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:AZACITIDINE FOR INJECTION 150mg「OHARA」

Active ingredient: Azacitidine

Dosage form:injection

Imprint or print on wrapping:

Effects of this medicine

This medicine shows cytocidal action by being incorporated into RNA and inhibiting protein synthesis. It is also reported to possibly show cytostatic action by being incorporated into DNA and inhibiting DNA methylation. It is usually used to treat myelodysplastic syndrome and acute myeloid leukemia.

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 a complication of infection.
  If you have hepatic/renal disease.
- 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 subcutaneously or with intravenous infusion over 10 minutes, once a day for 7 days. Repeat administration with a drug cessation period of 3 weeks.
- The treatment span depends on the effect of this medicine after administering it for a certain period of time.

Precautions while taking this medicine

- Female patients with a possibility of pregnancy or male patients whose partner have a possibility of pregnancy should avoid pregnancy adequately.

Possible adverse reactions to this medicine

The most commonly reported adverse reactions include constipation, injection site reaction (erythema, rash, itch, induration), malaise, fever, loss of appetite and rash. 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.

- anemia, fever, bleeding tendency [bone marrow suppression]
- fever, body dullness, cold-like symptoms [infection]
- headache, abdominal pain, bleeding from eyes, bloody urine, bleeding from surgical wound [bleeding]
- cough, respiratory distress, fever [interstitial lung disease]
- palpitations, chest pain, edema, shortness of breath [cardiac disorder]
- respiratory distress, facial pallor, general itching, hives [shock, anaphylaxis]

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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