

**A GUIDE FOR PATIENTS  
AND CAREGIVERS**  
**Starting treatment with**



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Please see Important Safety Information on pages 4-10. Click for the full [Prescribing Information and Medication Guide](#) for **BAVENCIO** and full [Prescribing Information/Patient Information](#) for **INLYTA**, or visit [BAVENCIO.com](http://BAVENCIO.com).

## What is BAVENCIO<sup>®</sup> (avelumab) plus INLYTA<sup>®</sup> (axitinib)?

BAVENCIO is a prescription medicine used to treat a type of kidney cancer called renal cell carcinoma (RCC). BAVENCIO may be used with the medicine INLYTA as your first treatment when your kidney cancer has spread or cannot be removed by surgery (advanced RCC).

It is not known if BAVENCIO plus INLYTA is safe and effective in children.

### How is BAVENCIO plus INLYTA taken?

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 decide how many treatments you need.

Take INLYTA exactly as prescribed by your healthcare provider. INLYTA comes in 1-mg and 5-mg tablets. Your healthcare provider will tell you which tablets you should take. Your healthcare provider may change your dose if needed. Take each dose about 12 hours apart, with or without food. Swallow INLYTA tablets whole with a glass of water.

### What happens if you miss a dose?

If you miss your appointment on the day you are scheduled to receive BAVENCIO, call your healthcare provider as soon as possible to reschedule your appointment. A Treatment Calendar has been created to help you keep track of your treatment. See page 14 of this guide for more information.

If you vomit or miss a dose of INLYTA, take your next dose at your regular time. Do not take 2 doses at the same time. If you take too much INLYTA, call your healthcare provider or go to the nearest hospital emergency room right away.

### Other medications and routine tests

Your healthcare provider will prescribe acetaminophen and an antihistamine before the first 4 infusions to help reduce infusion reactions (reactions on the skin from the infusion). After the first 4 infusions, these medicines will then be prescribed as needed.

During treatment with BAVENCIO plus INLYTA, your healthcare provider will also do blood tests to check for certain side effects. Your healthcare provider will also check your blood pressure regularly during treatment.



### What to avoid during treatment

Do not drink grapefruit juice or eat grapefruit. Grapefruit may increase the amount of INLYTA in your blood. Patients taking INLYTA should also avoid St John's wort. It may reduce the amount of INLYTA in your blood.

Please see Important Safety Information on pages 4-10. Click for the full [Prescribing Information and Medication Guide for BAVENCIO](#) and full [Prescribing Information/Patient Information for INLYTA](#), or visit [BAVENCIO.com](#).

## Important Safety Information

### BAVENCIO (avelumab)

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.

**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 delay or completely stop treatment with BAVENCIO if you have severe side effects.

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

### BAVENCIO can cause serious side effects, including:



- **Lung problems (pneumonitis)**—signs and symptoms of pneumonitis may include new or worsening cough; shortness of breath; and chest pain



- **Liver problems, including hepatitis**—signs and symptoms of liver problems may include yellowing of your skin or the whites of your eyes; severe nausea or vomiting; pain on the right side of your stomach-area (abdomen); drowsiness; dark urine (tea colored); and 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; and severe stomach-area (abdomen) pain or tenderness

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- **Hormone gland problems (especially the adrenal glands, thyroid, 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; constipation; your voice gets deeper; very low blood pressure; urinating more often than usual; dizziness or fainting; nausea or vomiting; stomach area (abdomen) pain; and feeling cold



- **Kidney problems, including nephritis**—signs and symptoms of kidney problems may include decrease in your amount of urine; blood in your urine; swelling in your ankles; and loss of appetite



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



- **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; and abdominal pain



- **Heart problems**—when BAVENCIO is used with the medicine INLYTA, severe heart problems can happen and can lead to death. Signs and symptoms of heart problems may include swelling of your stomach-area, legs, hands, feet or ankles; shortness of breath; nausea or vomiting; chest discomfort, including pain or pressure; weight gain; pain or discomfort in your arms, back, neck, or jaw; breaking out in a cold sweat; and feeling lightheaded or dizzy

## Important Safety Information (cont'd)

### BAVENCIO (avelumab)

**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.

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## Important Safety Information

### INLYTA (axitinib)

**Before taking INLYTA, tell your healthcare provider about all of your medical conditions, including if you:**

- have high blood pressure
- have thyroid problems
- have liver problems
- have a history of blood clots in your veins or arteries (types of blood vessels), including stroke, heart attack, or change in vision
- have any bleeding problems
- have a history of heart failure
- have an unhealed wound
- plan to have surgery. You should stop taking INLYTA at least 24 hours before planned surgery
- have any other medical conditions

#### **For females, tell your healthcare provider if you:**

- are pregnant or plan to become pregnant. Taking INLYTA during pregnancy can harm your unborn baby. You should not become pregnant while taking INLYTA. Talk to your healthcare provider if you are pregnant or plan to become pregnant
- are able to become pregnant. You should have a pregnancy test before you start treatment with INLYTA. Use effective birth control during treatment and for at least 1 week after your last dose of INLYTA. Talk to your healthcare provider about birth control methods that you can use to prevent pregnancy during this time
- are breastfeeding or plan to breastfeed. It is not known if INLYTA passes into your breast milk. Do not breastfeed during treatment and for at least 2 weeks after your last dose of INLYTA

#### **For males with female partners who are able to become pregnant:**

- use effective birth control during treatment and for at least 1 week after your last dose of INLYTA
- if your female partner becomes pregnant during your treatment with INLYTA, tell your healthcare provider right away

## Important Safety Information (cont'd)

### INLYTA (axitinib)

**INLYTA may cause fertility problems** in males and females, which may affect your ability to have a child. Talk to your healthcare provider if this is a concern for you.

**Tell your healthcare provider about all the medicines you take**, including prescription and over-the-counter medicines, vitamins, and herbal supplements. INLYTA and certain other medicines can affect each other causing serious side effects.

**Talk with your healthcare provider before you start taking any new medicine.** Know the medicines you take. Keep a list of them to show your healthcare provider and pharmacist when you get a new medicine.

**Do not drink grapefruit juice or eat grapefruit.** Grapefruit may increase the amount of INLYTA in your blood.

### INLYTA may cause serious side effects, including:



• **High blood pressure (hypertension)**—High blood pressure is common with INLYTA and may sometimes be severe. Your healthcare provider should check your blood pressure regularly during treatment with INLYTA. If you develop blood pressure problems, your healthcare provider may prescribe medicine to treat your high blood pressure, lower your dose, or stop your treatment with INLYTA



• **Problem with blood clots in your veins or arteries**—INLYTA can cause blood clots which can be serious, and sometimes lead to death. Get emergency help and call your healthcare provider if you get any signs or symptoms that include chest pain or pressure; pain in your arms, back, neck, or jaw; shortness of breath; numbness or weakness on one side of your body; trouble talking; headache; and vision changes



• **Bleeding**—INLYTA can cause bleeding which can be serious, and sometimes lead to death. Call your healthcare provider right away or get medical help if you develop any signs or symptoms that include: unexpected bleeding or bleeding that lasts a long time, such as unusual bleeding from the gums, menstrual bleeding or vaginal bleeding that is heavier than normal, bleeding that is severe or you cannot control, pink or brown urine, red or black stools (looks like tar), bruises that happen without a known cause or get larger, cough up blood or blood clots, and vomit blood or your vomit looks like “coffee grounds”; unexpected pain, swelling, or joint pain; and headaches, feeling dizzy or weak



• **Heart failure**—Your healthcare provider should check for signs or symptoms of heart failure regularly during treatment with INLYTA. Heart failure can be serious and can sometimes lead to death. Tell your healthcare provider if you have any of the following symptoms during your treatment with INLYTA: tiredness; swelling of your stomach-area (abdomen), legs, or ankles; shortness of breath; and protruding neck veins



• **Tear in your stomach or intestinal wall (perforation)**—A tear in your stomach or intestinal wall can be serious and can sometimes lead to death. Get medical help right away if you get any symptoms that include severe stomach-area (abdominal) pain or stomach-area pain that does not go away; vomit blood; and red or black stools



• **Thyroid gland problems**—Your healthcare provider should do blood tests to check your thyroid gland function before and during your treatment with INLYTA. Tell your healthcare provider if you have any symptoms during your treatment with INLYTA that include tiredness that worsens or does not go away; feeling hot or cold; your voice deepens; weight gain or weight loss; hair loss; and muscle cramps and aches



• **Reversible Posterior Leukoencephalopathy Syndrome (RPLS)**—A condition called reversible posterior leukoencephalopathy syndrome (RPLS) can happen while taking INLYTA. Call your healthcare provider right away if you get headache; seizures; weakness; confusion; high blood pressure; blindness or change in vision; or problems thinking



• **Protein in your urine**—Your healthcare provider should check your urine for protein before and during your treatment with INLYTA. If you develop protein in your urine, your healthcare provider may decrease your dose of INLYTA or stop your treatment



• **Change in liver function**—Your healthcare provider should do blood tests before and during your treatment with INLYTA to check your liver function

Click for the full [Prescribing Information and Medication Guide](#) for **BAVENCIO** and full [Prescribing Information/Patient Information](#) for **INLYTA**, or visit [BAVENCIO.com](#).

**The most common side effects of BAVENCIO (avelumab) when given with INLYTA (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 in combination with INLYTA. Ask your healthcare provider or pharmacist for more information. You may report side effects to EMD Serono at 1-800-283-8088 ext 5563. You may also report side effects to the FDA at 1-800-FDA-1088, or [www.fda.gov/medwatch](http://www.fda.gov/medwatch).

**Questions for your healthcare provider**



You and/or your caregiver will likely have questions about your treatment. Be sure to reach out to your healthcare provider with any concerns or questions you have. Here are some questions you may find helpful to ask your healthcare provider:

- Why do I need both medications?**
- What can I expect during my first 2 weeks of treatment?**
- Is there anything I should do before treatment?**
- How will I know if treatment is working?**
- What are some common side effects of these 2 medications? Do you have any tips to help manage them?**
- I read that I should avoid grapefruit, grapefruit juice, and St. John's wort while taking INLYTA<sup>®</sup> (axitinib). Is there anything else I should avoid?**
- What support resources are available?**

Write down other questions you may have:

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Support for eligible patients prescribed  
BAVENCIO® (avelumab) plus INLYTA® (axitinib)

BAVENCIO support

CoverOne®

CoverOne® provides patient access and reimbursement support services.

We recognize that each patient's situation is different, and are  
dedicated to helping BAVENCIO patients one at a time.

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



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

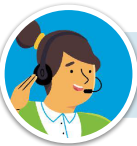


Web: Visit [CoverOne.com](https://CoverOne.com)

INLYTA support

Pfizer Oncology together™

We're committed to helping you get your prescribed Pfizer Oncology medicine. Pfizer Oncology Together can help you understand your insurance and identify what financial support may be available for your INLYTA prescription. In addition, we can help find a specialty pharmacy that can fill your prescription.



FOR LIVE, PERSONALIZED SUPPORT  
Call 1-877-744-5675 (Monday–Friday 8 AM–8 PM ET)

VISIT  
[PfizerOncologyTogether.com](https://PfizerOncologyTogether.com)

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Your oncology team at a glance

Keep a list of your important contacts together in one  
place for easy access.

Healthcare provider \_\_\_\_\_

Address \_\_\_\_\_

Phone \_\_\_\_\_

Email \_\_\_\_\_

Other Healthcare Team member \_\_\_\_\_

Address \_\_\_\_\_

Phone \_\_\_\_\_

Email \_\_\_\_\_

Notes \_\_\_\_\_

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## Treatment Calendar for BAVENCIO<sup>®</sup> (avelumab) plus INLYTA<sup>®</sup> (axitinib)

Use this checklist to help fill out the Treatment Calendar.

- Step 1:** On the Treatment Calendar, write down the day of your first infusion with BAVENCIO. Two weeks from this date, mark the calendar with your next BAVENCIO treatment date.
- Step 2:** Once you have noted the first day of your BAVENCIO treatment, mark each day that you take INLYTA over the next 2 weeks.
- Step 3:** INLYTA must be taken 2 times a day. Check the AM box every morning when you take your INLYTA and check the PM box every evening when you take your INLYTA.

	Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
Week 1 DATE							
BAVENCIO	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
INLYTA	AM <input type="checkbox"/> PM <input type="checkbox"/>	AM <input type="checkbox"/> PM <input type="checkbox"/>	AM <input type="checkbox"/> PM <input type="checkbox"/>	AM <input type="checkbox"/> PM <input type="checkbox"/>	AM <input type="checkbox"/> PM <input type="checkbox"/>	AM <input type="checkbox"/> PM <input type="checkbox"/>	AM <input type="checkbox"/> PM <input type="checkbox"/>
Week 2 DATE							
BAVENCIO	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
INLYTA	AM <input type="checkbox"/> PM <input type="checkbox"/>	AM <input type="checkbox"/> PM <input type="checkbox"/>	AM <input type="checkbox"/> PM <input type="checkbox"/>	AM <input type="checkbox"/> PM <input type="checkbox"/>	AM <input type="checkbox"/> PM <input type="checkbox"/>	AM <input type="checkbox"/> PM <input type="checkbox"/>	AM <input type="checkbox"/> PM <input type="checkbox"/>
Week 3 DATE							
BAVENCIO	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
INLYTA	AM <input type="checkbox"/> PM <input type="checkbox"/>	AM <input type="checkbox"/> PM <input type="checkbox"/>	AM <input type="checkbox"/> PM <input type="checkbox"/>	AM <input type="checkbox"/> PM <input type="checkbox"/>	AM <input type="checkbox"/> PM <input type="checkbox"/>	AM <input type="checkbox"/> PM <input type="checkbox"/>	AM <input type="checkbox"/> PM <input type="checkbox"/>
Week 4 DATE							
BAVENCIO	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
INLYTA	AM <input type="checkbox"/> PM <input type="checkbox"/>	AM <input type="checkbox"/> PM <input type="checkbox"/>	AM <input type="checkbox"/> PM <input type="checkbox"/>	AM <input type="checkbox"/> PM <input type="checkbox"/>	AM <input type="checkbox"/> PM <input type="checkbox"/>	AM <input type="checkbox"/> PM <input type="checkbox"/>	AM <input type="checkbox"/> PM <input type="checkbox"/>

Example:

	Sunday	Monday	Tuesday	Wednesday
Week 1 DATE		6/3/19	6/4/19	6/5/19
BAVENCIO	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
INLYTA	AM <input type="checkbox"/> PM <input type="checkbox"/>	AM <input checked="" type="checkbox"/> PM <input checked="" type="checkbox"/>	AM <input checked="" type="checkbox"/> PM <input checked="" type="checkbox"/>	AM <input checked="" type="checkbox"/> PM <input checked="" type="checkbox"/>
Week 2 DATE	6/9/19	6/10/19	6/11/19	6/12/19
BAVENCIO	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
INLYTA	AM <input checked="" type="checkbox"/> PM <input checked="" type="checkbox"/>	AM <input checked="" type="checkbox"/> PM <input checked="" type="checkbox"/>	AM <input checked="" type="checkbox"/> PM <input checked="" type="checkbox"/>	AM <input checked="" type="checkbox"/> PM <input checked="" type="checkbox"/>

**Note:** If you miss your appointment on the day you are scheduled to receive BAVENCIO, call your healthcare provider as soon as possible to reschedule your appointment.

If you vomit or miss a dose of INLYTA, take your next dose at your regular time. Do not take 2 doses at the same time.

## Wallet Card

This wallet card should be printed, cut out, and kept on you at all times. Be sure to fill out all the information and show it during any doctor or emergency room visits.

Scroll down to print out your wallet card.

I have received a combination treatment that contains an immunotherapy (BAVENCIO<sup>®</sup> [avelumab]) and a tyrosine kinase inhibitor (INLYTA<sup>®</sup> [axitinib]).

Patient's name:

Oncologist's name:

Oncologist's phone number:

Other medications:

Show this card at doctor or emergency room visits.

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Notes

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# Here's your wallet card

Print out this page and cut on the dotted line. Then simply fold down the middle and place in your wallet or handbag after you have filled out all the necessary information.



**I have received a combination treatment that contains an immunotherapy (BAVENCIO® [avelumab]) and a tyrosine kinase inhibitor (INLYTA® [axitinib]).**

Patient's name: \_\_\_\_\_

Oncologist's name: \_\_\_\_\_

Oncologist's phone number: \_\_\_\_\_

Other medications: \_\_\_\_\_


**Show this card at doctor or emergency room visits.**



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**For more information, visit [BAVENCIO.com](http://BAVENCIO.com) or call 1-844-8COVER1 (1-844-826-8371)**

**Show this card at doctor or emergency room visits.**

**ATTENTION**  
**PATIENT HAS RECEIVED IMMUNOTHERAPY**  
**AND A TYROSINE KINASE INHIBITOR.**



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