

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

Self-injection
Revised: 09/2020

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: Repatha SC injection 420mg auto mini doser

Active ingredient: Evolocumab (genetical recombination)

Dosage form: colorless to slight brownish liquid; clear to opalescent liquid for injection in cartridge (clear to opalescent liquid may contain translucent to white amorphous particles)

Print on wrapping:



Effects of this medicine

This medicine promotes cholesterol uptake in liver and reduces blood cholesterol level. It is used to treat familial hypercholesterolemia and hypercholesterolemia.

Before 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.
- 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))
- For heterozygous familial hypercholesterolemia or hypercholesterolemia: In general, for adults, evolocumab (as active ingredient) is administered subcutaneously once every 4 weeks.
- For homozygous familial hypercholesterolemia: In general, for adults, evolocumab (as active ingredient) is administered subcutaneously once every 4 weeks. In case of insufficient response, or is administered as adjunctive therapy for patients with LDL apheresis, evolocumab may be administered subcutaneously once every 2 weeks. Strictly follow the instructions.
- Take out the carton from the refrigerator 45 minutes before use.
- Receive explanations and/or instructions from your doctor until you become familiar with how to use the medicine.
- The sites for injection are abdomen, thighs and upper arms. You cannot inject this medicine into the outside of upper arm by yourself.
- If you miss a dose, contact your doctor. You should never inject 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

- Strictly follow the instructions on dietary/exercise therapy or cessation of smoking if instructed to do so by your doctor.

Possible adverse reactions to this medicine

The most commonly reported adverse reactions include diabetes mellitus, injection site reaction, muscular pain and muscle spasms. 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.

No pertinent entries.

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. Keep the medicine in the outer carton, store away from light, and avoid freezing. Store it in the refrigerator, etc. (at 2 to 8 degrees Celsius).
- Discard the remainder. Do not store them. Ask the pharmacist and the medical institution how to discard them.

For healthcare professional use only / /

For further information, talk to your doctor or pharmacist.