

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 and can affect the way they work. These problems can sometimes become serious or life-threatening and can lead to death.

Call or see your healthcare provider right away if you get any symptoms of the following problems or these symptoms get worse:

Lung problems (pneumonitis). Signs and symptoms of pneumonitis may include:

- new or worsening cough
- shortness of breath
- chest pain

Liver problems, including hepatitis. Signs and symptoms of liver problems may include:

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

Intestinal problems (colitis). Signs and symptoms of colitis may include:

- 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

Hormone gland problems (especially the adrenal glands, thyroid, and pancreas). Signs and symptoms that your hormone glands are not working properly may include:

- rapid heartbeat
- constipation
- increased sweating
- your voice gets deeper
- extreme tiredness
- very low blood pressure
- weight gain or weight loss
- urinating more often than usual
- feeling more hungry or thirsty than usual
- dizziness or fainting
- hair loss
- nausea or vomiting
- changes in mood or behavior, such as irritability or forgetfulness
- stomach area (abdomen) pain
- feeling cold

Kidney problems, including nephritis. Signs and symptoms of kidney problems may include:

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

Problems in other organs. Signs and symptoms may include:

- severe muscle weakness
- tiredness, sleepiness
- severe or persistent muscle or joint pains
- swelling of the feet and legs
- chest pain and tightness
- dizziness or fainting
- trouble breathing
- fever, flu-like symptoms
- skin rash, blisters, or peeling
- changes in eyesight
- changes in heartbeat, such as beating fast, or seeming to skip a beat, or pounding sensation

Severe infusion reactions. Signs and symptoms of severe infusion reactions may include:

- chills or shaking
- low blood pressure
- hives
- fever
- flushing
- back pain
- shortness of breath or wheezing
- stomach area (abdomen) pain

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
- weight gain
- shortness of breath
- pain or discomfort in your arms, back, neck, or jaw
- nausea or vomiting
- breaking out in a cold sweat
- chest discomfort, including pain or pressure
- 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 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 or ulcerative colitis
- have had an organ transplant
- have lung or breathing problems
- have liver or kidney problems
- have diabetes
- have heart problems or high blood pressure
- have a high cholesterol level in your blood
- are pregnant or plan to become pregnant. BAVENCIO can harm your unborn baby. If you 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.
- 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 final 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 any appointments, 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
- diarrhea
- nausea
- infusion-related reaction including chills, fever, and back pain
- rash
- decreased appetite
- swelling in your hands, feet, or ankles

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 reaction 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
- liver problems
- blisters or rash on the palms of your hands and soles of your feet
- hoarseness
- decreased appetite
- low levels of thyroid hormone
- rash
- shortness of breath
- cough
- stomach area (abdomen) pain
- headache

These are not all the possible side effects of BAVENCIO. Ask your healthcare provider or pharmacist for more information.

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. If you would like more information about BAVENCIO, talk with your healthcare provider. 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. One Technology Place, Rockland, MA 02370 USA, U.S. License No. 1773.

Marketed by: EMD Serono, Inc. and Pfizer Inc., NY, NY 10017 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.

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