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

Injection
Revised: 03/2019

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:Rituxan Intravenous Infusion 500mg
Active ingredient: Rituximab (genetical recombination)
Dosage form:injection
Print on wrapping:

Effects of this medicine

This medicine attacks CD20 positive B cells (lymphocytes) and B cell lymphoma. It follows that this medicine suppresses growth of specific cells with CD20 positive.
It is usually used for treatment of non-Hodgkin's lymphoma (NHL), chronic lymphocytic leukemia (CLL), lymphoproliferative disorders (LPD), granulomatosis with polyangiitis (GPA), microscopic polyangiitis (MPA) and refractory nephrotic syndrome (RNS), chronic idiopathic thrombocytopenic purpura (cITP), and for prevention of antibody mediated rejection in ABO-incompatible kidney transplantation and liver transplantation.

Before 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.
If you have or have previously experienced: hepatitis B infection, cardiac or pulmonary dysfunctions.
If you have: infections (sepsis, pneumonia, viral infections), myelosuppression.
・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))
・For non-Hodgkin's lymphoma: In general, administer by intravenous infusion once weekly for up to 8 doses. If this medicine is used in combination with other antitumor medicines, administer by intravenous infusion once per each chemotherapy cycle according to the administration interval of the combined medicines. If this medicine is used for maintenance therapy, administer as a single intravenous infusion every 8 weeks for up to 12 doses.
For chronic lymphocytic leukemia: In combination with other antitumor medicines, in general, administer by intravenous infusion once per each chemotherapy cycle according to the administration interval of the combined medicines. Administer by intravenous infusion up to 6 doses.
For lymphoproliferative disorders: In general, administer by intravenous infusion once weekly for up to 8 doses.
For granulomatosis with polyangiitis, microscopic polyangiitis, refractory nephrotic syndrome and chronic idiopathic thrombocytopenic purpura: In general, administer by intravenous infusion once weekly for 4 doses.
For ABO-incompatible kidney transplantation and liver transplantation: In general, administration by intravenous infusion twice before kidney transplantation, once or twice before liver transplantation.
As a pre-administration for an administration of indium-111-(^{111}In) ibritumomab tiuxetan (genetical recombination) and yttrium-90- (^{90}Y) ibritumomab tiuxetan (genetical recombination): In general, administer by intravenous infusion once.
・The treatment period with this medicine depends on your medication plan.

Precautions while taking this medicine

Possible adverse reactions to this medicine

The most commonly reported adverse reactions include fever, nausea, loss of appetite, canker sore, taste abnormality, chills, itching, conjunctivitis, headache, flushing, eczema, rash, hypertension, tachycardia, excessive sweating, urinary tract infections, weariness/dullness, nausea, night sweat, respiratory distress, uncomfortable feeling in the mouth or throat, vomiting, low body temperature, hypoesthesia, nasopharyngitis, diarrhea, constipation, hypotension and maculopapular skin 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, see your doctor immediately.

・lassitude, dizziness, breathing difficulty, swelling around the eye/lip, decreased consciousness, chest pain [anaphylactoid symptoms, pulmonary disorder, cardiac disorder]
・flank pain, bloody urine, hypouresis [tumor lysis syndrome, renal disorder]
・fever, lassitude, yellowing of the skin and white of eyes, vomiting, loss of appetite, hand tremor like flapping [fulminant hepatitis and aggravated hepatitis caused by hepatitis B virus reactivation, hepatic dysfunction,

jaundice]

- high fever, redness of the eye and eyelid, lip and mouth sore, red speckle with swelling in the center, overall intense itchiness [mucocutaneous symptoms]
- fever, sore throat, dizziness, shortness of breath, heart palpitation, nosebleed, bleeding tendency [blood disorder, e.g. pancytopenia]
- cold-like symptoms, lassitude, fever, vomiting [infections]
- spasm, lightheadedness, loss of consciousness, difficult to talk, difficult to remember [cranial nerve symptom related to progressive multifocal leukoencephalopathy and reversible posterior leukoencephalopathy syndrome]
- fever, dry cough, breathing difficulty, shortness of breath [interstitial pneumonia]
- nausea, vomiting, severe abdominal pain, nauseousness, failure of passing stool [intestinal perforation and obstruction]

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.