

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

Internal

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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: Smyraf Tablets 50mg

Active ingredient: Peficitinib hydrobromide

Dosage form: yellow tablet, diameter: approx. 7.6 mm, thickness: approx. 3.5 mm

Print on wrapping: (face) Smyraf 50mg, 50mg, スマイラフ 50mg, アステラス製薬,
(back) Smyraf 50mg, スマイラフ 50mg, company mark, アステラス製薬



Effects of this medicine

This medicine affects the action of several substances associated with expression of inflammation or pain by inhibiting the activity of an enzyme called Janus Kinase (JAK), thereby showing improvement on symptoms of rheumatoid arthritis.

It is usually used for the treatment of patients with rheumatoid arthritis (including prevention of structural joint damage) who have not had shown enough efficacy with existing therapies.

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: infections, active tuberculosis, liver dysfunction, neutropenia, lymphopenia, decreased hemoglobin, malignant tumor, hepatitis B, congenital short QT syndrome or history of herpes zoster or interstitial pneumonia.
- 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))
- In general, for adults, take 3 tablets (150 mg of peficitinib) at a time, once a day, after a meal. The dosage may be decreased to 2 tablets (100 mg) at a time, once a day, after a meal, according to the condition. If you have moderate liver dysfunction, take 1 tablet (50 mg) at a time, once a day, after a meal. Strictly follow the instructions.
- If you miss a dose, take the missed dose as soon as possible. However, 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

- You should routinely undergo laboratory tests such as blood test or chest X-ray, and chest CT scan if necessary, according to the instruction by your doctor in order to find any adverse reaction earlier during the treatment with this medicine.
- If you have prolonged cough or fever, contact with your doctor before the next consultation day and see your doctor as soon as possible.
- If you are planning to become pregnant, avoid the pregnancy while using 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 nasopharyngitis and herpes zoster. 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.

- small blisters appearing in a belt-like shape, fever, general malaise [infection]
- sore throat, headache, muscle pain [neutropenia, lymphopenia, decreased hemoglobin]
- severe abdominal pain, nausea, vomiting [gastrointestinal perforation]
- general malaise, loss of appetite, yellowing of the skin and the white of eyes [liver dysfunction, jaundice]
- fever, 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

- Keep out of reach of children. Store away from direct sunlight, heat and moisture.
- Discard the remainder. Do not store them. Consult with your dispensing pharmacy or medical institution how to

discard.

- You should never receive live vaccines (for measles, rubella, mumps, chickenpox, etc., and BCG) 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.