

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

Internal

Revised: 08/2023

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

Imprint or print on wrapping: Smyraf 50mg, スマイラフ 50mg, アステラス製薬,
company mark



Effects of this medicine

This medicine suppresses 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 such as pain or swelling of the joint.

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.

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: infections, active tuberculosis, liver dysfunction, neutropenia, lymphopenia, decreased hemoglobin, intestinal diverticulum (pouch-like cavity formed in the intestine), congenital short QT syndrome or a risk of venous thromboembolism.
- If you have or have a history of malignant tumor.
- If you have a history of interstitial pneumonia or herpes zoster.
- If you have a history of tuberculosis or are suspected to have tuberculous infection.
- If you are suspected to have or susceptible to infections.
- If you are a hepatitis B virus carrier or have a history of hepatitis B.
- 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.
- Before using this medicine, in addition to a medical interview and chest X-ray, blood test, and possibly a chest CT scan, should be performed to determine the presence of tuberculosis infection.
- Before using this medicine, blood test should be performed to determine the presence of hepatitis B virus infection and decrease in the number of blood cells.
- 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

- If you have any symptoms such as fever, dull, prolonged cough, skin abnormality and yellowing of the skin and the white of eyes, contact with your doctor before the next consultation day and see your doctor immediately.
- Chest X-ray or other examination should be performed periodically while you are using this medicine since you may develop tuberculosis.
- Blood test should be performed periodically while you are using this medicine since neutropenia, lymphopenia, decreased hemoglobin, abnormal lipid test value or liver dysfunction may occur.
- If you are a hepatitis B virus carrier or have been infected with hepatitis B virus in the past, examinations should be periodically performed since there is a risk of the reactivation of hepatitis B virus.
- Female patients with a possibility of getting pregnant should properly avoid 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 herpes zoster, pharyngitis, nasopharyngitis, upper respiratory tract infection, bronchitis, influenza and cystitis. 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, feeling dull [infection]
- sore throat, headache, anemia/dizziness [neutropenia, lymphopenia, decreased hemoglobin]
- severe abdominal pain, nausea, vomiting [gastrointestinal perforation]
- feeling dull, loss of appetite, yellowing of the skin and the white of eyes [liver dysfunction, jaundice]
- fever, dry cough, respiratory distress [interstitial pneumonia]
- skin/lips/nails turning blueish purple, swelling/edema/pain in the lower limbs, respiratory distress and chest pain [venous thromboembolism]

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 room temperature (1 to 30 degrees Celsius), away from direct sunlight and moisture.
- Discard the remainder. Do not store them. If you do not know how to discard, seek advice of your dispensing pharmacy or medical institution. Do not give the unused medicines to others.
- 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.