daily to be used around the same time each day (preferably in the morning to have the highest concentration during the daytime period).

Safety considerations[1,2]

Common adverse reactions are:

- Serious infections
- Headache
- Neutropenia
- Injection site reactions
- Thrombocytopaenia
- Increased cholesterol

Injection-site reactions are the most common adverse reactions with Kineret treatment.

Neutropenia

Kineret treatment should not be initiated in patients with neutropenia (ANC $<1.5 \times 10^9$/L). As neutropenia may occur in patients treated with Kineret, it is important to monitor neutrophil counts prior to initiating Kineret treatment and monthly after initiation of therapy for the first six months and quarterly thereafter.

Should a patient develop neutropenia, Kineret treatment should be discontinued and neutrophil counts should be monitored closely.

Please see approved Product Information for full list of precautions, contraindications and adverse reactions.

Managing injection site reactions

Explain that injecting Kineret (anakinra) can sometimes make the skin react. Such reactions typically appear within weeks of starting treatment and disappear within 4-6 weeks. The reactions are usually mild to moderate and take the form of **redness, bruising, inflammation, pain, itching or discomfort**. Skin reactions are unlikely to occur if they haven't happened in the first month of treatment.

Tips that might help alleviate the signs and symptoms of injection site reactions (ISRs) are included in the booklet, *An Introduction to Kineret*, for patients and caregivers. Feel free to discuss them together:

The syringe should be left out of the fridge for approximately 30 minutes and allowed to warm to room temperature or be warmed in the hand before injecting

The patient should be clearly instructed NOT to heat the syringe in hot water, in a microwave oven, or by any other means.

Be sure to rotate injection sites

Cool the injection site with an ice pack before and after injecting

You may recommend applying hydrocortisone or antihistamine cream to the injection site if the patient's general health status allows. Prophylaxis with hydrocortisone cream, ideally 30-60 minutes before the injection, may be used in all patients for the first 3-6 months of treatment to reduce the frequency of ISRs

For optimal Kineret use by patients and caregivers, please ensure you provide them with the following:

- Training on good subcutaneous injection technique and site rotation
- The approved patient booklet, *An Introduction to Kineret*
- Education on how to give the correct dose using the graduated syringe
- Information on safe disposal of medical sharps in accordance with local requirements
- An HCP's contact number in case the patient/caregiver needs additional support using Kineret

PBS Information: This product is not PBS listed for SJIA or RA

PBS Information: Authority Required. Moderate to severe CAPS (STREAMLINED Authority)
This product is listed on the PBS as a section 100 item. Refer to PBS Schedule for full authority information.

PLEASE REVIEW THE KINERET PRODUCT INFORMATION BEFORE PRESCRIBING (available from www.mbclink.com.au/kineretPI)

Useful resources

Download a digital copy of this guide

Download the Kineret Product Information

Download the Kineret Consumer Medicine Information

Download a digital copy of *An introduction to Kineret: A guide for patients and caregivers*

Request printed copies of *An introduction to Kineret: A guide for patients and caregivers*

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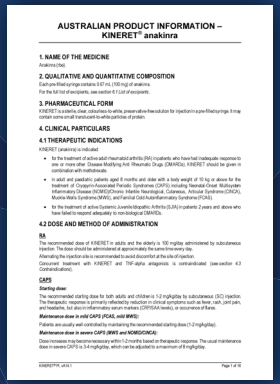
Consumer Medicine Information (CMI)

What is in this leaflet

What KINERET is used for

Before you use KINERET


AUSTRALIAN PRODUCT INFORMATION – KINERET® anakinra

1. NAME OF THE MEDICINE

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

3. PHARMACEUTICAL FORM

4. CLINICAL PARTICULARS

4.1 THERAPEUTIC INDICATIONS

4.2 DOSE AND METHOD OF ADMINISTRATION

AN INTRODUCTION TO KINERET® (anakinra)

A guide for patients and caregivers

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Swedish Orphan Biovitrum Pty Ltd, Suite 3, Level 2, Building D, 12-24 Talavera Road, Macquarie Park, NSW 2113
Website: https://au.sobi.com **Medical enquiries:** 1800 570 605

References: 1. Kineret (anakinra) Product Information. 2. Kineret (anakinra) Consumer Medicine Information.

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