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

Injection

Published: 08/2021

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:UNITUXIN I.V. injection 17.5mg/5mL

Active ingredient: Dinutuximab(genetical recombination)

Dosage form:injection

Print on wrapping:

Effects of this medicine

This medicine is thought to bind to Disialoganglioside (GD)2 expressed on cell membrane of neuroblastoma cells and to suppress proliferation of cancer cells by Antibody Dependent Cellular Cytotoxicity (ADCC) activity and Complement Dependent Cytotoxicity (CDC).

It is usually used to treat neuroblastoma after high-dose chemotherapy.

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 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, inject this medicine by intarvenous drip infusion once a day. The dosing schedule is 28 days for 1 cycle and 6 cycles in total, with the injections on the 4th to 7th days for the 1st, 3rd and 5th cycles and on the 8th to 11th days for the 2nd, 4th and 6th cycles.

Precautions while taking this medicine

Possible adverse reactions to this medicine

The most commonly reported adverse reactions include constipation, diarrhea, facial edema, malaise, decreased appetite, peripheral edema, edema, regional edema, fatigue, dysphonia, itching, dry skin, rash, eczema, headache, fever, vomiting, anemia, abdominal pain, pain and cough. 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.

- respiratory distress, decreased consciousness, loss of consciousness, swelling of eyelids/lips/tongue, fever, chill, vomiting, cough, dizziness, palpitation [infusion reaction]
- pain, abdominal pain, pain of limbs, neck pain, back pain, muscle pain [pain]
- no sensing of light, blind, pupil dilation, sensitive to light [eye disorder]
- general edema, rapid increased body weight, shortness of breath, breathing difficulty, increased heart rate, light-headedness, dizziness [capillary leak syndrome]
- lassitude, dizziness, light-headedness, dizziness on standing up, loss of consciousness [hypotension]
- fever, chill, body dullness [infection]
- fever, chill, sore throat, nasal bleeding, gum bleeding, bruise, prolonged bleeding, dull headache, palpitation, shortness of breath [myelosuppression]
- convulsion, numbness, body dullness, weakness, unable to move, body numbness, body itching, faint, decreased consciousness, unable to concentrate, unable to motivate, headache, thirst, nausea, vomiting, palpitation, breathing difficulty, abdominal bloating, trembling of limbs, diarrhea, difficult to defecate, increased urine output [electrolyte abnormality]

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. SIE①