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

Self-injection Published: 08/2024

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: METRELEPTIN for subcutaneous Injection 11.25mg [Chiesi]

Active ingredient: Metreleptin (genetical recombination)

Dosage form: white and clumped injectable preparation

Imprint or print on wrapping:

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Effects of this medicine

Leptin is one of the hormones secreted from fatty tissues, and it shows an inhibitory effect on food intake and enhancing effect on energy consumption and on sensitivity of insulin. This medicine enhances sugar and/or lipid metabolism by covering the action of leptin.

It is usually used for the treatment of lipodystrophy.

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 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))
- This medicine can be used after dissolving in water for injection.
- In general, 0.04 mg as the active ingredient per 1 kg of body weight for male, 0.06 mg for female aged under 18 years old, or 0.08 mg for female aged 18 years old or more is administered by a subcutaneous injection once a day. The initial dose is 0.02 mg, 0.03 mg or 0.04 mg as the active ingredient per 1 kg of body weight, respectively, and it can be increased to the above dose over about one month. The dosage may be decreased according to your age and symptoms. Strictly follow the instructions.
- •This medicine may be self-injected only if you have received proper training at a medical facility and your doctor has judged you are capable of it. Please receive full explanation from your doctor and be sure to read the "Instructions for Self-Injection at Home" for this medicine before self-injecting at home.
- •The site of subcutaneous injection should be changed each time, such as the abdomen or thigh.
- If you miss a dose, you should be instructed by your doctor or pharmacist..
- If you accidentally use more than your prescribed dose, consult with your doctor or pharmacist.
- •Do not stop using this medicine unless your doctor instructs you to do so.

Precautions while taking this medicine

•Pay attention to hypoglycemic symptoms (weakness, trembling limbs, sweating, palpitations, dizziness, etc.) as hypoglycemia can lead to accidents when working at heights or driving a car.

Possible adverse reactions to this medicine

The most commonly reported adverse reactions include injection site reactions (swelling, pain, itch, redness). 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.

hives, generalized rash, fever [hypersensitivity]

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 the medicine out of the reach of infants and children. Store it in an outer case and in a refrigerator (2 to 8 degrees Celsius).
- •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.
- •Do not reuse syringe needles or syringes.

For healthcare professional use only

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