Patient Medication Information

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

[Pr]BAVENCIO® (buh-VEN-see-oh)
Avelumab for Injection

This patient medication information is written for the person who will be taking Bavencio. This may be you or a person you are caring for. Read this information carefully. Keep it as you may need to read it again.

This patient medication information is a summary. It will not tell you everything about this medication. If you have more questions about this medication or want more information about Bavencio, talk to a healthcare professional.

What Bavencio is used for:
Bavencio is a medicine used to treat a rare type of skin cancer in adult patients that has spread called metastatic Merkel cell carcinoma.
Bavencio is a medicine used to treat a type of cancer in the bladder or urinary tract called urothelial carcinoma when it cannot be removed by surgery (advanced urothelial carcinoma) or has spread, and

- your cancer has not progressed following first-line platinum-based chemotherapy, or
- you have already been treated with a certain type of chemotherapy, which did not work or is no longer working.

Bavencio should not be used in children less than 18 years of age.

How Bavencio works:
Bavencio works by helping your immune system fight your cancer.

The ingredients in Bavencio are:
Medicinal ingredients: Avelumab
Non-medicinal ingredients: D-mannitol, glacial acetic acid, polysorbate 20, sodium hydroxide, water for injection

Bavencio comes in the following dosage form(s):
Bavencio comes in a 10 mL glass vial containing 200 mg of avelumab. The container closure does not contain natural rubber latex material.

Do not use Bavencio if:

- you are allergic to avelumab or any of the other ingredients of this medicine. Talk to your healthcare professional if you are not sure.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take Bavencio. Talk about any health conditions or problems you may have, including if you have:

- Lung problems such as breathing difficulties or cough. These may be signs of inflammation of the lungs (pneumonitis)

- Inflammation of the liver (hepatitis). Signs and symptoms of hepatitis may include abnormal blood tests (liver function tests), eye or skin yellowing (jaundice), pain on the right side of your stomach area or drowsiness
- Diarrhea (watery, loose or soft stools) or more bowel movements than usual or any symptoms of inflammation of the intestines (colitis), such as stomach pain and mucus or blood in stool
- Problems with your hormone producing glands (the thyroid, adrenal or pituitary glands) that may affect how these glands work. Signs and symptoms that these glands are not working properly may include extreme tiredness, rapid heartbeat, increased sweating, changes in mood or behavior, such as irritability or forgetfulness, feeling cold, very low blood pressure, weight change or headache
- Inflammation of your pancreas (pancreatitis). Inflammation of your pancreas may include abdominal pain, nausea and vomiting
- Inflammation of your heart (myocarditis). Inflammation of the heart may include trouble breathing, dizziness or fainting, fever, chest pain and chest tightness or flu like symptoms
- Inflammation of your muscles (myositis). Inflammation of your muscles may include muscle pain or weakness
- Muscle weakness (myasthenia gravis or myasthenic syndrome) which may include drooping eyelids and/or double vision, facial drooping, slurred speech, chewing or swallowing problems, difficulty walking and climbing stairs, difficulty lifting objects or raising your arms
- Infusion reactions, which may include chills, hives, shortness of breath, fever or back pain
- Had an organ transplant (liver or kidney)
- Kidney problems
- A condition that affects your nervous system
- A condition requiring immunosuppressive drug therapy
- An autoimmune disease (a condition where the body attacks its own cells), such as rheumatoid arthritis, Crohn's disease, ulcerative colitis, or lupus
- Taken other medicines that make your immune system weak. Examples of these may include steroids, such as prednisone

Other warnings you should know about:

Tell your healthcare professional immediately if you have any of these signs or symptoms or if they get worse. Do not try to treat your symptoms with other medicines on your own. Your healthcare professional may:

- give you other medicines in order to prevent complications and reduce your symptoms;
- withhold the next dose of Bavencio; or
- stop your treatment with Bavencio altogether.

Please note that these signs and symptoms are sometimes delayed, and may develop after your last dose. Before treatment, your healthcare professional will check your general health. You will also have blood tests during your treatment.

Pregnancy:
Tell your healthcare professional if you are pregnant or think you might be, or if you are planning to become pregnant. You must not use Bavencio if you are pregnant unless your

healthcare professional specifically recommends it. Bavencio can cause harm to your unborn baby.

If you are a woman who could become pregnant, you must use effective birth control while you are being treated with Bavencio and for at least 1 month after your last dose.
Breastfeeding:
Tell your healthcare professional if you are breast-feeding. Do not breast-feed while receiving Bavencio and for at least 1 month after your last dose.

It is unknown if Bavencio passes into your breast milk. A risk to the breast-fed infant cannot be excluded.

Driving and using machines:
It is not known whether Bavencio affects your ability to drive or use tools or machines. However, if you feel tired, do not drive or use tools or machines until you feel better.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

How to take Bavencio:
You will receive Bavencio in a hospital or clinic under the supervision of an experienced healthcare professional.

You will receive Bavencio as an infusion (a drip) into a vein (intravenously) over a period of 60 minutes every 2 weeks. Your healthcare professional will determine how many treatments you need.

Usual dose:
The amount of Bavencio you will receive will be calculated based on your body weight. The recommended dose is 10 mg of Bavencio per kilogram of your body weight.
Stopping your treatment may stop the effect of the medicine. Do not stop treatment with Bavencio unless you have discussed this with your healthcare professional.

Overdose:

If you think you, or a person you are caring for, have taken too much Bavencio, contact a healthcare professional, hospital emergency department, regional poison control centre or Health Canada's toll-free number, 1-844 POISON-X (1-844-764-7669) immediately, even if there are no signs or symptoms.

Missed Dose:
It is important to keep your appointments. If you miss any appointments, call your healthcare professional as soon as possible to reschedule your appointment.

Possible side effects from using Bavencio:
These are not all the possible side effects you may have when taking Bavencio. If you experience any side effects not listed here, tell your healthcare professional.
The following side effects have been reported in clinical trials with Bavencio:

Very common (may affect more than 1 in 10 people)
- Itching

- High blood pressure
- Headache
- Joint pain

Common (may affect up to 1 in 10 people)

- Allergic reaction to the drug, increased tendency of body to have allergic reactions
- Redness of the skin
- Increase liver enzymes in the blood
- Increase thyroid hormone in the blood

Serious side effects and what to do about them			
Frequency / Side Effect / Symptom	**Talk to your healthcare professional**		**Stop taking drug and get immediate medical help**
	Only if severe	**In all cases**	
VERY COMMON			
Decrease in number of red blood cells		✓	
COMMON			
Urinary tract infection		✓	
UNCOMMON			
Inflammation of the lungs (pneumonitis): new or worsening cough, shortness of breath, chest pain		✓	
Inflammation of the liver (hepatitis): yellowing of your skin or the whites of your eyes, dark urine (tea coloured), severe nausea or vomiting, bleeding or bruising more easily than normal, pain on the right side of your stomach area (abdomen), feeling less hungry than usual, drowsiness		✓	
Inflammation of the intestines (colitis): diarrhea (loose stools) or more bowel movements than usual, blood in your stools or dark, tarry, sticky stools, severe stomach area (abdomen) pain or tenderness		✓	
Inflammation of a hormone gland (especially the thyroid, adrenal or pituitary glands): rapid heart-beat, constipation, increased sweating, your voice gets deeper, extreme tiredness, very low blood pressure, weight gain or weight loss, urinating		✓	

Serious side effects and what to do about them			
Frequency / Side Effect / Symptom	**Talk to your healthcare professional**		**Stop taking drug and get immediate medical help**
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more often than usual, feeling more hungry or thirsty than usual, dizziness or fainting, hair loss, changes in mood or behavior (such as irritability or forgetfulness), feeling cold, headache			
Blood sugar problems (type 1 diabetes mellitus): hunger or thirst, a need to urinate more often, weight loss		✓	
Inflammation of the kidneys (nephritis): urinating less than usual, swelling in your ankles, blood in your urine, loss of appetite		✓	
Inflammation of the heart (myocarditis): shortness of breath, irregular heartbeat, feeling tired, chest pain		✓	
Inflammation of the muscles (myositis): muscle weakness, swelling, pain		✓	
Muscle problems (myasthenia gravis/myasthenic syndrome): drooping eyelids and/or double vision, facial drooping, slurred speech, chewing or swallowing problems, difficult walking and climbing stairs, difficulty lifting objects or raising your arms		✓	
Severe infusion reactions: chills or shaking, low blood pressure, hives, fever, flushing, back pain, shortness of breath or wheezing, abdominal pain		✓	
Inflammation of the eye (uveitis)		✓	
Nervous system problems: Guillain-Barré Syndrome (pain, numbness, muscle weakness, difficulty in walking);		✓	
RARE			
Inflammation of the pancreas (pancreatitis): abdominal pain, nausea and vomiting		✓	

Serious side effects and what to do about them			
Frequency / Side Effect / Symptom	**Talk to your healthcare professional**		**Stop taking drug and get immediate medical help**
	Only if severe	**In all cases**	
Inflammation of the glands that make moisture for the body which may include dry eyes and dry mouth (Sjogren's syndrome)		✓	
UNKNOWN			
Inflammation and scarring of the bile ducts (sclerosing cholangitis): pain in the upper right part of the stomach, swelling of the liver or spleen, fatigue, itching, or yellowing of the skin or the whites of eyes		✓	
Inflammation of the stomach lining (gastritis): stomach pain or tenderness, nausea or vomiting		✓	

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (canada.ca/drug-device-reporting) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:
Store in a refrigerator (2°C to 8°C). Do not freeze. Store in the original package to protect from light.

Keep out of reach and sight of children.

If you want more information about Bavencio:
- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada Drug Product Database website: (https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html); EMD Serono website (http://www.emdserono.ca), or

by calling EMD Serono at 1-888-737-6668.

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