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

Injection

Revised: 08/2020

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:EVENITY subcutaneous injection 105mg syringe

Active ingredient: Romosozumab

Dosage form:injection

Print on wrapping:

Effects of this medicine

This medicine is an anti-sclerostin antibody preparation. It increases bone formation, inhibits bone mass reduction and increases bone mineral density, thus preventing fracture.

It is usually used to treat osteoporosis at a high risk of fracture.

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 have hypocalcemia.

If you have ever experienced angina pectoris, myocardial infarction or cerebrovascular disorder.

If you have renal disorder.

If you are on dialysis.

・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, inject this medicine subcutaneously once a month for 12 months.

After the completion of the treatment for 12 months, use another type of osteoporosis medicine.

Precautions while taking this medicine

・In order to reduce onset of hypocalcemia, ingest calcium and vitamin D under the instruction of your doctor. If you have difficulty in taking them orally, consult with your doctor.

・Maintain your oral hygiene during the treatment. Jaw pain/swelling/numbness and loose tooth may occur.

・Inform your dentist or oral surgeon that you are using this medicine when you receive a dental treatment.

・If any of the following symptoms occur, see your doctor immediately. chest pain, chest pressure, chest tightness, cold sweats, headache, nausea, vomiting, temporarily impaired consciousness, hemiparalysis (paralysis of one side), speech difficulties

Possible adverse reactions to this medicine

The most commonly reported adverse reactions include arthralgia, injection site pain/erythema and nasopharyngitis.

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, see your doctor immediately.

・shivering of limbs, muscle lassitude, convulsion, numbness, arrhythmia [hypocalcemia]

・swelling of mouth/gum, pain of tooth/gum/jaw, loose tooth [osteonecrosis of jaw, osteomyelitis of the jaw]

・ pain of thigh or inguinal region [atypical fractures of the subtrochanteric and proximal diaphyseal femur]

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

For healthcare professional use only / /

For further information, talk to your doctor or pharmacist.