MEDICATION GUIDE

BAVENCIO® (buh-VEN-see-oh)

(avelumab)

injection

What is the most important information I should know about BAVENCIO?

BAVENCIO is a medicine that may treat certain cancers by working with your immune system. BAVENCIO can cause your immune system to attack normal organs and tissues in any area of your body and can affect the way they work. These problems can sometimes become severe or life-threatening and can lead to death**.** You can have more than one of these problems at the same time. These problems may happen anytime during treatment or even after your treatment has ended.

Call or see your healthcare provider right away if you get any new or worsening signs or symptoms, including:

Lung problems.

- cough
- shortness of breath
- chest pain

Intestinal problems.

- diarrhea (loose stools) or more frequent bowel movements than usual
- stools that are black, tarry, sticky, or have blood or mucus
- severe stomach-area (abdomen) pain or tenderness

Liver problems.

- yellowing of your skin or the whites of your eyes
- severe nausea or vomiting
- pain on the right side of your stomach-area (abdomen)
- dark urine (tea colored)
- bleeding or bruising more easily than normal

Hormone gland problems.

- headache that will not go away or unusual headaches
- eye sensitivity to light
- eye problems
- rapid heartbeat
- increased sweating
- extreme tiredness
- weight gain or weight loss
- feeling more hungry or thirsty than usual
- urinating more often than usual
- hair loss
- feeling cold
- constipation
- your voice gets deeper
- dizziness or fainting
- changes in mood or behavior, such as decreased sex drive, irritability, or forgetfulness

Kidney problems.

- decrease in your amount of urine
- blood in your urine
- swelling of your ankles
- loss of appetite

Skin problems.

- rash
- itching
- skin blistering or peeling
- painful sores or ulcers in mouth or nose, throat, or genital area
- fever or flu-like symptoms
- swollen lymph nodes

Problems can also happen in other organs and tissues. These are not all of the signs or symptoms of immune system problems that can happen with BAVENCIO. Call or see your healthcare provider right away for any new or worsening signs or symptoms, which may include:

- chest pain, irregular heartbeat, shortness of breath or swelling of ankles
- confusion, sleepiness, memory problems, changes in mood or behavior, stiff neck, balance problems, tingling or numbness of the arms or legs

- double vision, blurry vision, sensitivity to light, eye pain, changes in eyesight
- persistent or severe muscle pain or weakness, muscle cramps
- low red blood cells, bruising

Infusion-related reactions can sometimes be severe or life-threatening. Signs and symptoms of infusion-related reactions may include:

- chills or shaking
- hives
- flushing
- shortness of breath or wheezing
- dizziness
- feel like passing out
- fever
- back pain
- stomach area (abdomen) pain

Complications, including graft-versus-host-disease (GVHD), in people who have received a bone marrow (stem cell) transplant that uses donor stem cells (allogeneic). These complications can be serious and can lead to death. These complications may happen if you underwent transplantation either before or after being treated with BAVENCIO. Your healthcare provider will monitor you for these complications.

Heart problems. When BAVENCIO is used with the medicine axitinib, severe heart problems can happen and can lead to death. Signs and symptoms of heart problems may include:

- swelling of your stomach area (abdomen), legs, hands, feet, or ankles
- shortness of breath
- nausea or vomiting
- new or worsening chest discomfort, including pain or pressure
- weight gain
- pain or discomfort in your arms, back, neck, or jaw
- breaking out in a cold sweat
- feeling lightheaded or dizzy

Getting medical treatment right away may help keep these problems from becoming more serious. Your healthcare provider will check you for these problems during your treatment with BAVENCIO. Your healthcare provider may treat you with corticosteroid or hormone replacement medicines. Your healthcare provider may also need to delay or completely stop treatment with BAVENCIO if you have severe side effects.

What is BAVENCIO?

BAVENCIO is a prescription medicine used to treat:

- a type of skin cancer called Merkel cell carcinoma (MCC) in adults and children 12 years of age and older. BAVENCIO may be used when your skin cancer has spread.
- a type of cancer in the bladder or urinary tract called urothelial carcinoma (UC) when it has spread or cannot be removed by surgery (advanced UC). BAVENCIO may be used:
  - as maintenance treatment when your cancer has responded or stabilized after you have received platinum-containing chemotherapy as your first treatment.
  - when you have received platinum-containing chemotherapy, and it did not work or is no longer working.
- a type of kidney cancer called renal cell carcinoma (RCC). BAVENCIO may be used with the medicine axitinib as your first treatment when your kidney cancer has spread or cannot be removed by surgery (advanced RCC).

It is not known if BAVENCIO is safe and effective in children under the age of 12.

Before you receive BAVENCIO, tell your healthcare provider about all of your medical conditions, including if you:

- have immune system problems such as Crohn's disease, ulcerative colitis, or lupus
- have received an organ transplant
- have received or plan to receive a stem cell transplant that uses donor stem cells (allogeneic)
- have a condition that affects your nervous system, such as myasthenia gravis or Guillain-Barré syndrome
- have heart problems or high blood pressure
- have diabetes

- have a high cholesterol level in your blood
- are pregnant or plan to become pregnant. BAVENCIO can harm your unborn baby.
  Females who are able to become pregnant:
  - You should use an effective method of birth control during your treatment and for at least 1 month after the last dose of BAVENCIO. Talk to your healthcare provider about birth control methods that you can use during this time.
- are breastfeeding or plan to breastfeed. It is not known if BAVENCIO passes into your breast milk. Do not breastfeed during treatment and for at least 1 month after the last dose of BAVENCIO.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

How will I receive BAVENCIO?

- Your healthcare provider will give you BAVENCIO into your vein through an intravenous (IV) line over 60 minutes.
- BAVENCIO is usually given every 2 weeks.
- Your healthcare provider will give you medicines before the first 4 infusions and then as needed to help reduce infusion reactions.
- Your healthcare provider will decide how many treatments you need.
- Your healthcare provider will do blood tests to check you for certain side effects.
- If you miss an appointment, call your healthcare provider as soon as possible to reschedule your appointment.

What are the possible side effects of BAVENCIO?

BAVENCIO can cause serious side effects, including:

- **See "What is the most important information I should know about BAVENCIO?"**

The most common side effects of BAVENCIO in people with MCC include:

- feeling tired
- muscle and bone pain
- infusion-related reactions including chills, fever, and back pain
- rash
- nausea
- constipation
- cough
- diarrhea

The most common side effects of BAVENCIO as maintenance treatment in people with UC whose cancer responded or stabilized after platinum-containing chemotherapy as first treatment include:

- feeling tired
- muscle and bone pain
- urinary tract infection
- rash

The most common side effects of BAVENCIO in people with UC after platinum-containing chemotherapy that did not work, or is no longer working, include:

- feeling tired
- infusion-related reactions including chills, fever, back pain, redness, and shortness of breath
- muscle and bone pain
- nausea
- decreased appetite
- urinary tract infection

The most common side effects of BAVENCIO when given with axitinib in people with RCC include:

- diarrhea
- feeling tired
- high blood pressure
- muscle and bone pain
- nausea
- mouth sores
- hoarseness
- decreased appetite
- low levels of thyroid hormone
- rash
- liver problems
- cough
- shortness of breath

- blisters or rash on the palms of your hands and soles of your feet
- stomach area (abdomen) pain
- headache

These are not all the possible side effects of BAVENCIO.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

General information about the safe and effective use of BAVENCIO.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. You can ask your pharmacist or healthcare provider for information about BAVENCIO that is written for health professionals.

What are the ingredients in BAVENCIO?

Active ingredient: avelumab

Inactive ingredients: D-mannitol, glacial acetic acid, polysorbate 20, sodium hydroxide, and Water for Injection

Manufactured by: EMD Serono, Inc., Boston, MA 02210, USA, U.S. License No. 1773.
Marketed by: EMD Serono, Inc., MA, USA.
BAVENCIO is a trademark of Merck KGaA, Darmstadt, Germany.

For more information, call toll-free 1-844-826-8371 or go to www.bavencio.com.

This Medication Guide has been approved by the U.S. Food and Drug Administration. Revised: 06/2025