

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

Self-injection  
Revised: 10/2022

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:** Cimzia 200mg Syringe for S.C. Injection

**Active ingredient:** Certolizumab pegol(genetical recombination)

**Dosage form:** colorless to yellow and limpid to milky solution for injection in prefilled syringe

**Imprint or print on wrapping:**



## Effects of this medicine

This medicine improves symptoms of rheumatoid arthritis and psoriasis by suppressing actions of TNF  $\alpha$  (tumor necrosis factor- $\alpha$ ), a main substance which is said to be the cause of immune abnormalities and inflammation. It is usually used to treat rheumatoid arthritis (including the prevention of structural disorder of joints), plaque psoriasis, psoriatic arthritis, generalized pustular psoriasis, and erythrodermic psoriasis.

## 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: infection or suspected infection, active tuberculosis or a history of it, demyelinating disease (multiple sclerosis, etc.) or a history of it, congestive heart failure, hematologic disease (pancytopenia, aplastic anemia, etc.) or a history of it or a history of interstitial pneumonia.
- If you are hepatitis B virus carrier, or previously infected.
- If you have just received a live vaccine.
- 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))
  - Rheumatoid arthritis: In general, for adults, subcutaneously administer 2 injections (400 mg of the active ingredient) at a time as an initial dose, and inject the same dose at 2 weeks and 4 weeks after the start of administration. Then onward, administer 1 injection (200 mg) at a time, at an interval of 2 weeks apart. You may be instructed to administer 2 injections (400 mg) at a time, at an interval of 4 weeks apart if the symptoms are stable.
  - Plaque psoriasis, psoriatic arthritis, generalized pustular psoriasis, and erythrodermic psoriasis: In general, for adults, subcutaneously administer 2 injections (400 mg of the active ingredient) at a time at an interval of 2 weeks apart. You may be instructed to administer 1 injection (200 mg) at a time at an interval of 2 weeks apart or 2 injections (400 mg) at a time, at an interval of 4 weeks apart if the symptoms are stable.
- In any case, strictly follow the instructions.
- Use this medicine after returning it to room temperature (In general, it takes about 30 minutes to return it to room temperature).
  - The sites for injection are abdomen, thighs and upper arms. If you are injecting this medicine by yourself, the injection site should be either abdomen or both thighs. If the injection is given by any of your family members, upper arm is another option.
  - If you are administering 2 injections at one time, change the injection site for each injection.
  - Avoid injecting this medicine into the skin with pain, redness, injury or stiffness.
  - If you miss a dose, contact with your doctor and receive advice.
  - 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

- To prevent infection, gargle, wash hands regularly, and regulate your daily life. If you develop fever, fatigue, or other symptoms, consult with your doctor immediately.

**Possible adverse reactions to this medicine**

The most commonly reported adverse reactions include bacterial infection (chills, fever, joint and muscle pain, cough, etc.), viral infection (rash, fever, sore throat, nerve pain, etc.), liver disorder, rash, nasopharyngitis and nausea. 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.**

- fever, chill, cough, sputum [sepsis, serious infection such as pneumonia]
- prolonged cough, slight fever, general malaise, loss of body weight [tuberculosis]
- respiratory distress, hives, loss of consciousness [serious allergic reaction]
- reduced visual acuity, double vision, numbness, pain [demyelinating disease]
- fever, dry cough, breathlessness on exertion [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**

- Keep out of the reach of children. Store at 2 to 8 °C (refrigerator) in the boxed form. After unsealing the outer box, please store under light shielding condition.
- You should never reuse the syringe which was already used. Put used syringes in a dedicated disposal container and dispose according to the instructions of your pharmacy or medical institution.
- 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.
- You should never receive live vaccines during the treatment with this medicine since it may cause infection. If you need to receive preventive vaccination, be sure to consult with your doctor beforehand.

**For healthcare professional use only** / /

For further information, talk to your doctor or pharmacist.