

B. PACKAGE LEAFLET

PACKAGE LEAFLET: INFORMATION FOR THE USER

Kineret 100 mg solution for injection in a pre-filled syringe Anakinra

Read all of this leaflet carefully before you start using this medicine.

- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet

1. What Kineret is and what it is used for
2. Before you use Kineret
3. How to use Kineret
4. Possible side effects
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6. Further information

1. WHAT KINERET IS AND WHAT IT IS USED FOR

Kineret (an immunosuppressive agent) is a type of cytokine that is used to treat rheumatoid arthritis. Cytokines are proteins made by your body that co-ordinate communication between cells and help control cell activity. In rheumatoid arthritis, your body produces too much of a cytokine called interleukin-1. This results in harmful effects such as swelling and tissue damage.

Normally, your body produces a protein that blocks the harmful effects of interleukin-1. In rheumatoid arthritis your body does not produce enough of this blocking protein. The active substance of Kineret is anakinra produced by DNA technology using the micro-organism *E. coli* and works in the same way as your natural blocking protein.

Kineret is used to treat the signs and symptoms of rheumatoid arthritis 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.

2. BEFORE YOU USE KINERET

Kineret is for use in adults only (age 18 years and over).

Do not use Kineret:

- if you are allergic (hypersensitive) to Kineret (anakinra) or to any of the other ingredients in Kineret;
- if you are allergic to other products that are produced by DNA technology using the micro-organism *E. coli*;
- if you have severe renal impairment (kidney damage).

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.

Take special care with Kineret

Discuss with your doctor:

- 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 require vaccinations. You must not be given live vaccines while being treated with Kineret;
- if you know you are allergic to latex. The needle cover on the pre-filled syringe contains a derivative of latex.

Using other medicines

Please tell your doctor if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Pregnancy and breast-feeding

Kineret has not been tested in pregnant women. It is important to tell your doctor if you:

- are pregnant;
- think you may be pregnant; or
- plan to get pregnant.

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

Important information about some of the ingredients of Kineret

This medicinal product contains less than 1 mmol sodium (23 mg) per 100 mg dose, i.e. essentially 'sodium-free'.

3. HOW TO USE KINERET

Always use Kineret exactly as your doctor has told you. Kineret must be injected under your skin (subcutaneous) once daily. You should try to have the injection at the same time each day.

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 with Kineret, please read the 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, Kineret may cause side effects, although not everybody gets them.

Very common side effects (seen in more than 1 in 10 people who take Kineret) are:

- Redness, swelling, bruising or itching at the injection site. This is generally mild to moderate and is more common at the start of your treatment.
- Headaches.

Common side effects (seen in more than 1, but less than 10 in 100 people taking Kineret) are:

- 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. Symptoms might include a fever, a cough or redness and tenderness of the skin.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor, nurse or pharmacist.

5. HOW TO STORE KINERET

Keep out of the reach and sight of children.

Do not use Kineret 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 – 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 12 hours or disposed of.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What Kineret contains

The active substance is anakinra. Each pre-filled syringe contains 100 mg of anakinra.

The other ingredients are:

- sodium citrate, sodium chloride, disodium edetate, 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 pre-filled syringes.
Not all pack sizes may be marketed.

Manufacturer:

Amgen Europe B.V.
Minervum 7061
4817 ZK Breda
The Netherlands

Marketing Authorisation Holder:

Biovitrum AB (publ)
SE-112 76 Stockholm
Sweden

This leaflet was last approved in

Detailed information on this medicine is available on the European Medicines Agency (EMA) web site: <http://www.emea.europa.eu/>

Information on how to give yourself an injection of Kineret

This section contains information on how to give yourself an injection of Kineret. It is important that you do not try to give yourself the injection unless you have received training from your 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 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 a subcutaneous injection you will need:

- a new pre-filled syringe of Kineret; and
- alcohol wipes or similar.

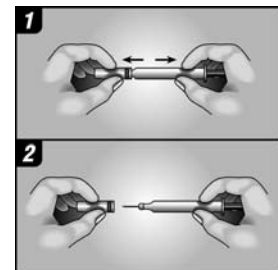
What should you do before you give yourself a subcutaneous injection of Kineret?

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.

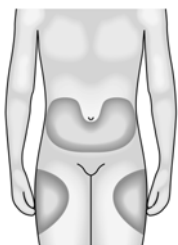
How do you prepare your Kineret injection?

Before you inject Kineret you must do the following:

1. Hold the syringe barrel and gently take the cover from the needle without twisting. Pull straight as shown in pictures 1 and 2. Do not touch the needle or push the plunger.
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.



Where should you give your injection?



The most suitable places to inject yourself are:

- the top of your thighs; and
- the abdomen, except for the area around the navel.

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 your 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. Pull slightly on the plunger to check that a blood vessel has not been punctured. If you see blood in the syringe, remove the needle and re-insert it in another place.
4. Inject the liquid slowly and evenly, always keeping your skin pinched.
5. After injecting the liquid, remove the needle and let go of your skin.
6. Only use each syringe for one injection.

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

- 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.
- The used pre-filled syringe 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.