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

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:Ustekinumab BS for I.V. Infusion 130mg "CT"
Active ingredient: Ustekinumab (genetical recombination)[ustekinumab biosimilar 3]
Dosage form:injection
Imprint or print on wrapping:

Effects of this medicine

This medicine improves symptoms by suppressing the function of IL (Interleukin) which is one of the possible primary causative substances of Crohn's disease.
It is usually used as an induction therapy for moderate to severe active Crohn's disease (only to patients with insufficient effect by existing treatments).

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 or are suspected of having infection.
  If you have a history of recurrent infection.
  If you have, are suspected of having or have a history of tuberculosis.
  If you have or have a history of malignant tumor.
  If you have received allergen immunotherapy.
- 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, at the beginning of the treatment, inject this medicine once with intravenous infusion for more than 1 hour. 8 weeks after the injection, a maintenance therapy with subcutaneous injection of ustekinumab preparation will be started.
- Before using this medicine, a medical interview, chest X-ray, interferon gamma release test or tuberculin reaction test, as well as chest CT scan as needed, are performed to determine the presence of tuberculosis infection. Antitubercular agents may be used before using this medicine as necessary.

Precautions while taking this medicine

- This medicine may lead to susceptibility to infections. If infectious symptoms (cold-like symptoms, body dullness, fever) occur, contact your doctor immediately.
- Periodical laboratory tests such as chest X-ray should be conducted in order to monitor for tuberculosis infection while using this medicine. If any symptoms suggestive of tuberculosis (persistent cough, fever) appear, contact your doctor immediately.
- If babies born to mothers who used this medicine during pregnancy receive live vaccines, consult with their doctor.

Possible adverse reactions to this medicine

The most commonly reported adverse reactions include nasopharyngitis, headache, nausea, itch and fatigue. 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.

- rash, hives, angioedema [anaphylaxis]
- fever, body dullness, breathing difficulty/shortness of breath [serious infection]
- prolonged slight fever/cough (2 weeks or over), body dullness, body weight loss [tuberculosis]
- fever, dry cough, respiratory distress [interstitial pneumonia]

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

- Avoid receiving live vaccines because this medicine has an immuno-suppressive action.

For healthcare professional use only

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For further information, talk to your doctor or pharmacist.