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: ERWINASE for intramuscular injection 10000

Active ingredient: Crisantaspase

Dosage form:injection

Imprint or print on wrapping:

Effects of this medicine

This medicine inhibits protein synthesis in the tumor cells by degrading and depleting L-asparagine and thus suppresses proliferation of the tumor cells.

It is usually used to treat acute 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 pancreatitis or have a history of it.

If you have abnormal blood clotting or have a history of it.

If you have diabetes mellitus, myelosuppression, infection or hepatic disorder.

- · 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, inject this medicine intramuscularly three times a week.
- •Ask the doctor about the treatment span.
- •This medicine may be injected to several separate sites, depending on the liquid volume or your conditions.

Precautions while taking this medicine

•If you have a possibility of pregnancy, avoid pregnancy while you are using this medicine and for a certain period after completing this medicine.

Possible adverse reactions to this medicine

The most commonly reported adverse reactions include headache, nausea/vomiting, fever and back pain. 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, see your doctor immediately.

- ·chills, breathing difficulty, hives [hypersensitivity]
- severe abdominal pain, back pain, nausea/vomiting [pancreatitis]
- •nasal bleeding, gum bleeding, bruise [abnormal blood clotting]
- •fever, nasal bleeding, dull headache [myelosuppression]
- •fatiguability, general dullness, loss of appetite [liver dysfunction]
- decreased body weight, thirst, excessive fluid intake/excessive urination [hyperglycemia]
- •fever, chills, general dullness [infection]
- decreased/loss of consciousness, decreased memory, speech difficulties [encephalopathy]

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.

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