

# The **FIRST** and **ONLY** immunotherapy maintenance treatment for certain patients with advanced urothelial carcinoma

## INDICATION

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BAVENCIO® (avelumab) is a prescription medicine used to treat 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. It is not known if BAVENCIO is safe and effective in children.

Please see Important Safety Information on pages 9 to 12.  
Click for full [Prescribing Information](#) and [Medication Guide](#)  
or visit [bavencio.com](http://bavencio.com).

All portrayals are  
not actual patients.

 **BAVENCIO**®  
avelumab Injection  
20 mg/mL



## About urothelial carcinoma (UC)

### What is UC?

Most bladder cancers develop in the innermost lining of the bladder, called the urothelium. If the cancer grows into the other layers of the bladder wall, it becomes more advanced and can be harder to treat.

UC develops in cells of the urinary system. While 90% of UC is found in the bladder, UC may also occur in parts of the kidney, ureter, or urethra.

### What is locally advanced or metastatic UC?

Over time, cancers such as UC can spread throughout your body.

When tumors spread to nearby tissue or lymph nodes, it is called **locally advanced**. When tumors spread to other parts of your body, it's called **metastatic**.

### How common is locally advanced and metastatic UC?

Bladder cancer is the sixth most common cancer in the United States, with approximately 80,000 new diagnoses a year.

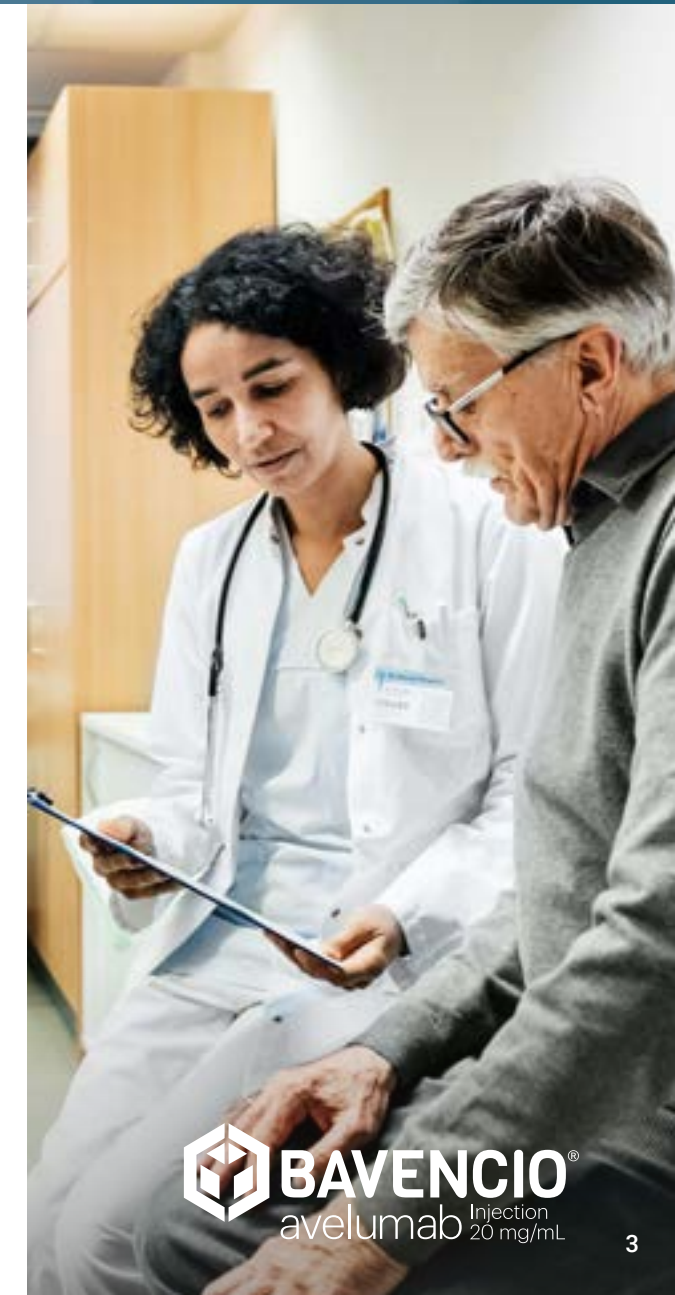
UC is the most common type of bladder cancer. In fact, almost 90% of all bladder cancers are UC. Of those, approximately 12% of patients (about 8,600) are diagnosed with either locally advanced or metastatic UC.

### How is UC treated?

There are a number of ways to treat this type of cancer. Four common treatments are:

- **Surgery**, which removes cancer cells from the body
- **Chemotherapy**, which kills cancer cells
- **Radiation therapy**, which uses high-energy radiation on cancer cells
- **Immunotherapy**, which helps your immune system kill cancer cells

Your doctor may also consider whether a clinical trial is right for you.



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 **BAVENCIO**<sup>®</sup>  
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## What is BAVENCIO® (avelumab)?

### Indication

**BAVENCIO is a prescription medicine used to treat 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. It is not known if BAVENCIO is safe and effective in children.

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

**BAVENCIO is an immunotherapy—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.

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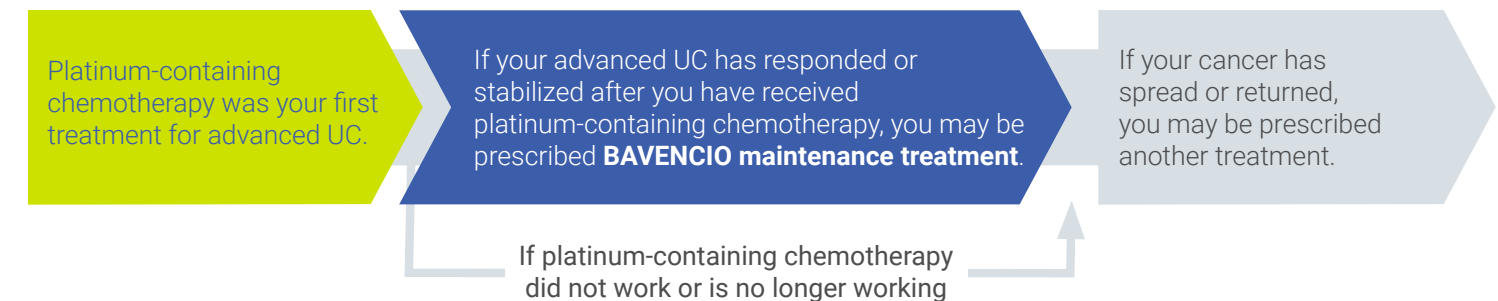
## The role of maintenance treatment

- Platinum-containing chemotherapy has been the recommended treatment for advanced UC for over 20 years
- But there may be more that can be done if platinum-containing chemotherapy has worked for you: **Maintenance treatment may help you keep fighting your advanced UC after it has responded to or stabilized with platinum-containing chemotherapy as your first treatment**

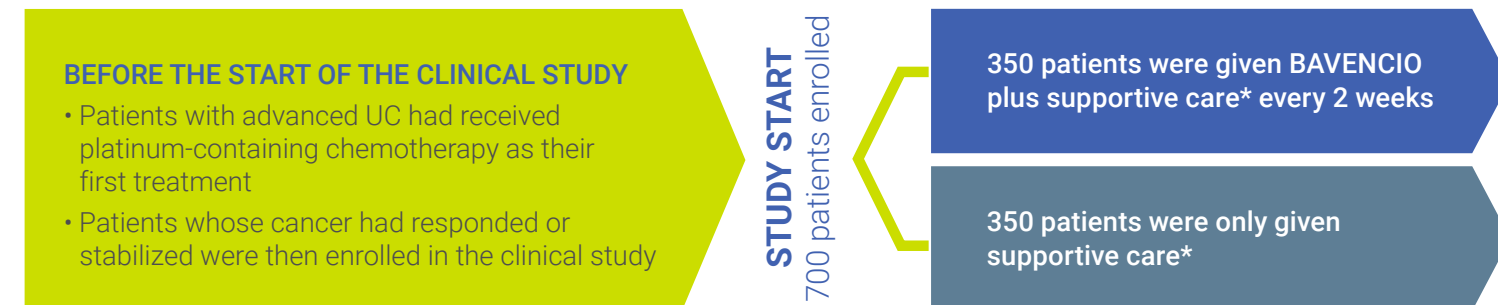
## BAVENCIO is the **FIRST** and **ONLY** approved immunotherapy maintenance treatment for certain patients with advanced UC

### BAVENCIO maintenance treatment may be an important part of your treatment plan

See the chart below to help you understand when BAVENCIO may be prescribed.



## See how BAVENCIO® (avelumab) was studied as maintenance treatment in certain patients with advanced UC



The main goal of the study was to measure **overall survival**—the total time patients in each treatment group were alive after starting the study

- Patients with either PD-L1<sup>+</sup>- positive or negative tumors were included
- Patients with autoimmune disease or a medical condition that required immunosuppression were not included

\*Supportive care included antibiotics, nutritional support, hydration, and pain management.

†In some cancer types, when cancer cells have high amounts of a protein called PD-L1, they can trick the immune system and avoid being attacked as harmful substances. Speak to your doctor to learn more about the role of PD-L1 in advanced UC.

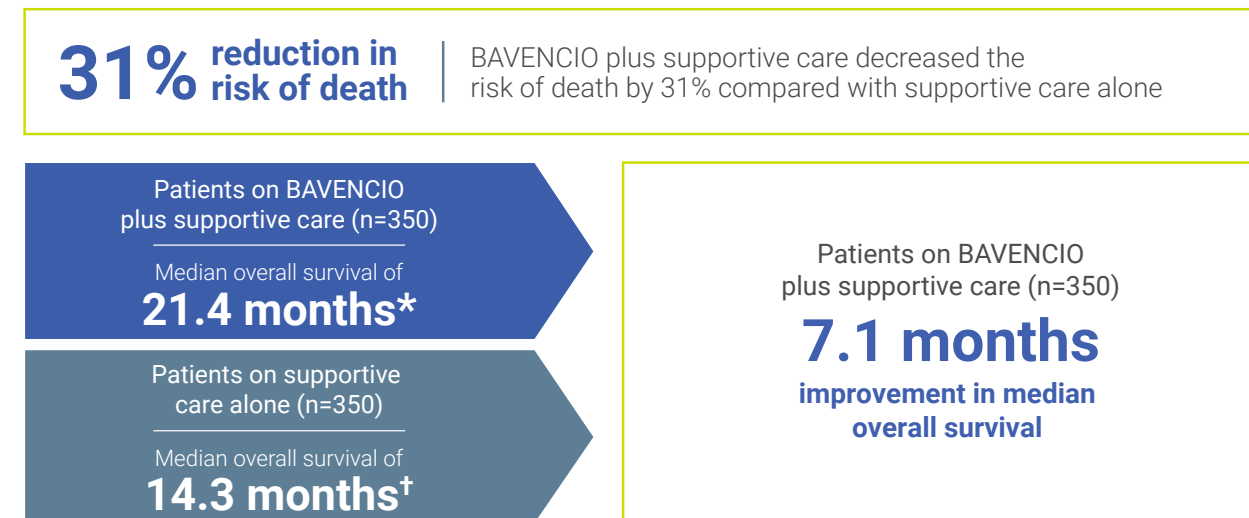
### Common side effects seen in the clinical study

**The most common side effects of BAVENCIO as maintenance treatment in people with urothelial carcinoma (UC) whose cancer responded or stabilized after platinum-containing chemotherapy as first treatment include:** feeling tired, muscle and bone pain, urinary tract infection, and rash.

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## BAVENCIO plus supportive care helped some patients live longer than those on supportive care alone

### CLINICAL STUDY RESULTS



\*Half the patients lived longer than 21.4 months and the other half lived less than 21.4 months.

†Half the patients lived longer than 14.3 months and the other half lived less than 14.3 months.

### BAVENCIO can be used as a maintenance treatment in patients, regardless of PD-L1 status

- In the study, 358 patients had PD-L1-positive tumors. In this group, BAVENCIO plus supportive care decreased the risk of death by 44% vs supportive care alone
- Also in the study, 271 patients had PD-L1-negative tumors. In this group, BAVENCIO plus supportive care decreased the risk of death by 15% vs supportive care alone

BAVENCIO is not a cure. The data represent an average of patients in the clinical trial, and not all patients will experience the same results.





## How does BAVENCIO® (avelumab) work?

- BAVENCIO is an immunotherapy: 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. *Please see Important Safety Information on the right side.*
- BAVENCIO is a man-made antibody. Your body naturally produces antibodies to help your immune system work
- The immune system is a part of your body that fights diseases to keep you healthy. One job of your immune system is to remove cells that are becoming cancerous. Over time, cancer cells may be able to stop your immune system from attacking them

### BAVENCIO may engage both your adaptive and innate immune systems

- > Your **adaptive immune system** learns to identify and adapt to threats over time, and delivers a response to defend against **specific** threats
- > Your **innate immune system** is your first line of defense against **general** threats

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## Important Safety Information

BAVENCIO® (avelumab) 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.

**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 corticosteroids or hormone replacement medicines. Your healthcare provider may also need to delay or completely stop treatment with BAVENCIO if you have severe side effects

**BAVENCIO can cause serious side effects. 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

**Continued on next page**



## Important Safety Information (cont'd)

**BAVENCIO can cause serious side effects. Call or see your healthcare provider right away if you get any new or worsening signs or symptoms, including:**

### 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 eye sight
- 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.

**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 a high cholesterol level in your blood
- are pregnant or plan to become pregnant. BAVENCIO can harm your unborn baby

**Continued on next page**

## Important Safety Information (cont'd)

### 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 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.

### 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

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 or [www.fda.gov/medwatch](http://www.fda.gov/medwatch).

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**Let your healthcare provider know right away if you're experiencing any side effect. He or she may give you ways to help manage it and may adjust or stop your treatment if needed.**

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## Taking BAVENCIO® (avelumab)

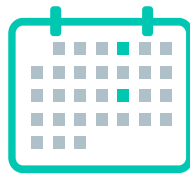
BAVENCIO is administered by a doctor or a nurse in an infusion center, hospital, or doctor's office



Intravenous infusion (IV)



Over 60 minutes



Every 2 weeks

Your healthcare provider will give you BAVENCIO via IV infusion over 60 minutes

- Your healthcare provider will give you medicines (an antihistamine and acetaminophen) before the first 4 infusions and subsequently as needed to help reduce infusion reactions
- BAVENCIO is usually administered every 2 weeks
- Your healthcare provider will decide how many treatments you need
- Your healthcare provider will do blood tests to check you for certain side effects

What do you do if you miss any appointments?

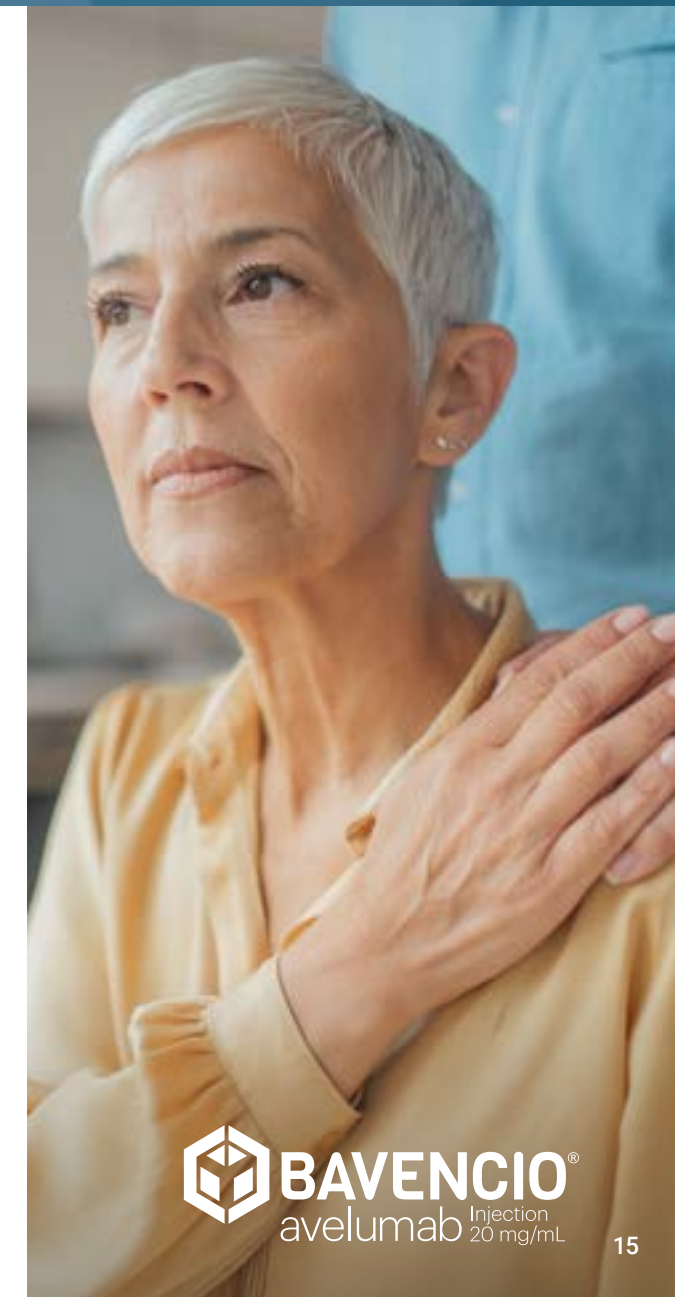
- Call your healthcare provider as soon as possible to reschedule your appointment



On BAVENCIO treatment days, you'll spend time at the infusion center, hospital, or doctor's office. Bring a book, tablet, or your favorite music to pass the time

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 **BAVENCIO**<sup>®</sup>  
Injection  
avelumab 20 mg/mL





## Tips to help manage certain side effects

Not all side effects are manageable. If you're having side effects, your doctor may decide to adjust or stop your treatment. That's why it's important to tell your doctor right away about ANY side effect you are experiencing while taking BAVENCIO® (avelumab). You can find a list of possible serious side effects in the [Important Safety Information starting on page 9](#) of this brochure.

Here are some general tips that may help to manage certain side effects, based on published guidance, and are not specific to treatment with BAVENCIO.

**Always remember: Before making any changes to your diet, physical activity, or treatment plan, please consult with your doctor.**



### Feeling tired

While on treatment, you may feel tired. Call your doctor for a full evaluation if you experience fatigue.

**Talk with your doctor if tiredness is a recurring problem. Your doctor may recommend that you:**

- Take short naps and breaks instead of long ones
- Eat well and drink plenty of fluids
- Stay physically active or introduce moderate physical activities
- Try to maintain normal work and social schedules

Talk to your doctor about the ways to help manage your fatigue.



### Muscle and bone pain

While on treatment, you may experience new or worsening muscle or bone pain. The pain may be in a specific area or may be more widespread. **Talk with your doctor if you're experiencing any muscle or bone pain.**

**Your doctor may recommend that you:**

- Take medications, if your doctor prescribes them for you
- Try massage or physical therapy
- Use hot or cold compresses

Talk to your doctor about the pain relief that may be right for you.

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### Urinary tract infection (UTI)

While on treatment, you may experience signs and symptoms of a UTI, such as a burning feeling when you urinate, back pain, or fever. **Call your doctor if you're experiencing any signs or symptoms of a UTI.**

**Your doctor may recommend that you:**

- Take medications, if your doctor prescribes them for you
- Drink plenty of liquids
- Go to the bathroom often
- Take showers instead of baths
- Wear cotton underwear and loose fitting pants

Talk to your doctor about the steps to manage and prevent UTIs.



### Rash

While on treatment, you may experience skin rashes on various parts of the body. Rashes can present in different ways such as flat or raised bumps or different colors. Rashes can also itch, burn, sting, or be painful. **Talk with your doctor if you're experiencing signs and symptoms of a rash. Your doctor may recommend that you:**

- Take medications, if your doctor prescribes them for you
- Use mild soaps and keep your skin moisturized with cream-based moisturizers
- Protect the affected area from heat and cold and wear loose-fitting, soft clothing
- Minimize sun exposure and use sunscreen

Talk to your doctor about the steps to relieve rash that may be right for you.

**BAVENCIO can cause serious side effects, including: lung problems, intestinal problems, liver problems, hormone gland problems, kidney problems, skin problems, other immune system problems, infusion-related reactions, and complications, including graft-versus-host-disease (GVHD), in people who have received a bone marrow (stem cell) transplant that uses donor stem cells (allogeneic). Please see pages 9 to 12 for more information on possible serious side effects.**



## Questions for your healthcare provider

You and your loved ones will likely have questions about your treatment. Be sure to reach out to your healthcare provider with any concerns or questions you may have.

Here are some questions you may find helpful to print out and ask:

Is there anything I should do before treatment?

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What can I expect during treatment?

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How will I know if the treatment is working?

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What are common side effects of the medicine? Do you have any tips to help manage them?  
Whom do I contact if I have side effects?

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Is there anything I should eliminate from my diet or avoid altogether?

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What support resources are available?

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Are there any support programs or groups I can join?

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Write down any other questions you may have:

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## CoverOne® provides patient access and reimbursement support

We recognize that each patient's situation is different and are dedicated to helping eligible BAVENCIO® (avelumab) patients one at a time

Please contact us at **1-844-8COVER1** if you have any questions.

### CoverOne®

CoverOne® provides eligible BAVENCIO patients access and reimbursement support services.\*

\*Eligibility requirements and restrictions may apply.



**Phone:** 1-844-8COVER1  
(1-844-826-8371)  
Monday–Friday  
8:00 AM–8:00 PM ET



**Fax:** 1-800-214-7295



**Web:** CoverOne.com

## Resources you might find helpful

Learn more about urothelial carcinoma, connect with others, and get information and support from these helpful organizations



**American Cancer Society**  
[www.cancer.org](http://www.cancer.org)



**Bladder Cancer Advocacy Network**  
[www.bcan.org](http://www.bcan.org)



**Bladder Cancer Patient Support Group**  
[www.cancercare.org/support\\_groups](http://www.cancercare.org/support_groups)

**American Bladder Cancer Society**  
[www.bladdercancersupport.org](http://www.bladdercancersupport.org)

**Cancer Hope Network**  
[www.cancerhopenetwork.org](http://www.cancerhopenetwork.org)

The organizations listed above are independent nonprofit organizations. Their inclusion here does not imply endorsement of BAVENCIO or EMD Serono, Inc. or Pfizer Inc.

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## Your oncology team at a glance

Print out this page so you can keep a list of your important contacts together in one place for easy access.

### Healthcare provider

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### Address

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### Phone

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### Email

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### Notes

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### Other healthcare team member

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### Address

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### Phone

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### Email

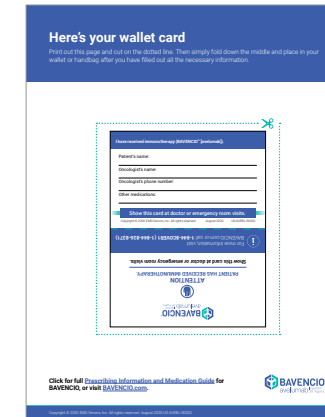
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## Wallet card

Download and print out this wallet card at [bavencio.com/patients-and-caregivers/resources-and-support](http://bavencio.com/patients-and-caregivers/resources-and-support).

Remember to keep it with you at all times.



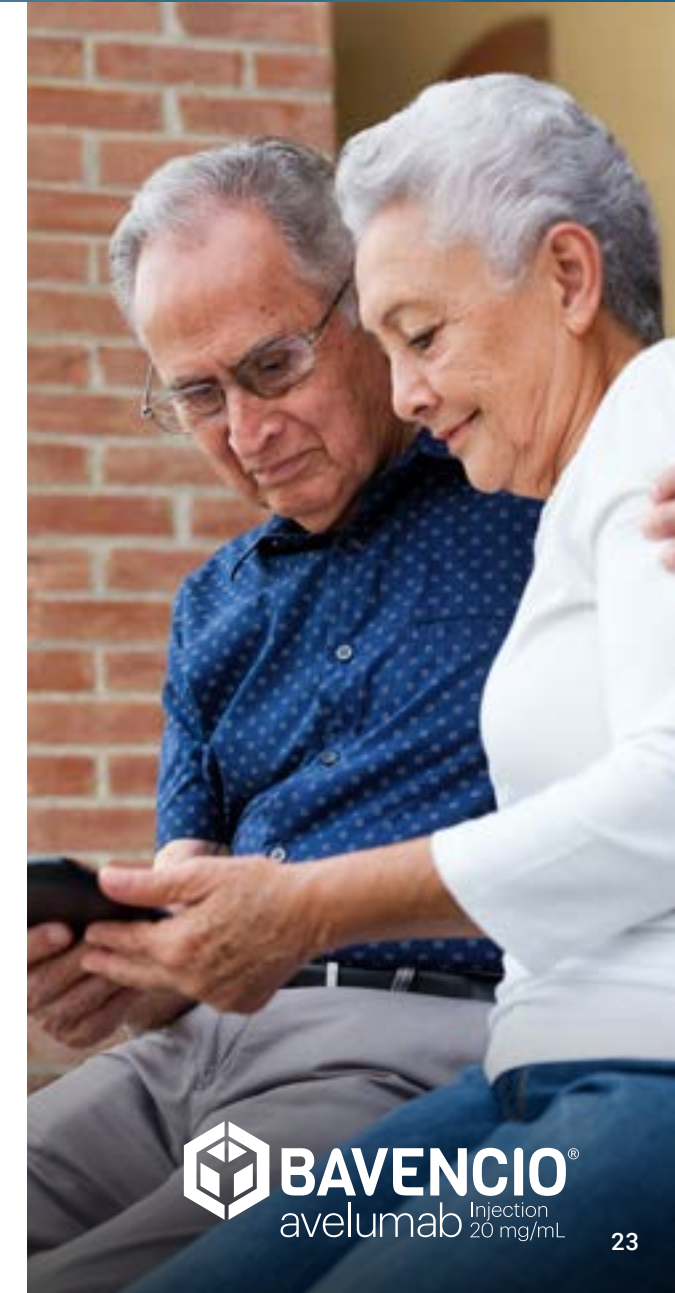
### Notes

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Visit [bavencio.com](https://www.bavencio.com) for more information.

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