

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 your type of skin cancer (Merkel cell carcinoma) or a cancer in the bladder or urinary tract by working with your immune system. BAVENCIO can cause your immune system to attack normal organs and tissues in many areas of your body 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 (hepatitis). Signs and symptoms of hepatitis may include:

- yellowing of your skin or the whites of your eyes
- dark urine (tea colored)
- 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

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 thyroid, adrenal glands and pancreas). Signs and symptoms that your hormone glands are not working properly may include:

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

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

- urinate less than usual
- 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
- hives
- flushing
- shortness of breath or wheezing
- low blood pressure
- fever
- back pain
- abdominal pain

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. BAVENCIO may be used when your skin cancer has spread.
- a type of cancer in the bladder or urinary tract called urothelial cancer. BAVENCIO may be used when your cancer:
 - has spread or cannot be removed by surgery (advanced urothelial cancer), **and**
 - you have received chemotherapy that contains a platinum-containing drug and it did not work or is no longer working.

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
- 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 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 subsequently 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 skin cancer (Merkel cell carcinoma) include:

- feeling tired
- swelling in your hands, feet, or ankles

- muscle and bone pain
- diarrhea
- nausea
- decreased appetite
- skin rash
- infusion-related reaction

The most common side effects of BAVENCIO in people with cancer in the bladder or urinary tract include:

- feeling tired
- infusion-related reaction
- muscle and bone pain
- nausea
- decreased appetite
- urinary tract infection

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 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, water for injection

Manufacturer: 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.

Issued: 5/2017