

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:PADCEV for I.V. infusion 20mg

Active ingredient:Enfortumab vedotin(genetical recombination)

Dosage form:injection

Imprint or print on wrapping:



Effects of this medicine

This medicine is incorporated into the cancer cells by binding to a protein Nectin-4 in cancer cells, and suppresses cancer cell proliferation.

It is usually used to treat radically unresectable urothelial carcinoma that has progressed after cancer chemotherapy.

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 or have a history of hyperglycemia or diabetes mellitus.
If you have any risk factor (obesity, etc.) for diabetes mellitus.
If you have peripheral neuropathy (peripheral nerve disorder).
If you have or have a history of interstitial lung disease.
If you have liver dysfunction.
- 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, administer by intravenous infusion for at least 30 minutes at a time, once a week for 3 consecutive weeks and the fourth week is a medicine cessation period. This dosing schedule should be repeated as 1 course.
- Blood glucose tests, blood tests and renal function tests will be performed before using this medicine.
- Ask the doctor about the treatment span.

Precautions while taking this medicine

- The patients or their family should receive explanation to fully understand about the efficacy and precautions of this medicine. This medicine is administered after their consent on the medication is obtained.
- Severe skin disorders may occur. If any abnormality of skin, mucosa or eyes is observed, consult with medical institution immediately.
- Since hyperglycemia may occur, blood glucose levels will be periodically measured while using this medicine.
- Since myelosuppression may occur, blood tests will be periodically performed while using this medicine.
- Since renal dysfunction may occur, renal function tests will be periodically performed while using this medicine.
- Since interstitial lung disease may occur, chest imaging tests will be periodically performed while using this medicine. If any initial symptoms of interstitial lung disease (breathing difficulty, cough, fever, etc.) is observed, consult with medical institution immediately.
- If you or your partner have a possibility of pregnancy, avoid pregnancy while you are taking 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 fatigue, loss of appetite, alopecia, itch, peripheral sensory neuropathy (sensory paralysis, numbness of limbs, pain in limbs), nausea, diarrhea, constipation, weight loss, asthenia (muscle weakness during waking hours, drooping eyelids, double vision, difficulty in swallowing), impaired taste, maculopapular rash (small dome-like rash), rash and dry skin. 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.

- widespread redness in the skin and multiple breakable blisters, erosion in lips and inside the mouth, multiple circular macules with edematous ring-like bulge in the marginal region [severe skin disorder]
- weight loss, drinking large amounts of water, increased urine output [hyperglycemia]
- numbness and/or pain of limbs, muscle weakness [peripheral neuropathy]
- anemia, chills, bleeding tendency [myelosuppression]
- fever, cough/phlegm, breathing difficulty [infection]
- decreased urine output, edema, general malaise [renal dysfunction]
- cough, shortness of breath, breathing difficulty [interstitial lung disease]

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.