AN INTRODUCTION TO KINERET®
"Anakinra"

A GUIDE FOR PATIENTS AND CAREGIVERS

This document is approved by The Executive Directorate of Pharmacovigilance, at SFDA

Kineret® (anakinra)

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Introduction

This booklet has been given to you because you, or someone in your care, has been prescribed Kineret® (anakinra).

Your doctor probably has already told you about the condition that Kineret® is being used to treat.

Coming to terms with a diagnosis may be challenging but finding a treatment that works for you may help you manage your symptoms.

Injecting yourself or your child may seem difficult when you first begin, but there are tips and tricks that might make it easier to incorporate Kineret into your daily routine. As you read through this booklet, keep in mind that every patient is different. You should talk to your doctor about how this information applies to you.

TIPS

If you come across an unfamiliar word or medical term, flip to the glossary on page 13 to find some helpful definitions.

Everybody is different and your doctor or nurse is best placed to answer any specific questions about the diagnosis and management in your particular situation.

What is Kineret®?

Kineret® (anakinra) is a liquid that is given by an injection under the skin. Kineret is the brand name for a product called anakinra – you may hear some doctors refer to it this way. The medication belongs to a category of drugs known as "human interleukin-1 receptor antagonists"; these are man-made proteins that are almost identical to proteins that are found naturally in the body. They are sometimes referred to as IL-1 antagonists or IL-1Ra, but in this booklet just call it Kineret.

Kineret works by blocking the protein (interleukin-1) that may be overproduced in certain diseases. This protein leads to inflammation. By controlling the inflammation, Kineret reduces the disease symptoms and may help to protect against long-term complications.

TIP:

Don't worry if this all seems complicated. You don't need to understand the science to get the best out of a medication. Your doctor and their team are the experts you can rely on them to advise on what's right in your case.

What conditions are treated with Kineret®?

Kineret is used to manage a range of conditions, such as Cryopyrin-Associated Periodic Syndromes (CAPS), Familial Mediterranean Fever (FMF), and Still's disease, including Systemic Juvenile Idiopathic Arthritis (SJIA) and Adult-Onset Still's Disease (AOSD). Your doctor or nurse will be able to answer all of your questions about the illness for which Kineret has been prescribed – you only need to ask.

Getting started with Kineret®

Injecting at home can seem like a challenge—but it will get easier once you get more experienced. You will always be trained by qualified healthcare professionals, which can help you feel confident in the process.

What does Kineret®(anakinra) look like?

Kineret® comes in packs of 7 syringes that need to be kept in the refrigerator.

Each syringe is pre-filled with Kineret® so there is no need to mix anything. It is ready to go.

The syringe is 'graduated'—it has marks on the side to help you inject the right amount.

Graduations are marked in milligrams (mg). The doctor will advise you on your dose.

Inside the syringe is a clear, colourless-to-white solution that may contain some white particles. The presence of these particles does not affect the quality of the product.

How much Kineret® is needed?

Your doctor will work out what dose is right for you or your child. It depends on weight and the severity of the symptoms, so the dose may change over time.

When should Kineret be given?

Kineret® is given daily by injection. It is a good idea to give the injection at the same time every day.

Set up for injection

Find a well-lit, comfortable, clear and clean area where you have enough space to have all the equipment you need within reach. Wash your hands thoroughly.

You will need:

- ✔ **Kineret®(anakinra) pre-filled syringe(s)**
- ✔ **Alcohol wipes**
- ✔ **A sterile gauze or tissue**

Make sure you will be able to dispose of any elements in the way your doctor or nurse advised before you go any further.

TIPS:

- *Remember to keep the remaining syringes in the fridge.*
- *Do not shake the syringe. If it seems foamy, allow a few minutes for the solution to clear.*
- *Make sure the alcohol wipe is easy to remove from the packaging as you will have a syringe in your hand when you wipe the skin.*

Inspect the syringe

Check the expiry date on the pre-filled syringe label (look for letters EXP). Don't use the syringe if the date is after the end of the month shown.

Check the appearance of liquid in the syringe. It must be a clear, colourless-to-white solution. There may be some translucent-to-white particles in the solution—this is normal. Don't use the syringe if the solution is discoloured or cloudy, or if any particles other than translucent-to-white ones can be seen.

Get ready to inject

Let the solution warm up

Kineret® (anakinra) needs to be stored in the refrigerator and out of reach and sight of children. For a more comfortable injection, take the syringe out of the refrigerator 30 minutes before you intend to give it. Make sure it is in a safe place out of the sight and reach of children and allow it to warm to room temperature. Alternatively, you can hold the pre-filled syringe in your hand gently warming it for a few minutes. Don't warm Kineret in any other way (for example, do not warm it in a microwave or in hot water).

Don't remove the cover from the syringe until you are ready to inject.

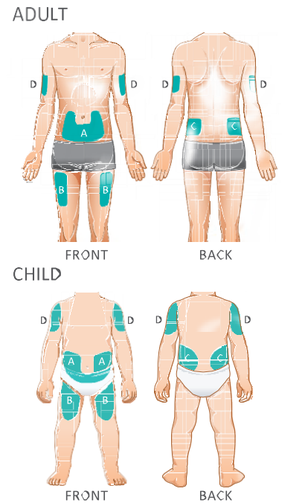
Choose an injection site

The best places to inject yourself or your child 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**



Change the place that you inject each time so one area does not become sore.

Prepare the dose

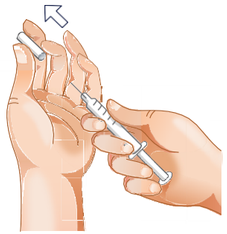
Before you inject Kineret® (anakinra) you need to hold the syringe barrel and gently remove the cover from the needle without twisting. Pull straight as shown. Don't touch the needle or push the plunger. Discard the needle cover straight away.

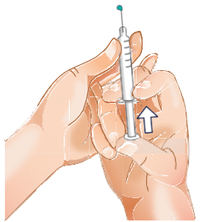
You may notice a small air bubble in the pre-filled syringe. You don't have to remove the air bubble before injecting. Injecting the solution with the air bubble is harmless.

If you are using less than 100 mg – that is less than all the solution in the syringe – you will need to discard some of the liquid

To do this:

- Hold the syringe in one hand with the needle pointing straight upwards as shown here. Put your thumb on the plunger rod and push slowly until you see a tiny liquid drop at the tip of the needle.
- Turn the syringe so 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.
- 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. Now the correct dose is ready to be injected.
- If you are not able to set the correct dose or if you drop the syringe, dispose of it and use a new one. This just means going to the next box earlier, so remember to order your next supply earlier too. Always follow the dosage instructions given by your doctor or nurse.





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

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).

2.
Pinch the skin between your thumb and forefinger, without squeezing.

3.
Put the needle fully into the skin as shown by your nurse or doctor.

4.
Inject the liquid slowly and evenly, always keeping the skin pinched.

5.
After injecting the liquid, remove the needle and let go of the skin.

If you'd like, you can hold a little cotton wool or tissue over the injection site.

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

TIPS FOR INJECTING A CHILD:

If possible, have someone hold your child or distract them while you deliver the injection.

If you are injecting a baby, face the baby toward you so they straddle your knee. This helps hold the baby securely so you can give the injection.

If your child likes a pacifier, 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.

Clean up

- *Don't put the cover back on the needle of the syringe.*
- *Keep used syringes out of reach and sight of children.*
- *Never put the pre-filled syringes that you have used into your normal household rubbish bin.*
- *If you used a dose lower than 100 mg you will have liquid from the syringe on a gauze or tissue. Discard the wet gauze or tissue with your syringe and clean the surface with a fresh tissue.*
- *The used syringe and any gauze or tissue with Kineret® (anakinra) solution on them should be disposed of as the doctor, nurse or pharmacist advised. If you have medicine you no longer need, ask the pharmacist what you should do—this will help to protect the environment.*

Injection site reactions

Injecting Kineret® (anakinra) 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 ISRs:

Cool the injection site or apply a cold pack (before and after the injection)

Allow the injection liquid to reach room temperature before injecting it (see page 7)

Leave at least an inch between injection sites

After consulting 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

Make a note in a diary to help you keep track of where you injected to ensure site rotation

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

Make a note of any questions you have for your next visit to the doctor

Glossary of terms

ABDOMEN – Tummy

ADULT-ONSET STILL'S DISEASE (AOSD) – A subset of Still's disease that affects people16 years and older

ALCOHOL WIPE – Disinfectant in a disposable cloth

ANTIHISTAMINE – A cream, ointment, or tablet that reduces swelling and irritation

BARREL – Central tube on syringe

BUTTOCKS – Bum or bottom

CRYOPYRIN-ASSOCIATED PERIODIC SYNDROMES (CAPS) – A name for a collection of rare conditions which cause episodes of, or continuous, inflammation

DOSE – Quantity of medicine

EXPIRY DATE (EXP) – The last date a medicine should be used

FAMILIAL MEDITERRANEAN FEVER (FMF) - A genetic disorder that causes recurrent episodes of fever that are typically accompanied by pain in the abdomen, chest, or joints.

GRADUATED – The marks on the side of the syringe to show how much medicine to give

HUMAN INTERLEUKIN-1 RECEPTOR ANTAGONIST – A man-made protein used as a medicine to block the natural interleukin-1 which causes inflammation

HYDROCORTISONE - An ointment, cream, or solution used on the skin to treat redness, itching, and discomfort

INFLAMMATION – Area of the body which shows signs of pain, redness, heat, swelling, and may have loss of function

INJECTION SITE – Place where the injection is given

KINERET® (ANAKINRA) – Brand name for a medicine called anakinra, a drug in a group known as 'human interleukin-1 receptor antagonists'

PARTICLE – Small object

PHARMACIST – Chemist

PLUNGER – The rod that is pushed into the syringe to push medicine out

PRE-FILLED SYRINGE – A syringe that comes with medicine already in it

STILL'S DISEASE – A rare inflammatory condition

SYSTEMIC JUVENILE IDIOPATHIC ARTHRITIS (SJIA) – A subset of Still's disease that affects children under 16 years

To report adverse events or safety concerns, contact:

The National Pharmacovigilance Centre (NPC) Saudi Food and Drug Authority (SFDA):

- SFDA call center: 19999
- E-mail: npc.drug@sfda.gov.sa
- Website: https://ade.sfda.gov.sa

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- Email: pv-ksa@sobi.com

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