

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:ENBREL 25mg Syringe 0.5mL for S.C. CLICWISE use

Active ingredient:Etanercept (genetical recombination)

Dosage form:colorless to yellow or faint brown, limpid to opalescent injectable preparation

Print on wrapping:



Effects of this medicine

This medicine suppresses action of TNF, which is considered to be a primary factor that is related to immune mechanism, inflammation and pain, improves symptoms associated with rheumatoid arthritis and prevents the damage of joints and bones.

It is usually used to treat rheumatoid arthritis.

Before using this medicine, be sure to tell your doctor and pharmacist

- If you have previously experienced any allergic reactions (itching, rash, etc.) to any medicines.
If you have: infection, tuberculosis, demyelinating disease such as multiple sclerosis and optic nerve inflammation or its past history, congestive heart failure, blood disease or its past history, a history of interstitial pneumonia or cancer or its past history.
- If you have received live vaccines (such as rubella/mumps vaccines) just before use of this medicine.
- 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, subcutaneously inject either 1 cassette (25 mg of the active ingredient per cartridge) at a time, once a day, twice a week (3 or 4 days apart), or 1 to 2 cassettes (25 to 50 mg) at a time, once a day, once a week. Strictly follow the instructions.
- The contents of a cassette should be used all at once.
- Choose a different injection site each time. (Inject at least 3 cm apart from the previous injected site.)
- Do not inject into an irritable skin site, or a site with wound, redness or induration (a site harder than around).
- Do not massage the injected site after subcutaneous injection.
- Before attaching to the dedicated injection device, leave this medicine at room temperature for about 15 to 30 minutes. Remove the cap after attaching this medicine to the device.
- Inspect the liquid in the cassette before attaching to the dedicated injection device. There may be small white particles, however you can use this medicine as usual. Do not use this medicine if there are any colored particles or the liquid has discolored. And consult with your doctor, pharmacist or nurse.
- You may self-inject this medicine (self-injection), only if you want to and the doctor has confirmed that you meet certain criteria for self-injection.
- If you miss a dose, consult with your doctor, pharmacist or nurse.
- 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

- Do not receive live vaccines (such as rubella/mumps vaccines) due to infection risk of the virus. If you wish to receive live vaccines for prevention, inform and consult with your doctor that you are using this medicine.

Possible adverse reactions to this medicine

The most commonly reported adverse reactions include infections (bronchitis, nasopharyngitis, etc.), injection site reactions (erythema, itching, swelling, pain, etc.), headache, nausea, dermatitis, dizziness, diarrhea, rash, pruritus (itching), liver disorder (general malaise, loss of appetite, etc.), rhinitis, stomatitis, alopecia, increased cough, abdominal pain, dry mouth, gastric ulcer, peripheral edema and fever. If any of these symptoms occur, consult with your doctor or pharmacist. Do not scratch or touch the injection site.

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.

- chills, fever, general malaise [sepsis, pneumonia (including pneumocystis pneumonia), opportunistic infections such as fungal infection]
- persistent slight fever, persistent cough (for 2 weeks or more), general malaise [tuberculosis]
- general redness, general edema, breathing difficulty [serious allergic reactions]
- persistent fever, sore throat, paleness of the face [serious blood disorders]
- reduced visual acuity/diplopia, numbness/pain/motor paralysis [demyelinating disorders]

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 reach of children. Store at 2 to 8 degrees Celsius (in the refrigerator), away from light and avoid freezing.
- Discard the remainder. Do not store them. Consult with the pharmacy and the medical institution how to discard them.

For healthcare professional use only / /

For further information, talk to your doctor or pharmacist.