

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

Internal

Revised: 07/2015

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: TSUMURA Shosaikoto Extract Granules for Ethical Use

Active ingredient: Shosaikoto

Dosage form: light yellowish brown granules

Imprint or print on wrapping: ツムラ小柴胡湯(ショウサイコトウ)2.5 g 「9」



Effects of this medicine

This medicine has been prescribed according to your symptoms and constitution.

This Kampo(Japanese traditional herbal) medicine has been prescribed to those patients with moderately strong constitution, upper abdominal tenderness accompanied by fullness and discomfort, coated tongue, oral cavity discomfort, loss of appetite, and/or those with slight fever and nausea.

It is usually used to treat liver dysfunction in chronic hepatitis, various acute febrile diseases such as bronchitis and lymphadenitis, bronchial asthma, chronic gastrointestinal disorder, and insufficient postpartum recovery.

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 are suspected to have cirrhosis.
- If you have hepatic cancer
- 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, for adults, take 7.5 g a day orally in 2 or 3 divided doses with cold or lukewarm water before or between meals. The dosage may be adjusted according to your age, body weight and symptoms. Strictly follow your instructions.
- If you miss a dose, take the missed dose as soon as possible. However, if the next dose is within two hours, skip the missed dose and continue with your regular dosing schedule. You should not 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

Possible adverse reactions to this medicine

The most commonly reported adverse reactions include rash, itching, hives, constipation, loss of appetite, gastric discomfort, nausea, vomiting, stomachache, diarrhea, cystitis, persistent urge to urinate, bloody urine, frequent urination and painful urination. 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, dry cough, shortness of breath, difficulty breathing [interstitial pneumonia]
- decreased urine output, edema of face and limbs, heavy feeling in the eyelids, hand stiffness [pseudoaldosteronism]
- body dullness, weakness, cramp and numbness of limbs, limbs cramp and feel numb, muscle pain [myopathy, rhabdomyolysis]
- body dullness, yellowing of the skin and the white of eyes [liver dysfunction]

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 away from direct sunlight, heat and moisture
- Discard the remainders. Do not store them.

For healthcare professional use only / /

For further information, talk to your doctor or pharmacist.