Kineret®
(anakinra)

# A guide for Healthcare Professionals (HCPs)

When prescribing Kineret in Cryopyrin-Associated Periodic Syndromes (CAPS), please communicate the information outlined in this booklet to the patient/caregiver, to ensure correct patient dosing and use of the graduated syringe including injection technique.

sobi
Pioneer in Rare Diseases

# What the Kineret user will need

## 1. Subcutaneous (s.c.) injection training by an appropriate healthcare professional

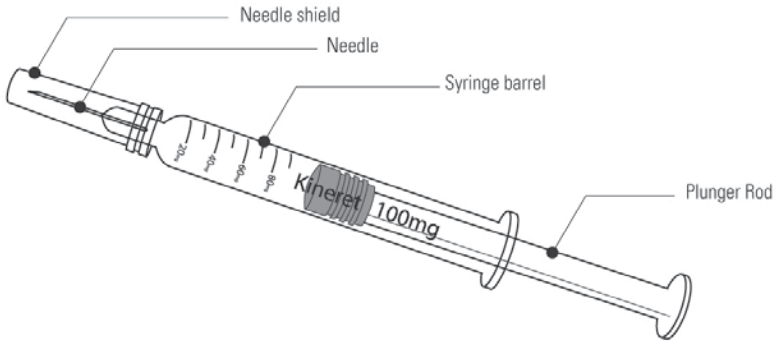
Although patients and carers can become confident in injecting at home, it can be daunting to begin with. The right education on s.c. injection technique when Kineret is initiated will ensure correct use. It is important to tell the patient/caregiver that injecting Kineret can sometimes make the skin react (see page 7).

## 2. Approved education material

Sobi has produced a comprehensive Kineret patient/caregiver booklet which should be given to all who use Kineret for reference to ensure appropriate use. This booklet, requested and approved by the regulatory authorities, should be handed to the patient/caregiver when they start using Kineret.


## 3. Specific instruction on the graduated syringe

To ensure the correct dose is administered, careful guidance will need to be communicated on use of the graduated syringe (see page 5).



# Facts patients and caregivers need to know about Kineret

Once you have discussed Kineret in principle with the patient/caregiver and agreed that Kineret should be prescribed, the following practical information should be covered.

## 1. How to give s.c. injection and appropriate sites

The patient and/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.

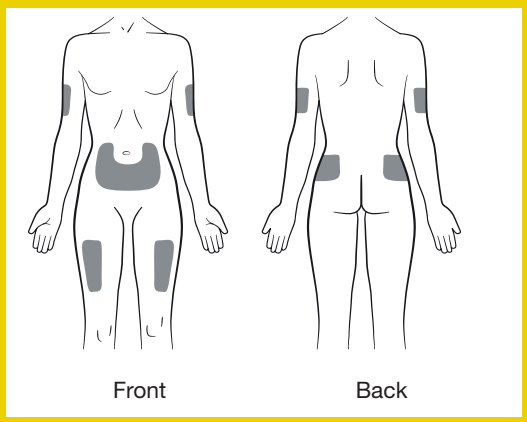
### Where to inject Kineret

The most suitable places to inject are:

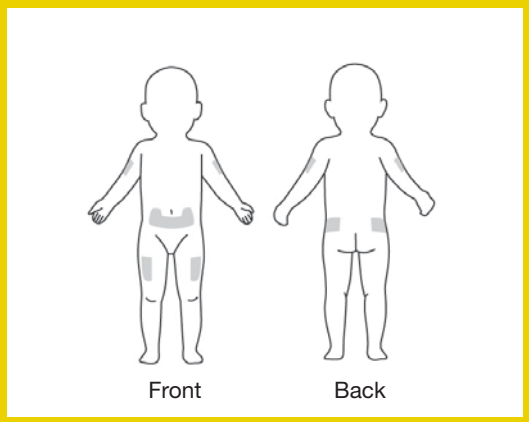
- the abdomen (except for the area around the navel)
- the top of the thighs (this is especially good for infants under a year if they have slightly chubby legs)
- the upper outer areas of the buttocks*; and
- the outer area of the upper arms*.

* Only really suitable if a caregiver is giving the injection

**Adult**




**Child**




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

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



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# Ensuring the appropriate dose is prescribed and delivered

**The dose of Kineret should be calculated and adjusted in line with the recommended dosage in the Summary of Product Characteristics. It is vital that the patient or caregiver fully understands the dose in milligrams and graduations on the syringe. See page 5 for further instructions on delivering the appropriate dose.**

| Kineret CAPS initiation dose |
|---|
| 1-2 mg/kg/day |

| Kineret CAPS maintenance dose | |
|---|---|
| FCAS/mild disease | Severe disease |
| Often not necessary to increase the dose | 3-4 mg/kg/day up to 8 mg/kg/day |

## 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):

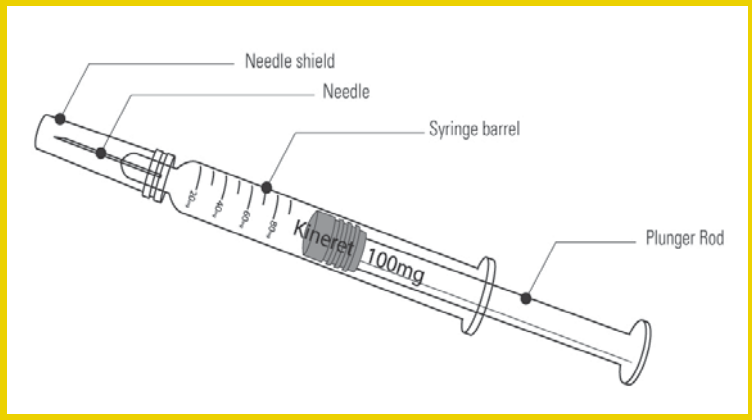
Dose increases may become necessary within 1-2 months based on therapeutic response. The usual maintenance dose in severe CAPS is 3-4 mg/kg/day, which can be adjusted to a maximum of 8 mg/kg/day.

In addition to the evaluation of clinical symptoms and inflammatory markers in severe CAPS, assessments of inflammation of the CNS, including the inner ear (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 Summary of Product Characteristics (SPC) for full dosage and follow-up details, including different patient populations.**

# Ensuring the appropriate dose is given

**Kineret is supplied ready for use in a graduated pre-filled syringe. The marks on the side of the syringe indicate the milligrams. The graduated syringe should be used as it enables accurate dosing in CAPS patients.**




The graduated pre-filled 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.

As a health care professional you will need to calculate the dose to be used, based initially on the weight of the patient and 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 20-100 mg per injection in 10 mg increments, it is important that the prescribed dose allows for this dosing.**

## Dose calculation examples:

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 4-5mg/kg/day = 180-225 mg/day.
Here it is most practical to prescribe 200 mg per day to be given at suitable times, roughly the same every day.

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.
Daily dose = 12 kg x 2-3 mg/kg/day = 24-36 mg/day.
You could prescribe 30 mg of Kineret once daily to be used around the same time each day (preferably in the morning to have the highest concentration during the daytime period).



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# Safety considerations

Adverse reactions may occur when treating with Kineret.

The most severe common adverse reactions are:

- **Serious infections**
- **Neutropenia**

## Infections

It is not recommended to initiate Kineret treatment in a patient with an ongoing infection. In CAPS patients, there is a risk of disease flares when discontinuing Kineret treatment. This should be taken into account when deciding on discontinuing Kineret during a severe infection.

## Neutropenia

Kineret treatment **should not be** initiated in patients with neutropenia. 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.

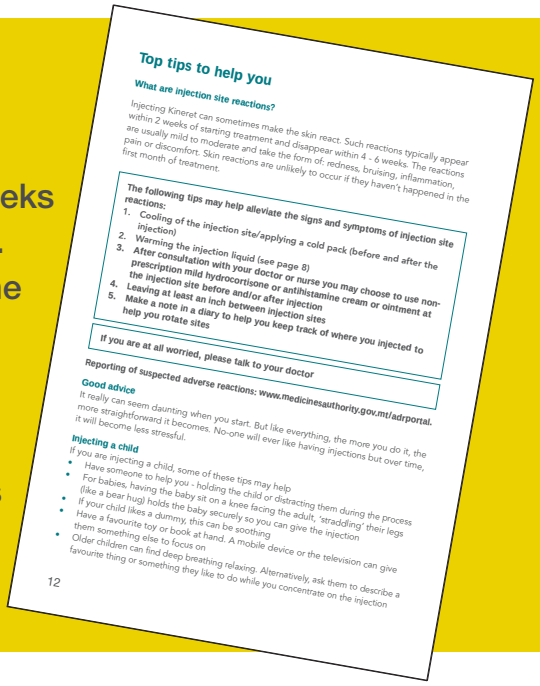
Should a patient develop neutropenia, Kineret treatment should be discontinued and neutrophil counts should be monitored closely.

## The most common adverse reactions are injection-site reactions

### General advice for patients and caregivers

**Explain that injecting Kineret can sometimes make the skin react. Such reactions typically appear within 2 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 or discomfort. Skin reactions are unlikely to occur if they haven't happened in the first month of treatment.**

**Tips which may help alleviate the signs and symptoms of injection site reactions are included in the Kineret Patient booklet.**



Top tips to help you

What are injection site reactions?

Injecting Kineret can sometimes make the skin react. Such reactions typically appear within 2 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 or discomfort. Skin reactions are unlikely to occur if they haven't happened in the first month of treatment.

The following tips may help alleviate the signs and symptoms of injection site reactions:

1. Cooling of the injection site/applying a cold pack (before and after the injection)
2. Warming the injection liquid (see page 8)
3. After consultation with your doctor or nurse you may choose to use non-prescription mild hydrocortisone or antihistamine cream or ointment at the injection site before and/or after injection
4. Leaving at least an inch between injection sites
5. Make a note in a diary to help you keep track of where you injected to help you rotate sites

If you are at all worried, please talk to your doctor

Reporting of suspected adverse reactions: www.medicinesauthority.gov.mt/adrportal.

Good advice

It really can seem daunting when you start. But like everything, the more you do it, the more straightforward it becomes. No-one will ever like having injections but over time, it will become less stressful.

Injecting a child

If you are injecting a child, some of these tips may help

- Have someone to help you - holding the child or distracting them during the process
- For babies, having the baby sit on a knee facing the adult, 'straddling' their legs (like a bear hug) holds the baby securely so you can give the injection
- If your child likes a dummy, this can be soothing
- Have a favourite toy or book at hand. A mobile device or the television can give them something else to focus on
- Older children can find deep breathing relaxing. Alternatively, ask them to describe a favourite thing or something they like to do while you concentrate on the injection

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**Reporting of suspected adverse reactions: www.medicinesauthority.gov.mt/adrportal.**

## Tips to manage injection site reactions

Patients should be advised to cool the injection site, e.g. by using an ice pack, before and after the injection.

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

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

To further alleviate any injection-site reactions you may recommend anti-histamine or hydrocortisone cream or ointment 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 injection-site reactions.

**In summary; for optimal Kineret use by patients and caregivers please make sure you cover the following important points:**

- **Training on good subcutaneous injection technique and site rotation**
- **Provide to all patients and caregivers the approved Kineret patient booklet**
- **Ensure they know how to give the right dose using the graduated syringe**

If there is a contact number to access a HCP for additional help please provide it to the patient/caregiver to support them in using Kineret in CAPS.

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