

Drug Information Sheet("Kusuri-no-Shiori")

Self-injection

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The information on this sheet is based on approvals granted by the Japanese regulatory authority. Approval details may vary by country. Medicines have adverse reactions (risks) as well as efficacies (benefits). It is important to minimize adverse reactions and maximize efficacy. To obtain a better therapeutic response, patients should understand their medication and cooperate with the treatment.

Brand name:Kineret for Subcutaneous Injection 100mg syringe

Active ingredient:Anakinra(genetical recombination)

Dosage form:injection

Imprint or print on wrapping:



Effects of this medicine

This medicine acts on interleukin-1 (IL-1) (IL-1alpha and IL-1beta), a substance responsible for inflammation or organ damage, and improves the symptoms.

It is usually used to treat systemic juvenile idiopathic arthritis and adult-onset Still's disease.

The following patients may need to be careful when using this medicine.Be sure to tell your doctor and pharmacist.

- If you have previously experienced any allergic reactions (itch, rash, etc.) to any medicines or foods.
If you have macrophage activation syndrome, renal dysfunction (including patients on dialysis) or neutropenia.
If you have a history of hypersensitivity to proteins derived from Escherichia coli.
If you have or are suspected of having infections.
If you have or have a history of tuberculosis, or are suspected of having tuberculous infection.
If you have or have a history of hepatitis B virus infection.
- If you are pregnant or breastfeeding.
- If you are taking any other medicinal products. (Some medicines may interact to enhance or diminish medicinal effects. Beware of over-the-counter medicines and dietary supplements as well as other prescription medicines.)

Dosing schedule (How to take this medicine)

- Your dosing schedule prescribed by your doctor is((to be written by a healthcare professional))
- In general, for adults and children aged 8 months or older who weigh 10 kg or more, this medicine should be injected at the following doses subcutaneously once a day according to body weight.
 - Weighing 50 kg or more: 1 syringe (100 mg of the active ingredient) at a time.
 - Weighing less than 50 kg: 2 mg per 1 kg of body weight at a time. For children aged less than 16 years, the dosage may be increased up to 4 mg per 1 kg of body weight at a time according to the symptoms.This preparation contains 100 mg of the active ingredient in a syringe. Strictly follow the instructions.
- After using this medicine for a certain period of time, the treatment span should be decided depending on its therapeutic effects.
- Only if you have received sufficient training at a medical facility and your doctor has judged you are capable of it, this medicine may be self-injected. Receive instructions not to reuse syringes, etc. and on how to discard all used injection devices including syringes, and follow them.
- When using less than 100 mg (1 syringe), discard the excess amount in the syringe in advance and use the remaining amount.
- Inject subcutaneously into the abdomen, thighs, upper arms or buttocks. Be sure to choose a different injection site each time and do not inject in the same site. If you inject into the abdomen, avoid injecting around the navel.
- Do not inject into an area with blotches, redness, wound, hardness or pain.
- If you miss a dose, consult with your doctor or pharmacist. You should never use two doses at one time.
- If you accidentally inject more than your prescribed dose, consult with your doctor or pharmacist.
- Do not stop injecting this medicine unless your doctor instructs you to do so.

Precautions while taking this medicine

- Infections may develop or worsen. If any symptoms suggestive of infection occur, contact your doctor immediately.
- Blood tests or chest X-ray, as well as chest CT scan as needed, should be performed periodically under the instruction of your doctor, before and while using this medicine.
- If you need to visit another medical facility, inform the doctor or pharmacist that you are using this medicine.

Possible adverse reactions to this medicine

The most commonly reported adverse reactions include injection site reaction (erythema, pain, etc.). If any of

these symptoms occur, consult with your doctor or pharmacist.

The symptoms described below are rarely seen as initial symptoms of the adverse reactions indicated in brackets. If any of these symptoms occur, stop taking this medicine and see your doctor immediately.

- fever, chills, general malaise [serious infections]
- fever, chills, sore throat [neutropenia]
- widespread reddened skin, general rash, fever, general malaise [drug-induced hypersensitivity syndrome]
- general itch, hives, palpitations, breathing difficulty [anaphylaxis]

The above symptoms do not describe all the adverse reactions to this medicine. Consult with your doctor or pharmacist if you notice any symptoms of concern other than those listed above.

Storage conditions and other information

- Keep out of the reach of children. Store at 2 to 8 degrees Celsius (such as in a refrigerator), away from light and avoid freezing.
- Discard the remainder. Do not store them. Since disposal needs attention, seek advice of your pharmacy or medical institution. Do not give the unused medicines to others.
- Discard used syringes in a dedicated trash containers as directed by the medical institution.
- You should not receive live vaccines (for measles, rubella, measles-rubella [MR], chickenpox, mumps, BCG, etc.) while using this medicine.

For healthcare professional use only / /

For further information, talk to your doctor or pharmacist.