

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

Injection

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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:Oncaspar I.V. Infusion

Active ingredient:Pegaspargase

Dosage form:injection

Imprint or print on wrapping:



Effects of this medicine

This medicine degrades amino acid necessary to proliferate tumor cells, inhibits protein synthesis of tumor cells and thus suppresses their proliferation.

It is usually used to treat acute lymphocytic leukemia and malignant lymphoma.

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 liver disorder.
If you have experienced thrombosis, bleeding or hypersensitivity due to L-asparaginase.
If you have experienced pancreatitis (including pancreatitis due to L-asparaginase).
- 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, inject this medicine intravenously with drip infusion for 1 to 2 hours once every 2 weeks.
- This medicine is used in combination with other anti-malignant tumor agents. An interval of the injections may depend on other concomitant medicine, symptoms/condition. Consult your doctor about the treatment span.
- Due to adverse drug reactions, this medicine may be suspended, discontinued or the infusion rate may be changed.

Precautions while taking this medicine

- As pancreatitis, bleeding tendency, thromboembolism, liver dysfunction, myelosuppression or hyperglycemia may occur, a periodical examination should be performed before and during the use of this medicine.
- As central nervous system disorder such as convulsive attack or faint may occur, pay attention when operating dangerous machinery such as driving a car while using this medicine.
- If you are a female patient with a possibility of pregnancy, avoid pregnancy adequately while you are using this medicine and for at least 1 month after completing this medicine. A female patient with a possibility of pregnancy should prevent pregnancy other than by oral contraceptives while using this medicine.

Possible adverse reactions to this medicine

The most commonly reported adverse reactions include loss of appetite, anemia, coagulation abnormality (bleeding tendency, bruise), alopecia, malaise, vomiting and nausea. 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.

- decreased consciousness, breathing difficulty, rash [hypersensitivity]
- strong abdominal pain, back pain, nausea [pancreatitis]
- nausea, abdominal pain, black stool [(small intestinal bleeding) bleeding]
- severe headache, chest pain, severe leg pain [thromboembolism]
- body dullness, nausea, loss of appetite [liver dysfunction]
- fever, prolonged bleeding, palpitation [myelosuppression]
- fever, chills, body dullness [infection]
- body dullness, decreased body weight, thirst [hyperglycemia]

• slurred speech, trembling limbs, decreased concentration [central nervous system disorder]

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

For healthcare professional use only / /

For further information, talk to your doctor or pharmacist.