

Package leaflet: Information for the user

Kineret 100 mg/0.67 ml solution for injection in pre-filled syringe Anakinra

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Kineret is and what it is used for
2. What you need to know before you use Kineret
3. How to use Kineret
4. Possible side effects
5. How to store Kineret
6. Contents of the pack and other information

1. What Kineret is and what it is used for

Kineret contains the active substance anakinra. This is a type of cytokine (an immunosuppressive agent) that is used to treat:

- Rheumatoid Arthritis (RA)
- Periodic fever syndromes:
 - Cryopyrin-Associated Periodic Syndromes (CAPS)
 - o Neonatal-Onset Multisystem Inflammatory Disease (NOMID), also called Chronic Infantile Neurological, Cutaneous, Articular Syndrome (CINCA),
 - o Muckle-Wells Syndrome (MWS),
 - o Familial Cold Autoinflammatory Syndrome (FCAS)
 - Familial Mediterranean Fever (FMF)
- Still's disease including Systemic Juvenile Idiopathic Arthritis (SJIA) and Adult-Onset Still's Disease (AOSD)

Cytokines are proteins made by your body that co-ordinate communication between cells and help control cell activity. In RA, CAPS, FMF and in Still's disease, your body produces too much of a cytokine called interleukin-1. This results in harmful effects leading to inflammation, causing the symptoms of the disease. Normally, your body produces a protein that blocks the harmful effects of interleukin-1. The active substance of Kineret is anakinra, this works in the same way as your natural interleukin-1 blocking protein. Anakinra is produced by DNA technology using the micro-organism *E. coli*.

For RA, Kineret is used to treat the signs and symptoms of the disease in adults (age 18 years and over) in combination with another medicine called methotrexate. Kineret is for patients whose response to methotrexate on its own is not good enough to control the rheumatoid arthritis.

For CAPS, Kineret is used to treat the signs and symptoms of inflammation associated with the disease such as rash, joint pain, fever, headache and fatigue in adults and children (age 8 months and older).

For FMF, Kineret is used to treat the signs and symptoms of inflammation associated with the disease such as recurrent fever, fatigue, abdominal pain, muscle or joint pain and rash. Kineret can be used together with colchicine, if appropriate.

For Still's disease, Kineret is used to treat the signs and symptoms of inflammation associated with the disease such as rash, joint pain and fever.

2. What you need to know before you use Kineret

Do not use Kineret

- if you are allergic to anakinra or any of the other ingredients of this medicine, listed in section 6;
- if you are allergic to other products that are produced by DNA technology using the micro-organism *E. coli*;
- if you have neutropenia (low white blood cell count) determined after a blood test.

Contact your doctor immediately

- if you get a rash all over your body, shortness of breath, wheezing, fast pulse or sweating after your Kineret injection. These may be signs that you are allergic to Kineret.
- if you have ever developed an atypical, widespread rash or skin peeling after taking Kineret.

Warnings and precautions

Talk to your doctor before using Kineret:

- if you have a history of recurring infections, or if you suffer from asthma. Kineret may worsen these conditions;
- if you have cancer. Your doctor will have to decide if you can still be given Kineret;
- if you have a history of increased levels of liver enzymes;
- if you require vaccinations. You must not be given live vaccines while being treated with Kineret.

Still's disease

- In rare cases patients with Still's disease, mainly children, may develop lung disease, also during Kineret treatment. The risk may be increased in patients with Down's syndrome (trisomy 21). Symptoms of lung disease can be e.g. shortness of breath during light exercise, morning cough, and difficulties breathing. If you develop signs of lung disease you should contact your health care provider as soon as possible.
- The serious skin reaction, DRESS (drug reaction with eosinophilia and systemic symptoms), has rarely been reported in association with Kineret treatment, predominantly in patients with systemic juvenile idiopathic arthritis (SJIA). Seek medical attention immediately if you notice an atypical, widespread rash, which may occur in conjunction with high body temperature and enlarged lymph nodes.

Children and adolescents

- RA: Use of Kineret in children and adolescents with Rheumatoid Arthritis has not been fully investigated and therefore cannot be recommended.
- CAPS, FMF, Still's disease: Kineret is not recommended for children younger than 8 months of age because there is no data in this age group.

Other medicines and Kineret

Tell your doctor if you are taking, have recently taken or might take any other medicines.

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

When you start taking Kineret the chronic inflammation in your body will decrease. This could mean that the doses of some other medicines, e.g. warfarin or phenytoin, have to be adjusted.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.

Kineret has not been tested in pregnant women. Use of Kineret is not recommended during pregnancy and in women of childbearing potential not using contraception. It is important to tell your doctor if you are pregnant, if you think you may be pregnant or are planning to have a baby. Your doctor will discuss with you the potential risks of taking Kineret during pregnancy.

It is not known whether anakinra is excreted in human milk. You must not breast-feed if you use Kineret.

Kineret contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per 100 mg dose, that is to say essentially 'sodium-free'.

3. How to use Kineret

Always use this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure. Kineret must be injected under your skin (subcutaneous) daily. You should try to have the injection at the same time each day.

The recommended dose is either 20 to 90 mg or 100 mg. Your doctor will tell you the dose that you need or whether you need a dose higher than 100 mg.

Injecting Kineret yourself

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 inject yourself if you have not been trained.

For instructions on how to inject yourself or your child with Kineret, please read the "Instructions for preparing and giving an injection of Kineret" section at the end of this leaflet.

If you use more Kineret than you should

You should have no serious problems if you accidentally take more Kineret than you need. However, you should contact your doctor, nurse or pharmacist if this does happen. If you feel unwell in any way you should contact your doctor or nurse immediately.

If you forget to use Kineret

If you have forgotten to take a dose of Kineret, you should contact your doctor to discuss when you should take the next dose.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Possible side effects are similar regardless if you are treated with Kineret for RA, CAPS, FMF or Still's disease.

If any of the following happen, tell your doctor immediately:

- **Serious infections** such as pneumonia (a chest infection) or infections of the skin can occur during Kineret treatment. Symptoms might be persistent high fever, shivers, cough, headache, and redness and tenderness of the skin. Also persistent low-grade fever, weight loss, and persistent cough can be signs of an infection.

- **Serious allergic reactions** are uncommon. However, any of the following symptoms may indicate an allergic reaction to Kineret, so you should seek immediate medical attention. Do not inject more Kineret.
 - Swelling of the face, tongue or throat
 - Trouble swallowing or breathing
 - Suddenly feeling fast pulse or sweating
 - Itchy skin or rash.

Very common side effects (may affect more than 1 in 10 people):

- Redness, swelling, bruising or itching at the injection site. These symptoms are generally mild to moderate and are more common at the start of your treatment.
- Headaches.
- Increased total blood cholesterol levels.

Common side effects (may affect up to 1 in 10 people):

- Neutropenia (low white blood cell count) determined after a blood test. This might increase the risk of you getting an infection. Symptoms of infection might include a fever or a sore throat.
- Serious infections such as pneumonia (a chest infection) or infections of the skin.
- Thrombocytopenia (low level of blood platelets).

Uncommon side effects (may affect up to 1 in 100 people):

- Serious allergic reactions including swelling of the face, tongue or throat, trouble swallowing or breathing, suddenly feeling fast pulse or sweating and itchy skin or rash.
- Elevated levels of liver enzymes determined after a blood test.

Side effects with frequency not known (frequency cannot be estimated from the available data):

- Signs of liver disorders such as yellow skin and eyes, nausea, loss of appetite, dark-coloured urine and light-coloured stools.
- If Kineret is injected repeatedly at the same place, there is a risk of a lump (amyloid deposit) forming under the skin. Rotate the injection site to avoid this.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via

United Kingdom

Yellow Card Scheme

Website: www.mhra.gov.uk/yellowcard

or search for MHRA Yellow Card in the Google Play or Apple App Store

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Kineret

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the label and carton after EXP. The expiry date refers to the last day of that month.

Store in a refrigerator (2 °C to 8 °C). Do not freeze.

Store in original carton in order to protect from light.

Do not use Kineret if you think it has been frozen. 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.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Kineret contains

- The active substance is anakinra. Each graduated pre-filled syringe contains 100 mg of anakinra.
- The other ingredients are anhydrous citric acid, sodium chloride, disodium edetate dihydrate, polysorbate 80 and sodium hydroxide and water for injections.

What Kineret looks like and contents of the pack

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.

Pack sizes of 1, 7 or 28 (multipack containing 4 packs of 7 pre-filled syringes) pre-filled syringes. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Swedish Orphan Biovitrum AB (publ)
SE-112 76 Stockholm
Sweden

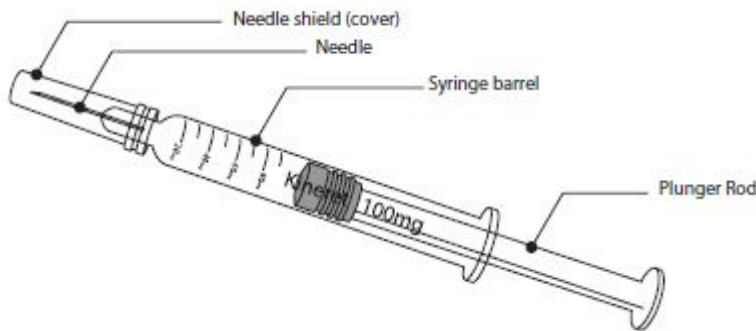
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INSTRUCTIONS FOR PREPARING AND GIVING AN INJECTION OF KINERET

This section contains information on how to give yourself or your child an injection of Kineret. It is important that you do not try to give yourself or your child the injection unless you have received training from a doctor, nurse or pharmacist. If you have questions about how to inject, please ask your doctor, nurse or pharmacist for assistance.

How do you or the person injecting you, use the Kineret pre-filled syringe?

You will need to give yourself or your child an injection at the same time every day. Kineret is injected just under the skin. This is called a subcutaneous injection.



Equipment:

To give yourself or your child a subcutaneous injection you will need:

- a pre-filled syringe of Kineret
- alcohol wipes or similar; and
- a sterile gauze or tissue

What should you do before you give yourself or your child a subcutaneous injection of Kineret?

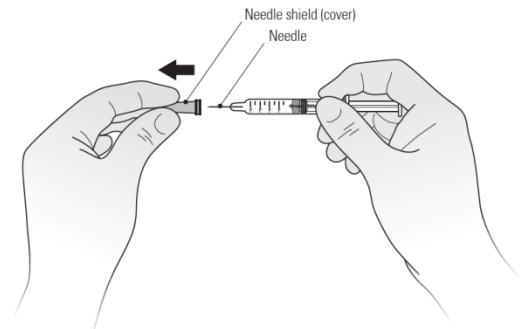
1. Take your Kineret pre-filled syringe out of the refrigerator.
2. Do not shake the pre-filled syringe.
3. Check the expiry date on the pre-filled syringe label (EXP). Do not use it if the date has passed the last day of the month shown.
4. Check the appearance of Kineret. It must be a clear, colourless-to-white solution. There may be some translucent-to-white particles of protein in the solution. The presence of these particles does not affect the quality of the product. The solution should not be used if it is discoloured or cloudy, or if any particles other than translucent-to-white particles are present.
5. For a more comfortable injection, leave at room temperature for approximately 30 minutes or hold the pre-filled syringe gently in your hand for a few minutes. **Do not** warm Kineret in any other way (for example, do not warm it in a microwave or in hot water).
6. **Do not** remove the cover from the syringe until you are ready to inject.
7. **Wash your hands thoroughly.**
8. Find a comfortable, well-lit, clean surface and put all the equipment you need within reach.

9. Make sure you know what Kineret dose your doctor has prescribed; 20 to 90 mg, 100 mg or higher.
 - If your doctor has prescribed a 100 mg dose you should continue to the “**How to prepare a 100 mg dose**” section.
 - If your doctor has prescribed a lower dose you should continue to 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:

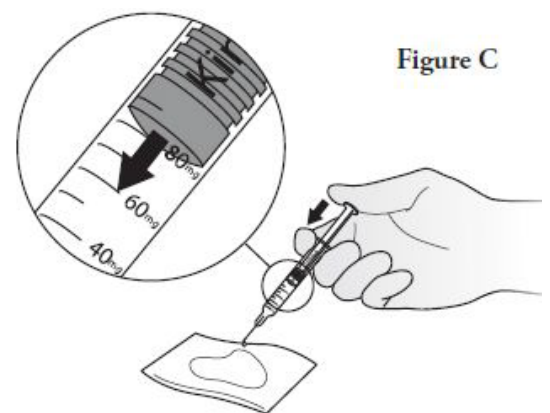
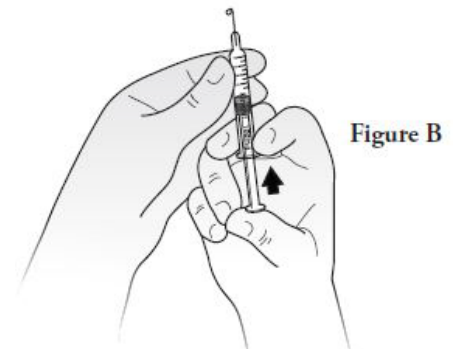
1. Hold the syringe barrel and gently remove the cover from the needle without twisting. Pull straight as shown in **Figure A**. Do not touch the needle or push the plunger. Immediately discard the needle cover.
2. You may notice a small air bubble in the pre-filled syringe. You do not have to remove 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. Immediately discard the needle cover.
2. You should position the syringe in one hand with the needle 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.
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.
4. Put your thumb on the plunger rod and push slowly until the plunger front has reached the scale mark of your Kineret dose. (Your doctor will have told you what dose you need to use.) The ejected 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, dispose of the syringe and use a new one.
6. You can now use the 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
- the upper outer areas of the buttocks; and
- the outer area of the upper arms.

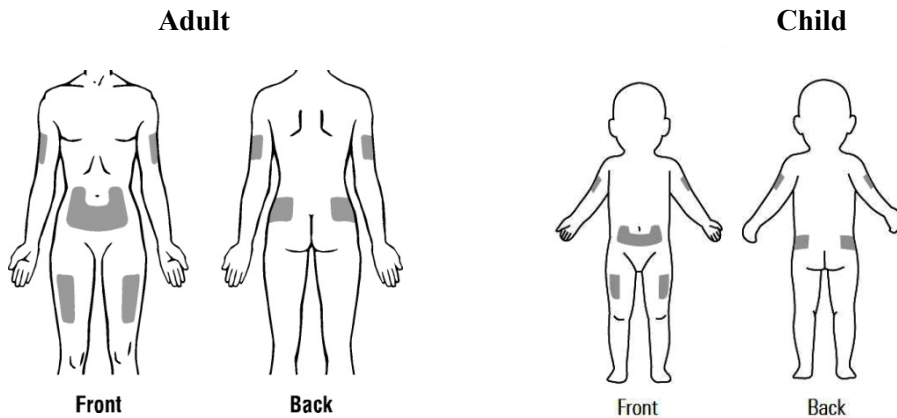
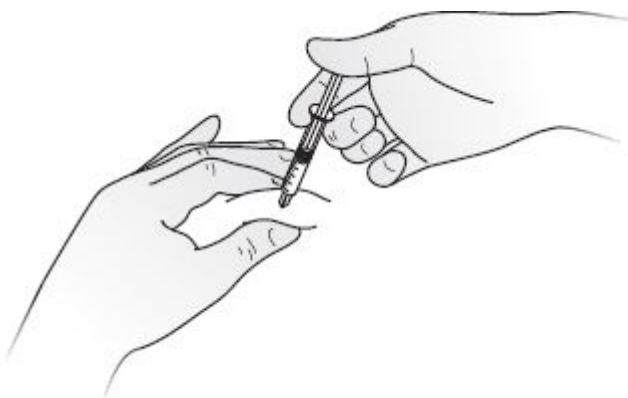


Figure D

Change the place that you inject each time so you don't become sore in one area. If someone else is injecting for you, they can also use the back of your arms.

How do you give your injection?

1. Disinfect the skin by using the alcohol wipe and pinch the skin between your thumb and forefinger, without squeezing it.
2. Put 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**.



4. After injecting the liquid, remove the needle and let go of the skin.
5. Any unused medicine must be discarded. Only use each syringe for one injection. Do not reuse a syringe as this can cause infection.

Remember

If you have any problems, please do not be afraid to ask your doctor or nurse for help and advice.

Disposing of used syringes and supplies

- Do not put the cover back on used needles.
- 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 had a dose lower than 100 mg you will have been told to eject liquid from the syringe onto a gauze or tissue. After your injection discard the wet gauze or tissue with your syringe and clean the surface with a fresh tissue.
- The used pre-filled syringe and any gauze or tissue with Kineret solution should be disposed of in accordance with local requirements. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.