

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

Injection

Revised: 12/2021

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:**RITUXIMAB BS Intravenous Infusion 100mg "Pfizer"

**Active ingredient:**Rituximab (genetical recombination) [rituximab biosimilar 2]

**Dosage form:**Injection

**Print on wrapping:**

バイアルに入っています

## Effects of this medicine

This medicine destroys CD20 positive B cells (lymphocytes) and B cell lymphoma cells to suppress growth of them.

It is usually used to treat non-Hodgkin's lymphoma, lymphoproliferative disorders, granulomatosis with polyangiitis, microscopic polyangiitis, chronic idiopathic thrombocytopenic purpura and acquired thrombotic thrombocytopenic purpura.

## Before using this medicine, be sure to tell your doctor and pharmacist

- If you have previously experienced any allergic reactions (itching, rash, etc.) to any medicines.  
If you have or have a history of hepatitis B or abnormal cardiac/lung function.  
If you have: infections (sepsis, pneumonia, viral infection) or 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 treatment of non-Hodgkin's lymphoma: In general, administer by intravenous infusion once a day, every week, 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 treatment 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 treatment of lymphoproliferative disorders: In general, administer by intravenous infusion once a day, every week, for up to 8 doses.  
For treatment of granulomatosis with polyangiitis, microscopic polyangiitis, chronic idiopathic thrombocytopenic purpura and acquired thrombotic thrombocytopenic purpura: In general, administer by intravenous infusion once a day, every week, for 4 doses.  
For premedication for indium (<sup>111</sup>In) ibritumomab tiuxetan (genetical recombination) injection and yttrium (<sup>90</sup>Y) ibritumomab tiuxetan (genetical recombination) injection: In general, administer by intravenous infusion once.
- The dose frequency and treatment interval with this medicine depend on combined medicines, your conditions, etc.

## Precautions while taking this medicine

### Possible adverse reactions to this medicine

The most commonly reported adverse reactions include infusion reaction (fever, chills, shortness of breath, palpitation, fast pulse, headache, nausea, dizziness, etc.), throat stimulation, itching, rash, fever, chills, nausea, headache, pain, feeling of collapse, malaise, infections, pharyngolaryngitis, rhinitis, uncomfortable feeling in the mouth or throat, tachycardia, vomiting, abdominal pain, stomatitis, hot flashes, increased sweating and anemia. 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.**

- weakness, dizziness, breathing difficulty, swelling around the eyes and lips, decreased consciousness, chest pain [infusion reaction]
- flank pain, bloody urine, decreased urine output [tumor lysis syndrome, renal disorder]
- fever, general malaise, yellowing of the skin and the white of eyes, vomiting, loss of appetite, shivering of hands like flapping [fulminant hepatitis/aggravated hepatitis caused by reactivation of hepatitis B virus, liver

dysfunction, jaundice]

- high fever, bloodshot of eyelids and eyes, sores on lips and inside mouth, red spots with swelling in the center, severe itching throughout the body [mucocutaneous symptoms]
- fever, sore throat, dizziness, shortness of breath, palpitation, nasal bleeding, bleeding tendency [decreased blood cells]
- cold-like symptoms, general malaise, fever, vomiting [infections]
- convulsion, light headedness, loss of consciousness, difficulty in speech, difficulty in remembering [cranial nerve symptoms related to progressive multifocal leukoencephalopathy and reversible posterior leukoencephalopathy syndrome]
- fever, dry cough, breathing difficulty, shortness of breath [interstitial pneumonia]
- weakness, dizziness on standing up, dizziness [decreased blood pressure]
- nausea, vomiting, severe abdominal pain, churning of stomach, failure of passing stool [gastrointestinal perforation/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.