

Avelumab (Bavencio)

About This Drug

Avelumab is used to treat cancer. This drug is given in the vein (IV).

Possible Side Effects

- Nausea
- Diarrhea (loose bowel movements)
- Tiredness
- While you are getting this drug in your vein (IV), you may have a reaction to the drug. Your nurse will check you closely for these signs: fever or shaking chills, flushing, facial swelling, feeling dizzy, headache, trouble breathing, rash, itching, chest tightness, or chest pain. You will be given medicines to help stop or lessen these symptoms. These reactions may happen after your infusion. **If this happens, call 911 for emergency care.**
- Decreased appetite (decreased hunger)
- Muscle and bone pain
- Rash
- Swelling of your legs, ankles and/or feet
- Urinary tract infection

Note: Each of the side effects above was reported in 20% or greater of patients treated with avelumab. Your side effects may be different if you are taking avelumab in combination with other agents. Not all possible side effects are included above.

Warnings and Precautions

- This drug works with your immune system and can cause inflammation (swelling) in any of your organs and tissues and can change how they work. This may put you at risk for developing serious medical problems, which can be life-threatening.
- Inflammation (swelling) of the lungs which can be life-threatening. You may have a dry cough or trouble breathing.
- Colitis, which is swelling in the colon. The symptoms are diarrhea, stomach cramping, and sometimes blood in the bowel movements.
- Severe changes in your liver function which can cause liver failure and be life-threatening
- This drug may affect some of your hormone glands (especially the thyroid, adrenals, pituitary and pancreas).

- Changes in your kidney function
- Blood sugar levels may change, and you may develop diabetes. If you already have diabetes, changes may need to be made to your diabetes medication.
- Allergic skin reaction, which can be life-threatening. You may develop blisters on your skin that are filled with fluid or a severe red rash all over your body that may be painful.
- Severe reaction to the drug, which can be life-threatening
- Severe changes in your heart function when taken in combination with axitinib, which can be life-threatening

Note: Some of the side effects above are very rare. If you have concerns and/or questions, please discuss them with your medical team.

Important Information

- This drug may be present in the saliva, tears, sweat, urine, stool, vomit, semen, and vaginal secretions. Talk to your doctor and/or your nurse about the necessary precautions to take during this time.

Treating Side Effects

- Manage tiredness by pacing your activities for the day.
- Be sure to include periods of rest between energy-draining activities.
- Drink plenty of fluids (a minimum of eight glasses per day is recommended).
- To help with nausea and vomiting, eat small, frequent meals instead of three large meals a day. Choose foods and drinks that are at room temperature. Ask your nurse or doctor about other helpful tips and medicine that is available to help stop or lessen these symptoms.
- To help with decreased appetite, eat small, frequent meals. Eat foods high in calories and protein, such as meat, poultry, fish, dry beans, tofu, eggs, nuts, milk, yogurt, cheese, ice cream, pudding, and nutritional supplements.
- Consider using sauces and spices to increase taste. Daily exercise, with your doctor's approval, may increase your appetite.
- If you throw up or have loose bowel movements, you should drink more fluids so that you do not become dehydrated (lack of water in the body from losing too much fluid).
- If you have diarrhea, eat low-fiber foods that are high in protein and calories and avoid foods that can irritate your digestive tracts or lead to cramping.
- Ask your doctor or nurse about medicines that are available to help stop or lessen diarrhea..
- If you get a rash do not put anything on it unless your doctor or nurse says you may. Keep the area around the rash clean and dry. Ask your doctor for medicine if your rash bothers you.
- If you have diabetes, keep good control of your blood sugar level. Tell your nurse or your doctor if your glucose levels are higher or lower than normal.
- Keeping your pain under control is important to your well-being. Please tell your doctor or nurse if you are experiencing pain.
- Get regular exercise, with your doctor's approval. If you feel too tired to exercise vigorously, try taking a short walk.



- If you experience signs and symptoms of a reaction to the drug such as; fever, chills, shaking chills, facial swelling, trouble breathing, rash, itching, chest tightness or chest pain, **call 911 for emergency care.**

Food and Drug Interactions

- There are no known interactions of avelumab with food.
- This drug may interact with other medicines. Tell your doctor and pharmacist about all the prescription and over-the-counter medicines and dietary supplements (vitamins, minerals, herbs and others) that you are taking at this time. Also, check with your doctor or pharmacist before starting any new prescription or over-the-counter medicines, or dietary supplements to make sure that there are no interactions.

When to Call the Doctor

Call your doctor or nurse if you have any of these symptoms and/or any new or unusual symptoms:

- Fever of 100.4° F (38° C) or higher
- Chills, flushing
- Signs of a local infection such as pain, redness, tenderness, warmth and/or swelling
- Headache that does not go away
- Changes in mood or behavior
- Feeling dizzy or lightheaded
- Tiredness or weakness that interferes with your daily activities
- Confusion
- Feeling that your heart is beating fast or in a not normal way (palpitations)
- Pain in your chest or abdomen
- Pain that does not go away, or its not relieved by prescribed medicines
- Dry cough
- Wheezing or trouble breathing
- Easy bleeding or bruising
- Nausea that stops you from eating or drinking and/or is not relieved by prescribed medicine
- Lasting loss of appetite or rapid weight loss of five pounds in a week
- Diarrhea, 4 times in one day or diarrhea with lack of strength or a feeling of being dizzy
- Blood in your stool
- Pain or burning when you pass urine
- Difficulty urinating
- Feeling like you have to pass urine often, but not much comes out when you do.
- Tender or heavy feeling in your lower abdomen
- Cloudy urine and/or urine that smells bad
- Pain on one side of your back under your ribs. This is where your kidneys are.
- Decreased urine



- Weight gain of 5 pounds in one week (fluid retention)
- Swelling of your legs, ankles and/or feet
- Abnormal blood sugar
- Unusual thirst, passing urine often, headache, sweating, shakiness, irritability
- New rash and/or itching
- Rash that is not relieved by prescribed medicines
- Signs of liver problems: dark urine, pale bowel movements, bad stomach pain, feeling very tired and weak, unusual itching, or yellowing of the eyes or skin
- Signs of infusion reaction: fever or shaking chills, flushing, facial swelling, feeling dizzy, headache, trouble breathing, rash, itching, chest tightness, or chest pain. **If this happens, call 911 for emergency care.**
- If you think you are pregnant

Reproduction Warnings

- **Pregnancy warning:** This drug can have harmful effects on the unborn baby. Women of childbearing potential should use effective methods of birth control during your cancer treatment and for at least 1 month after treatment. Let your doctor know right away if you think you may be pregnant.
- **Breastfeeding warning:** Women should not breastfeed during treatment and for at least 1 month after treatment because this drug could enter the breast milk and cause harm to a breastfeeding baby.
- **Fertility warning:** Human fertility studies have not been done with this drug. Talk with your doctor or nurse if you plan to have children. Ask for information on sperm or egg banking.

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