

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

Injection

Revised: 02/2021

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:**BAVENCIO intravenous infusion

**Active ingredient:**Avelumab (genetical recombination)

**Dosage form:**injection

**Print on wrapping:**

バイアルに入っています

## Effects of this medicine

This medicine inhibits the binding between the substances expressed on tumor cells (PD-L1) and its receptors (PD-1), thereby enhancing immune cells (T cells) activation and suppresses tumor growth.

It is usually used for curatively unresectable Merkel cell carcinoma, curatively unresectable or metastatic renal cell carcinoma, or maintenance following chemotherapy in curatively unresectable urothelial carcinoma.

## 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: autoimmune disorder or its history or interstitial lung disease or its history.
- 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 curatively unresectable Merkel cell carcinoma and maintenance following chemotherapy in curatively unresectable urothelial carcinoma: In general, for adults, inject by intravenous infusion over at least 1 hour every 2 weeks.  
For treatment of curatively unresectable or metastatic renal cell carcinoma: In general, for adults, inject by intravenous infusion over at least 1 hour every 2 weeks in combination with axitinib.
- Ask the doctor about the treatment span.
- To reduce infusion reaction, you will be administered antihistamine agents, antipyretic analgesics, etc. before drip infusion of this medicine.

## Precautions while taking this medicine

- Since interstitial lung disease may occur, initial symptoms such as shortness of breath, respiratory distress and cough are checked and chest X-ray and others are performed while using this medicine. If any of these initial symptoms of interstitial lung disease occur, contact your doctor.

## Possible adverse reactions to this medicine

The most commonly reported adverse reactions include diarrhea, hypertension, fatigue, infusion reaction, hypothyroidism (intolerance to cold, edema of whole face, malaise, slow in conversation or in motion), palmar-plantar erythrodysesthesia syndrome (redness, swelling, crack, pain, etc. of limbs), nausea, hyperthyroidism (sweat, weight loss, fast pulse, tremor of limbs), stomatitis, vomiting, chills, asthenia, fever, mucosal inflammation, loss of appetite, weight loss, joint pain, muscle pain, headache, dysgeusia, dysphonia, dyspnea, itch, 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, stop taking this medicine and see your doctor immediately.**

- shortness of breath, respiratory distress, cough [interstitial lung disease]
- severe pain in the upper abdomen, back pain, nausea [pancreatitis]
- general malaise, loss of appetite, yellow discoloration of skin and/or conjunctiva [liver failure, liver dysfunction, hepatitis]
- persistent diarrhea, abdominal pain, bloody stool [colitis, severe diarrhea]
- sweat, edema, enervation [disturbed thyroid function]
- general malaise, decreased consciousness, hypotension [adrenal dysfunction]
- general malaise, decreased consciousness, decreased blood pressure [pituitary dysfunction]
- dry mouth, nausea, vomiting [type 1 diabetes mellitus]
- chest pain, shortness of breath, palpitation [myocarditis]

- paralysis, numbness of limbs, pain [nervous disorder]
- decreased urine output, edema, general malaise [renal disorder]
- muscle weakness, muscle pain, reddish brown urine [myositis, rhabdomyolysis]
- anaphylactic reaction, fever/chills, respiratory distress [infusion reaction]
- muscle weakness, drooping of upper eyelids, dyspnea [myasthenia gravis]

**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.