

Medication Information Sheet**avelumab** (a VEL ue mab)

This document provides general information about your medication. It does not replace the advice of your health care professional. Always discuss your therapy with your health care professional and refer to the package insert for more details.

Other Name: Bavencio

Appearance: solution mixed into larger bags of fluids

What is this medication for?

- For treating a type of skin cancer called Merkel cell carcinoma and type of cancer in the bladder or urinary system in patients who have received previous treatments.
- Avelumab is an immune therapy drug. For more information on immune therapy, click [here](#).

What should I do before I have this medication?

Tell your health care team if you have or had significant medical condition(s), such a

- an organ transplant
- immune conditions (such as ulcerative colitis, Crohn's, rheumatoid arthritis or lupus)
- problems with your hormone producing glands (such as the thyroid or adrenal glands)
- liver, heart, kidney or lung problems
- active infections or
- any allergies

Tell your health care team if you are taking corticosteroids (such as prednisone)

How will this medication affect sex, pregnancy and breastfeeding?

- The use of this medication in men or women may cause harm to the unborn baby if pregnancy occurs. Let your health care team know if you or your partner is pregnant, becomes pregnant during treatment, or if you are breastfeeding

- If there is **any chance** that you or your partner may become pregnant, you and your partner together must:
- ► **Use 2 effective forms of birth control at the same time** while taking this drug. Keep using birth control for at least **1 month** after your last dose unless your health care team told you differently. Talk to your health care team to figure out the best method(s) for you and/or your partner.
- Do not breastfeed while using this drug and for at least **1 month** after your last dose.
- This medication may affect fertility (ability to get pregnant)

How is this medication given?

- This drug is given by injection into a vein, usually every 2 weeks. Talk to your health care team about your treatment schedule.
- You may be given this treatment along with other medications to help prevent side effects.
- If you missed your treatment appointment, talk to your health care team to find out what to do.

What else do I need to know while on this medication?

- This medication does not normally interfere with other medications. Tell your health care team about all of your medicines (prescription or over-the-counter medications, herbals and supplements). Check with your health care team before starting or stopping any of them.
- **For mild aches and pain or fever:**
 - ◊ If you feel unwell, take your temperature before taking any medications for pain or fever. They may hide a fever.
 - ◊ You may take acetaminophen (Tylenol®) tablets. Ask your health care team about the right dose for you.
 - ◊ Ibuprofen (Advil®, Motrin®), naproxen (Aleve®) or aspirin (acetylsalicylic acid, ASA), including low dose aspirin for heart conditions, may increase your chance of bleeding. Talk to your health care team before you start or stop these medications.
 - ◊ **Talk to your health care team or go to the closest emergency room right away if you have a fever.**
 - ◊ See the [Fever](#) pamphlet for more information.
- Avelumab may make you feel tired; if you feel tired, do not drive or use tools or machines until you feel well.

- Drinking alcohol and smoking during your treatment may increase some side effects and make your medication less effective. Speak to your health care team about smoking and drinking alcohol while on treatment.

What are the side effects of this medication?

- Avelumab makes your immune system work harder. Your immune system is what fights infections and your cancer.
- When your immune system is working harder, you may have side effects in your bowels, liver, lungs, skin, kidneys, hormones and other organs.
- These side effects may be mild or may become serious or life-threatening in rare cases.
- They may happen during your treatment or weeks to months after your treatment ends.
- You may need urgent treatment (such as a corticosteroid for up to 4 weeks) to treat side effects

Side effects and what to do	When to contact doctor?
Common Side Effects (25-49 out of 100 people)	
<p>Fatigue (tiredness)</p> <ul style="list-style-type: none"> • Be active and aim to get 30 minutes of moderate exercise (you are able to talk comfortably while exercising) on most days. Check with your health care team before starting any new exercise. • Pace yourself, do not rush. Put off less important activities. Rest when you need to. • Eat well and stay hydrated by drinking at least 6 to 8 glasses of water or other liquids every day (unless your doctor told you to drink more or less). • Avoid driving or using machinery if you are feeling tired <p>See our Fatigue pamphlet for more information.</p>	<p>Talk to your health care team if it does not improve or if it is severe</p>
<p>Salt imbalances</p> <p>It may cause muscle twitching, severe weakness or cramping, confusion and irregular heartbeat.</p>	<p>Get emergency medical help right away</p>
<p>Abnormal liver lab tests</p> <ul style="list-style-type: none"> • You may have yellowish skin or eyes, unusually dark pee or pain on the 	<p>Talk to your health care team if it does not improve</p>

Side effects and what to do	When to contact doctor?
Common Side Effects (25-49 out of 100 people)	
right side of your belly. • Your doctor may monitor your liver regularly with a blood test.	or if it is severe
Mild joint, muscle pain or cramps • Take your pain medication as prescribed by your doctor. • You can take acetaminophen (Tylenol®) tablets as needed for mild aches and pains. Ask your doctor or pharmacist about the right dose for you. • Talk to your doctor or pharmacist first before taking ibuprofen (Advil®, Motrin®), naproxen (Aleve®) or aspirin. These medication may increase bleeding risk. • Rest often and try light exercise as it may help.	Talk to your health care team if it does not improve or if it is severe

Side effects and what to do	When to contact doctor?
Less Common Side Effects (10-24 out of 100 people)	
Nausea and vomiting (generally mild) May occur in hours to days after your treatment. If you have nausea or vomiting: <ul style="list-style-type: none"> • Take anti-nausea medication(s) as prescribed to you by your doctor. • Drink clear liquids and have small meals. Get fresh air and rest. • Do not eat spicy, fried foods or foods with a strong smell. • Limit caffeine (e.g. coffee, tea) and alcohol. • Contact your health care team if the prescribed anti-nausea medications are not helping to control your nausea and vomiting. Also see Nausea & Vomiting pamphlet for more information.	Talk to your healthcare team if nausea lasts more than 48 hours or vomiting lasts more than 24 hours
Infusion Reactions (may be severe) What to look for: <ul style="list-style-type: none"> • You may have chills or shaking, low blood pressure, hives, fever, flushing, back pain, shortness of breath or wheezing, abdominal pain • It may occur during or shortly after the medication is given to you. Let your health care team know right away if this happens to you. • You may be given medicines to prevent or treat this reaction 	Talk to your health care team if it does not improve or if it is severe

Side effects and what to do	When to contact doctor?
Less Common Side Effects (10-24 out of 100 people)	
<p>What to do:</p> <ul style="list-style-type: none"> • Talk to your health care team if no improvement or if severe. 	
<p>Low appetite, weight loss</p> <ul style="list-style-type: none"> • You may not feel like eating or you may lose weight. • Try to eat foods that you like and eat small meals throughout the day. • You may need to take meal supplements to help keep your weight up. • Talk to your health care team if you have a low appetite. • See our Loss of appetite pamphlet for more information. 	<p>Talk to your health care team if it does not improve or if it is severe</p>
<p>Pains or cramps in the belly</p> <ul style="list-style-type: none"> • If you have constipation or diarrhea it may be causing the pain in your belly. • If the pain is severe, gets worse or doesn't go away, talk to your health care team about other possible causes. 	<p>Talk to your health care team if it does not improve or if it is severe</p>
<p>Anemia (low red blood cells)</p> <ul style="list-style-type: none"> • You may feel more tired or weak than normal and have pale skin. • This may occur in days to weeks after you start or receive your medication. • Rest often and eat well. • Light exercise, such as walking may help. • You may need medication or a blood transfusion. • If it is very bad, your doctor may ask you to stop the medication that is causing the low red blood cells. 	<p>Talk to your health care team if it does not improve or if it is severe</p>
<p>Constipation</p> <p>To help prevent constipation :</p> <ul style="list-style-type: none"> • Drink more liquids and eat well. Drink at least 6 to 8 cups of liquids each day unless you have been told otherwise. • Be Active. Exercise can help to keep you regular. • Try to eat more fiber (e.g. fruits with skin, leafy greens and whole grains). If you take opioid pain medication, ask your health care team if eating more fibre is right for you. <p>To help treat constipation :</p> <ul style="list-style-type: none"> • If you have not had a bowel movement in 2 to 3 days you may need to take a laxative. Ask your health care team what to do. <p>See the Constipation Pamphlet for more information.</p>	<p>Talk to your health care team if it does not improve or if it is severe</p>

Side effects and what to do	When to contact doctor?
Less Common Side Effects (10-24 out of 100 people)	
<p>Diarrhea</p> <p>May happen days to weeks after you get your treatment.</p> <p>If you have diarrhea :</p> <ul style="list-style-type: none"> • Take anti-diarrhea medication if your health care team prescribed it. • Avoid foods or drinks with artificial sweetener (e.g. chewing gum, “diet” drinks), coffee and alcohol. • Eat many small meals and snacks instead of 2 or 3 large meals. • Drink at least 6 to 8 cups of liquids each day. Talk to your health care team if you can’t drink 6-8 cups of liquids each day when you have diarrhea. You may need special liquids with salt and sugar, called Oral Rehydration Therapy. <p>See the Diarrhea pamphlet for more information.</p> <p><i>Talk to your health care team for advice.</i></p> <p>In rare cases, may be severe due to inflammation of intestines</p> <ul style="list-style-type: none"> • If you have blood in your stool (poo) or 4 to 6 bowel movements a day (if that is not normal for you) <p><i>Talk to your health care team or go to the emergency room right away.</i></p>	<p>Talk to your health care team if it does not improve or if it is severe.</p> <p>If you can't talk to your health care team, go to the emergency room right away for severe symptoms.</p>
<p>Cough; feeling short of breath</p> <p>You may have cough and feel short of breath without any signs of infection, such as a sore throat or a stuffed nose.</p> <p>Rarely this may be severe with chest pain, trouble breathing or coughing up blood. If this happens get medical help right away.</p>	<p>Talk to your health care team if it does not improve or if it is severe</p>
<p>Mild swelling in arms and legs; puffiness</p> <p>To help prevent swelling :</p> <ul style="list-style-type: none"> • Eat a low-salt diet. • Avoid tight fitting clothing. <p>If you have swelling in your legs, keep your feet up when sitting.</p>	<p>Talk to your health care team if it does not improve or if it is severe</p>

Side effects and what to do	When to contact doctor?
Less Common Side Effects (10-24 out of 100 people)	
<p>Kidney problems</p> <ul style="list-style-type: none"> You may have lower back pain, swelling, pee less than usual and have unusual weight gain. Your doctor may monitor for proteins in your pee. You may have blood in your pee. <p>To prevent bladder or kidney problems:</p> <ul style="list-style-type: none"> Drink lots of water or other liquids. Drink at least 6 to 8 cups (2 L) of liquids per day on treatment days, unless you have been told otherwise. 	<p>Get emergency medical help right away</p>
<p>Rash</p> <p>You may experience itching with a mild rash.</p> <p>To prevent and treat dry skin,</p> <ul style="list-style-type: none"> Use skin moisturizer. Protect your skin from the sun and the cold. Use sunscreen with UVA and UVB protection and a SPF of at least 30. <p><i>Talk to your health care team for advice</i></p> <p>In rare cases, rash may be severe</p> <ul style="list-style-type: none"> If the rash covers more than a third of your skin (for example your whole trunk or an arm AND a leg) or your skin blisters <p><i>Talk to your health care team or go to the emergency room right away.</i></p>	<p>Talk to your health care team or go to the emergency room right away</p>
<p>Abnormal levels of pancreas tests (lipase, amylase)</p> <p>Your doctor may monitor these regularly.</p>	<p>Talk to your health care team if it does not improve or if it is severe</p>
<p>High pressure</p> <ul style="list-style-type: none"> Check your blood pressure regularly. Your doctor may prescribe medication to treat high blood pressure. If you have a severe headache, severe dizziness, or if you faint get emergency help right away as it may be a sign your blood pressure is too high or too low. 	<p>Talk to your health care team if it does not improve or if it is severe</p>

Other rare, but serious side effects are possible and have been described with avelumab or other similar drugs.

If you experience ANY of the following, speak to your cancer health care provider or get emergency medical help right away:

- Usual weight gain with some of the following: feeling tired or having low energy, dry skin, nails or hair that breaks easily, and sensitivity to cold
- Usual weight loss with some of the following: increased sweating and/or appetite, trouble sleeping, feeling irritable or overactive, rapid or irregular heartbeats
- Feel tired, have muscle weakness or skin darkening
- Irregular heartbeat, shortness of breath, chest pain, fainting spells or swelling in your legs, ankles and belly
- Signs of high blood sugar like confusion, feeling sleepy, more thirst, more hungry, passing urine more often, flushing, fast breathing, or breath that smells like fruit
- Very bad muscle pain, swelling or weakness
- Pins and needles sensations in your fingers, toes, ankles or wrists, weakness in your legs that spreads to your upper body and unsteady walking
- Change in eyesight, trouble with eye or facial movements, including speaking, chewing or swallowing

For more links on how to manage your symptoms go to www.cancercareontario.ca/symptoms.

The information set out in the medication information sheets, regimen information sheets, and symptom management information (for patients) contained in the Drug Formulary (the "Formulary") is intended to be used by health professionals and patients for informational purposes only. The information is not intended to cover all possible uses, directions, precautions, drug interactions or side effects of a certain drug, nor should it be used to indicate that use of a particular drug is safe, appropriate or effective for a given condition.

A patient should always consult a healthcare provider if he/she has any questions regarding the information set out in the Formulary. The information in the Formulary is not intended to act as or replace medical advice and should not be relied upon in any such regard. All uses of the Formulary are subject to clinical judgment and actual prescribing patterns may not follow the information provided in the Formulary.