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

Injection
Revised: 04/2022

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:MYLOTARG Injection 5mg

Active ingredient: Gemtuzumab ozogamicin (genetical recombination)

Dosage form:injection

Print on wrapping:

Effects of this medicine

This medicine, a combination of humanized anti-CD33 antibody and anti-tumor antibiotic derivative, has an anti-tumor effect through cytocidal activation after internalization into CD33 expressing leukemia cells.
It is usually used to treat relapsed or refractory CD33-positive acute myelocytic 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: liver dysfunction, renal dysfunction, infection or lung disease.
・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, this medicine is injected by intravenous infusion for 2 hours at a time. This preparation is injected twice with dosing interval of at least 14 days.
・The treatment period with this medicine is determined according to the symptoms.

Precautions while taking this medicine

・Follow your doctor's instructions and regularly undergo blood tests.
・You may regularly undergo liver and renal function tests for prolonged administration of this medicine. In that case, undergo the tests at specified dates and times.
・If you or your partner have a possibility of pregnancy, avoid pregnancy while you are using this medicine and for a certain period after you discontinue this medicine.

Possible adverse reactions to this medicine

The most commonly reported adverse reactions include fever, chills, nausea, vomiting, loss of appetite, diarrhea, abdominal pain, constipation, arrhythmia (tachycardia, etc.), hypotension, petechia, headache, lassitude and malaise.
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.

・chills, fever, nausea [infusion reaction]
・general malaise, fever, bleeding tendency [hematological disorder (myelosuppression, etc.)]
・sudden high fever with shivering, palpitation, chest discomfort [infection]
・headache, abdominal pain, vomiting of blood [bleeding]
・general malaise, loss of appetite, nausea [liver 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.