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 Still's disease—including Systemic Juvenile Idiopathic Arthritis (SJIA) and Adult-Onset Still's Disease (AOSD), Cryopyrin-Associated Periodic Syndromes (CAPS) and Familial Mediterranean Fever (FMF).

Kineret® (anakinra)

sobi

What you as a HCP need to know

What the Kineret® patient will need:

1 Subcutaneous (s.c.) 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 s.c. injection technique when Kineret® 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 12).

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 10).

3 Approved education material

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

What patients and caregivers need to know

Once you have discussed Kineret® 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.

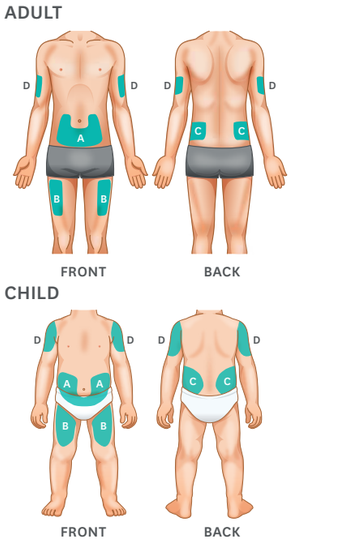
Where to inject Kineret®

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 the area does not become sore.

Indications for Kineret®

Cryopyrin-Associated Periodic Syndromes (CAPS)

Kineret® is indicated in adults, adolescents, children and infants aged 8 months and older with a body weight of 10 kg or above for the treatment of CAPS, including:

- Neonatal-Onset Multisystem Inflammatory Disease (NOMID) / Chronic Infantile Neurological, Cutaneous, Articular Syndrome (CINCA)
- Muckle-Wells Syndrome (MWS)
- Familial Cold Autoinflammatory Syndrome (FCAS)

Familial Mediterranean Fever (FMF)

Kineret® is indicated for the treatment of Familial Mediterranean Fever (FMF). Kineret® should be given in combination with colchicine, if appropriate.

Still's disease

Kineret® is indicated in adults, adolescents, children and infants aged 8 months and older with a body weight of 10 kg or above for the treatment of Still's disease, including Systemic Juvenile Idiopathic Arthritis (SJIA) and Adult-Onset Still's Disease (AOSD), with active systemic features of moderate to high disease activity, or in patients with continued disease activity after treatment with non-steroidal anti-inflammatory drugs (NSAIDs) or glucocorticoids.

Kineret® can be given as monotherapy or in combination with other anti-inflammatory drugs and disease-modifying antirheumatic drugs (DMARDs).

Calculate your patient's dose

The dose of Kineret® should be calculated and adjusted in line with the recommended dosage in the Summary of Product Characteristics (SPC). 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.

See the SPC for full dosage and follow-up details, including different patient populations.

For Still’s disease, dose by weight

Starting dose for patients weighing 50 kg or more:

The recommended starting dose in patients who weigh 50 kg or more is 100 mg/day by subcutaneous injection.

Starting dose for patients weighing less than 50 kg:

Patients who are less than 50 kg should be dosed by body weight with a starting dose of 1-2 mg/kg/day by subcutaneous injection.

Dose adjustment in children (<18 years):

Response to treatment should be evaluated after 1 month. In case of persistent systemic manifestations or inadequate response, dose can be escalated up to 4 mg/kg/day, or continued treatment with Kineret® should be reconsidered.

Dosing for Still’s disease

Kineret® Still's disease initiation dose	
Weighs 50 kg or more	**Weighs less than 50 kg**
100 mg/day	1-2 mg/kg/day
Kineret® Still’s disease dose adjustment	
Can be increased up to 4 mg/kg/day for patients under 18 years	

Dosing for CAPS

The dose of Kineret® should be calculated and adjusted in line with the recommended dosage in the Summary of Product Characteristics (SPC). It is vital that the patient or caregiver fully understands the dose in milligrams and graduations on the syringe.

See page 10 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
1-2 mg/kg/day (often not necessary to increase the dose)	3-4 mg/kg/day up to 8 mg/kg/day

For CAPS, dose by severity

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 the SPC for full dosage and follow-up details, including different patient populations.

Dosing for FMF

The recommended dose for patients weighing 50 kg or more is 100 mg/day by subcutaneous injection.
In patients weighing less than 50 kg, Kineret® should be dosed by body weight with a recommended dose of 1-2 mg/kg/day.

In children with inadequate response the dose can be escalated up to 4 mg/kg/day.

Kineret® FMF initiation dose	
Weighs 50 kg or more	**Weighs less than 50 kg**
100 mg/day	1-2 mg/kg/day
Kineret® FMF dose adjustment	
Can be increased up to 4 mg/kg/day for patients under 18 years	

Ensure 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 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 healthcare professional, you will need to calculate the dose to be used, based initially on the weight of the patient, and may later be adjusted based on therapeutic response.[1] 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

Still's disease and FMF

Julia is being treated for Still's disease and needs a dose of 1-2 mg/kg/day.

Julia's weight is 13 kg.

Daily dose = 13 x 1-2 mg/kg/day = 13-26 mg/day

Here, it is most practical to prescribe 20 mg per day to be given at suitable times, approximately the same every day.

Andrei is being treated for FMF and has ceased responding to his initial dose of 1-2 mg/kg/day. He now needs a dose increase to 4 mg/kg/day.

Andrei's weight is 17 kg.

New daily dose = 17 x 4 mg/kg/day = 68 mg/day

In this case, you will want to prescribe 70 mg per day to be given at suitable times, approximately the same every day.

CAPS

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, approximately 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.

New 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).

Managing injection site reactions

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 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 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 make sure to 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 medicine sharps in accordance with local requirements
- An HCP's contact number in case the patient/caregiver needs additional support using Kineret®

Please refer to the Kineret® SmPC available from www.medicines.ie or www.ema.europa.eu for complete information on how to use the product safely and effectively.

Reporting of adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via: HPRA Pharmacovigilance Website www.hpra.ie

Adverse events should also be reported to Swedish Orphan Biovitrum Ltd by email at medical.info.uk@sobi.com or by telephone +44 (0) 800 111 4754

Further information:

Should you require additional information regarding the use of anakinra or require additional materials please contact Sobi UK & Ireland Medical Information team via

Email: medical.info.uk@sobi.com

Phone: +44 (0) 800 111 4754.

Notes

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