

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

Injection

Revised: 11/2022

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: TORISEL Injection 25mg

Active ingredient: Temsirolimus

Dosage form: injection

Imprint or print on wrapping:



Effects of this medicine

This medicine has an anti-tumor effect by suppressing tumor proliferation and neoangiogenesis.

It is usually used to treat radically unresectable or metastatic renal cell carcinoma.

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: respiratory symptoms, liver dysfunction, infection, hepatitis virus, tuberculosis, etc. or its history.
- 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, this medicine is administered by intravenous drip infusion for 30 to 60 minutes once a week.
- The treatment duration depends on your symptoms. Antihistamines are used prior to the use of this medicine to reduce infusion reaction.

Precautions while taking this medicine

- Chest CT scans are periodically performed before and during the use of this medicine, since interstitial lung disease may occur. In addition, lung function tests are performed as needed. If symptoms such as dyspnea, cough and fever occur, contact your doctor immediately.
- Patients will be checked for hepatitis viruses and tuberculosis infection before the use of this medicine, since reactivation of hepatitis viruses and tuberculosis may occur. In addition, liver function tests will be periodically performed during and after the use of this medicine.
- Fasting blood glucose levels are measured periodically before and during the use of this medicine, since hyperglycemia may occur.
- Blood tests are performed before and during the use of this medicine, since abnormal lipid metabolism may occur.
- Renal function tests are periodically performed before and during the use of this medicine, since renal failure may occur.
- Avoid operating dangerous machinery, such as driving a car, if you suspect alcohol or others may affect you after use of this medicine due to interactions with medicines you have taken before the use of this medicine to reduce the side effects.
- Blood tests are performed periodically, since hypokalemia and hypophosphatemia may occur.
- Avoid taking any food containing St. John's wort (a kind of herb), since it may diminish medicinal effects.
- Avoid taking grapefruit (juice) with this medicine, since it may intensify the therapeutic effects of this medicine.

Possible adverse reactions to this medicine

The most commonly reported adverse reactions include rash, asthenia, itch, nail disorder, acne, dry skin, nose bleeding, cough, dyspnea, loss of appetite, nausea, diarrhea, vomiting, abdominal pain, upper respiratory tract infection, edema, mucositis, fever, fatigue, pain and chills. 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, cough, breathing difficulty [interstitial lung disease]
- chills/fever, breathing difficulty/temporal cessation of breathing, symptoms of anaphylaxis such as unconsciousness [severe infusion reaction]
- thirst, polyuria, general malaise [hyperglycemia]

- oral mucosal erosion, small painful red ulcer in the mouth with white spot inside [stomatitis]
- palpitation/shortness of breath, malaise, bleeding tendency (nose bleeding, gingival bleeding, etc.) [anemia, decreased platelets, decreased white blood cell, decreased neutrophils, decreased lymphocytes]

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

- Do not receive live vaccinations during the use of this medicine. If you wish to receive live vaccinations, be sure to consult with your doctor, since live vaccinations may result in the onset.

For healthcare professional use only / /

For further information, talk to your doctor or pharmacist.