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

Internal

Revised: 11/2021

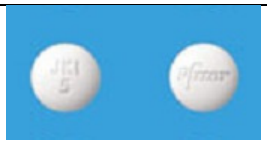
The information on this sheet is based on approvals granted by the Japanese regulatory authority. Approval details may vary by country. Medicines have adverse reactions (risks) as well as efficacies (benefits). It is important to minimize adverse reactions and maximize efficacy. To obtain a better therapeutic response, patients should understand their medication and cooperate with the treatment.

Brand name:XELJANZ Tablets 5mg

Active ingredient: Tofacitinib citrate

Dosage form:white tablet, diameter: approx. 8.0 mm, thickness: approx. 4.2 mm

Print on wrapping:(Face) ゼルヤンツ 5mg, 5, (Back) XELJANZ 5mg, ゼルヤンツ 5mg, Pfizer, JKI 5



Effects of this medicine

This medicine strongly blocks an enzyme called Janus Kinase (JAK) to suppress the action of the immune-related cytokines relating to lymphocyte response, and inhibits inflammation associated with rheumatoid arthritis or ulcerative colitis.

It is usually used to treat rheumatoid arthritis with inadequate response to existing therapies. It is also used for remission-induction and maintenance therapies for moderate to severe ulcerative colitis (only in the case of inadequate response to existing therapies).

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: infections (pneumonia, sepsis, viral infection), active tuberculosis, liver dysfunction, decreased neutrophils, decreased lymphocytes, low hemoglobin level, malignant tumor/hepatitis B, history of malignant tumor/herpes zoster or risk factor for cardiovascular diseases (smoking, hypertension, diabetes mellitus, etc.).
- If you are pregnant, possibly 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))
- For rheumatoid arthritis: In general, take 1 tablet (5 mg of tofacitinib) at a time, twice a day. The dosage may be decreased to 5 mg once a day according to the severity of liver or renal disorder.

  For ulcerative colitis: In general, for adults, take 2 tablets (10 mg) at a time, twice a day for induction therapy for 8 weeks. If the effect is insufficient, the treatment may be continued for extra 8 weeks. For maintenance therapy, for adults, take 1 tablet (5 mg) at a time, twice a day. The dosage may be increased to 2 tablets (10 mg) at a time, twice a day, if the effect is diminished during the maintenance therapy. If the disease has been refractory to the previous medicinal therapy, the dosage may be increased to 2 tablets (10 mg) at a time, twice a day. The dosage may be decreased according to the severity of liver or renal disorder.

  In any case, strictly follow the instructions.
- If you miss a dose, take the missed dose as soon as possible. If it is almost time for the next dose, skip the missed dose and follow your regular dosing schedule. You should never take two doses at one time.
- If you accidentally take more than your prescribed dose, consult with your doctor or pharmacist.
- Do not stop taking this medicine unless your doctor instructs you to do so.

Precautions while taking this medicine

- Do not receive live vaccinations [for measles, rubella, mumps, chickenpox, BCG and polio] while taking this medicine. Please consult with your doctor when you need to receive a vaccination.
- Avoid taking any food containing St. John's wort (a kind of herb) with this medicine, since it may diminish medicinal effects.
- Avoid taking grapefruit with this medicine, since the content of grapefruit may intensify the therapeutic effects of this medicine.
- If you are planning to become pregnant, avoid the pregnancy while taking this medicine and at least 1 menstrual cycle after the completion of the therapy with this medicine.

Possible adverse reactions to this medicine

The most commonly reported adverse reactions include upper respiratory tract infection, headache,

nasopharyngitis, diarrhea, herpes zoster (small blisters appearing in a belt-like figure associated with nerve pain), hypertension, cough, fever, nausea and bronchitis. 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.

- ・cold-like symptoms, general malaise, fever [infection]
- ・nausea, vomiting, severe abdominal pain [gastrointestinal perforation]
- ・fever, sore throat, anemia [decreased lymphocytes, decreased neutrophils, decreased hemoglobin]
- ・general malaise, loss of appetite, yellowing of the skin and the white of eyes [liver dysfunction, jaundice]
- ・fever, dry cough, breathing difficulty [interstitial pneumonia]
- ・skin/lips/nails of hand and feet turning blueish purple, swelling/edema of lower limbs, breathing difficulty [venous thromboembolism]
- ・squeezing chest pain, breathing difficulty, cold sweat [cardiovascular event such as myocardial infarction]
- ・fever, loss of appetite, general malaise [malignant tumor]

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 away from direct sunlight, heat and moisture.
- ・Discard the remainder. Do not store them. If you dispose of unused medicines, seek advice of your pharmacist or healthcare provider about proper disposal of them.

For healthcare professional use only / /

For further information, talk to your doctor or pharmacist.