



To help prevent a type of bladder or urinary tract cancer (urothelial carcinoma) from coming back after it was removed by surgery

# A CHANCE TO REDUCE THE RISK OF BLADDER OR URINARY TRACT CANCER RETURNING

Actor portrayals. OPDIVO is not approved for patients younger than 18 years of age.

OPDIVO® will not work for everyone. Individual results may vary. Please see information about the clinical trial, including serious side effects, on pages 2-3.

## What is OPDIVO?

OPDIVO is a prescription medicine used to help prevent cancer of the lining of the urinary tract (**urothelial carcinoma**) from coming back in people who:

- ✓ Have cancer of the urinary tract (including the bladder, ureters, or renal pelvis) **AND**
- ✓ Had surgery to remove the cancer.

It is not known if OPDIVO is safe and effective in children younger than 18 years of age.

OPDIVO is a medicine that may treat certain cancers by working with your immune system. It can cause your immune system to attack normal organs and tissues in any area of your body and can affect the way these organs work.

Information provided in this brochure is not a substitute for talking with your healthcare professional. Your healthcare professional is the best source of information about your disease.

**OPDIVO**<sup>®</sup>  
(nivolumab)

INJECTION FOR INTRAVENOUS USE 10 mg/mL

**i** Please see **Important Facts about OPDIVO, including serious side effects, on pages 7-8** and **U.S. Full Prescribing Information and Medication Guide.**

# After surgery, you may have another option. Ask your doctor about OPDIVO adjuvant therapy.



## GENERAL TREATMENT OPTIONS AFTER SURGERY

### SURGERY

Radical resection  
(removal of the bladder or  
parts of the urinary tract)

### MONITOR (WATCH AND WAIT)

Your doctor will regularly monitor you for any signs of cancer coming back

### IMMUNOTHERAPY

FDA-approved treatment with OPDIVO, which works with the immune system, may be recommended as an option that could help certain people lower the risk of cancer coming back

For some people who are at a higher risk of cancer returning, chemotherapy or radiation may be considered after surgery to help reduce that risk. Chemotherapy may also be recommended before surgery. Treatment plans may vary.

## What is adjuvant therapy?

Adjuvant (preventative) therapy is a treatment given to people after surgery to help lower the risk of cancer coming back.

## How does OPDIVO work?

OPDIVO is an immunotherapy treatment—a type of medicine that works with your immune system. OPDIVO works differently from chemotherapy. To learn more about how OPDIVO works, please see [page 5](#).

## Is OPDIVO right for me?

Only your doctor can recommend the treatment plan that's appropriate for you. Ask your doctor if OPDIVO immunotherapy could be part of your treatment plan.

## What are the serious side effects of OPDIVO?

A **serious side effect** is a side effect that can sometimes become severe or life-threatening and can lead to death. They may happen anytime during treatment or even after your treatment has ended. You may have more than one of these problems at the same time.

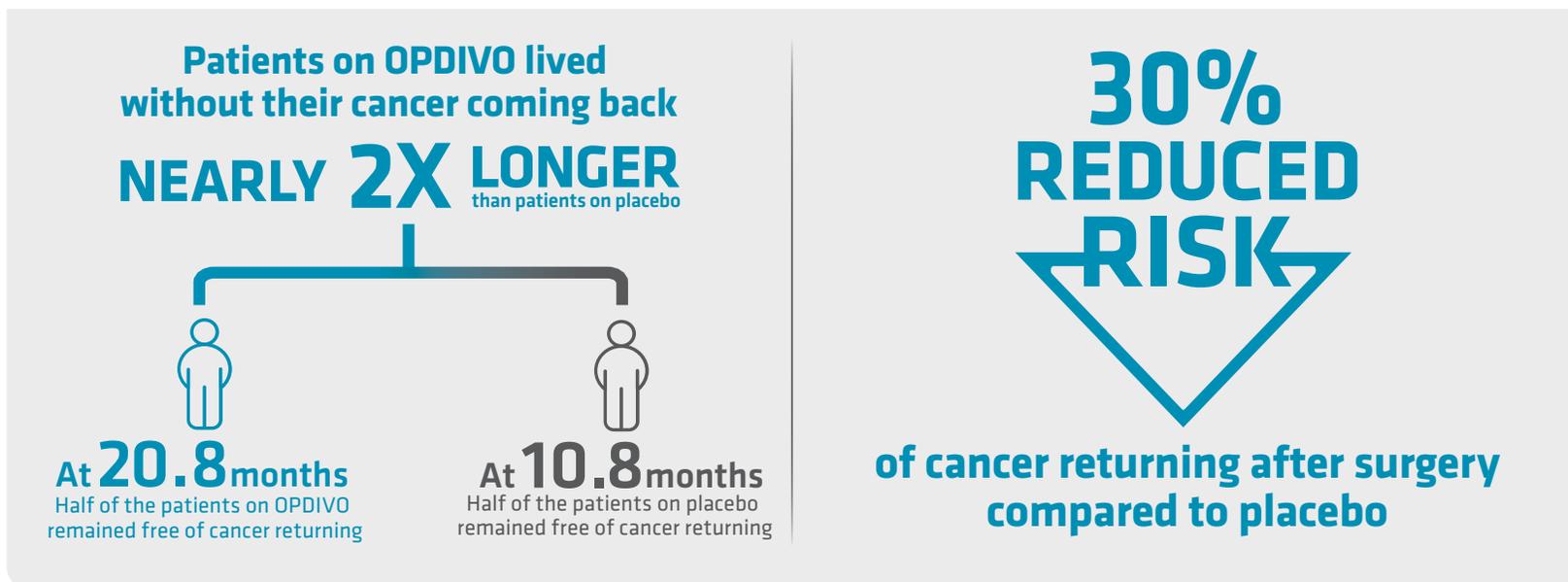
### Call or see your healthcare provider right away if you develop any new or worse signs or symptoms, including:

- lung problems
- intestinal problems
- liver problems
- hormone gland problems
- kidney problems
- skin problems
- problems in other organs and tissues
- severe infusion reactions
- complications of bone marrow (stem cell) transplant that uses donor stem cells (allogeneic)

**i** Please see [Important Facts about OPDIVO, including serious side effects, on pages 7-8](#) and [U.S. Full Prescribing Information and Medication Guide](#).

# OPDIVO immunotherapy helped reduce the risk of cancer coming back after surgery, compared to a placebo

In a clinical trial of 709 patients who had surgery to remove cancer in the lining of the bladder or urinary tract (urothelial carcinoma), 353 received OPDIVO and 356 received a placebo.



OPDIVO will not work for everyone. Individual results may vary.

## What are the most common side effects of OPDIVO?

The most common side effects of OPDIVO when used alone include:

- feeling tired
- rash
- pain in muscles, bones, and joints
- itchy skin
- diarrhea
- nausea
- weakness
- cough
- vomiting
- shortness of breath
- constipation
- decreased appetite
- back pain
- upper respiratory tract infection
- fever
- headache
- stomach-area (abdominal) pain
- urinary tract infection

These are not all the possible side effects. **Talk to your healthcare team** or pharmacist for more information. You are encouraged to report side effects of prescription drugs to the FDA. Call 1-800-FDA-1088.



**Please see Important Facts about OPDIVO, including serious side effects, on pages 7-8 and [U.S. Full Prescribing Information and Medication Guide](#).**



To help prevent a type of bladder or urinary tract cancer (urothelial carcinoma) from coming back after it was removed by surgery



**FIRST  
& ONLY**

**FDA-approved chemo-free treatment  
that works with your immune system**

# Help Seek and Attack

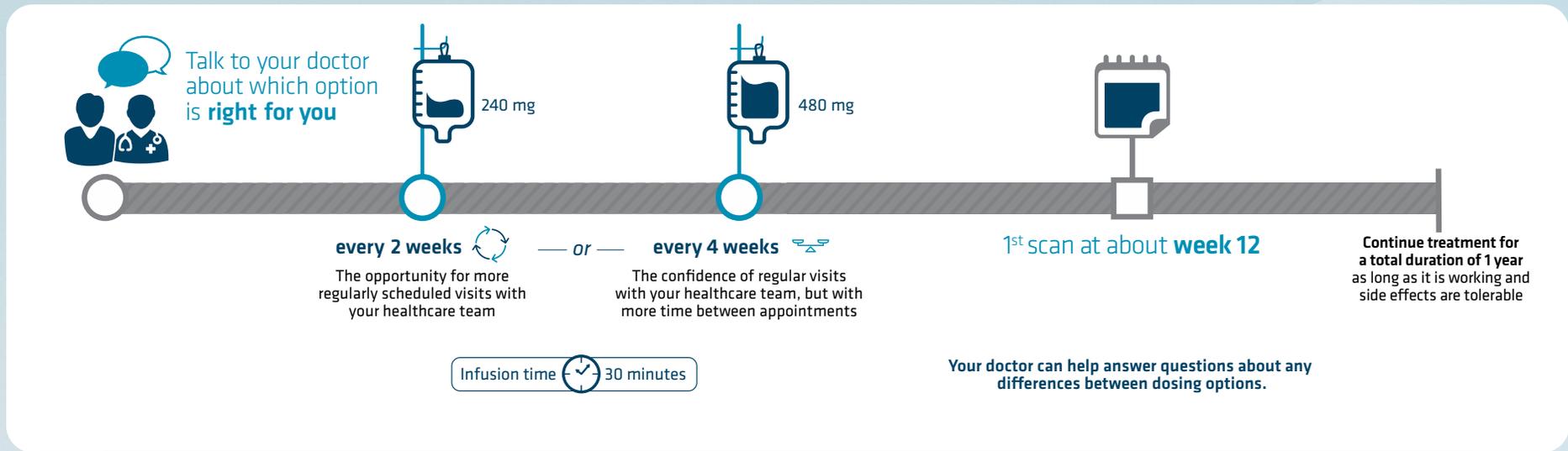
## How OPDIVO works with your immune system



OPDIVO can cause your T cells to attack healthy cells contained within organs and tissues in any area of your body and can affect the way they work. These problems can sometimes become serious or life-threatening and can lead to death, and may happen anytime during treatment or even after treatment has ended. You may have more than one of these problems at the same time. Your doctor will check you for these problems during treatment.

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

## The OPDIVO option: Offering a balance between treatment schedules and regular visits with your healthcare team



OPDIVO is given through intravenous (IV) infusion. The medicine is given directly into the bloodstream through a needle placed in a vein by a healthcare professional—usually in the arm or hand.



**Talk to your doctor about which treatment schedule may be right for you.** Your doctor will decide how many treatments you need. Your healthcare provider will do blood tests to check you for side effects, and may treat you with corticosteroid or hormone replacement medicines, and delay or completely stop treatment if you have side effects that are severe. Be sure to talk to your healthcare team about side effects.

Frequent communication with your healthcare team is an important part of treatment. Use your appointments to let them know how you're feeling and ask any questions you may have.



**If you miss an appointment,** call a healthcare provider right away. Try to schedule your appointments for the same day of the week and the same time of day to make them easier to remember. It is important for you to keep all appointments with your healthcare provider.

**1** Please see Important Facts about OPDIVO, including serious side effects and information about pregnancy, nursing, health problems, and other medicines that you should discuss with your healthcare team before starting treatment, on pages 7-8 and [U.S. Full Prescribing Information and Medication Guide](#).

# Important Facts About OPDIVO®

This is a summary of important information that you need to know about OPDIVO. Your healthcare team can work with you to help answer any questions you may have about OPDIVO. Keep this information in a safe place so you can refer to it before and during your treatment.

**Look out for the following icons as you read:**

 Talk to your healthcare team

 Call a healthcare provider right away

 Helpful information to remember

## What is OPDIVO?

OPDIVO is a prescription medicine used to help prevent cancer of the lining of the urinary tract (**urothelial carcinoma**) from coming back in people who:

- ✓ Have cancer of the urinary tract (including the bladder, ureters, or renal pelvis) **AND**
- ✓ Had surgery to remove the cancer.

It is not known if OPDIVO is safe and effective in children younger than 18 years of age.

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

OPDIVO is a medicine that may treat certain cancers by working with your immune system. OPDIVO can cause your immune system to attack normal organs and tissues in any area of your body and can affect the way they work.

 **Get medical help immediately** if you develop any of these signs or symptoms or they get worse. It may keep these problems from becoming more serious. Your healthcare team will check you for these problems during treatment and may treat you with corticosteroid or hormone replacement medicines. If you have severe side effects, your healthcare team may also need to delay or completely stop your treatment.

## What are the serious side effects of OPDIVO?

A **serious side effect** is a side effect that can sometimes become severe or life-threatening and can lead to death. They may happen anytime during treatment or even after your treatment has ended. You may have more than one of these problems at the same time.

**Call or see your healthcare provider right away if you develop any new or worse signs or symptoms, including:**

**Lung problems** – Things to look out for may include:

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

**Intestinal problems** – Things to look out for may include:

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

**Liver problems** – Things to look out for 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)
- dark urine (tea colored)
- bleeding or bruising more easily than normal

**Hormone gland problems** – Things to look out for may include:

- headaches 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** – Things to look out for may include:

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

**Skin problems** – Things to look out for may include:

- rash
- itching
- skin blistering or peeling
- painful sores or ulcers in the mouth or nose, throat, or genital area

**Problems can also happen in other organs and tissues. These are not all the signs and symptoms of immune system problems that can happen with OPDIVO. 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, 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

## What are the possible side effects of OPDIVO?

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

See the previous section, “What is the most important information I should know about OPDIVO?”

**Severe infusion reactions** – Things to look out for may include:

- chills or shaking
- shortness of breath or wheezing
- feel like passing out or fever
- itching or rash
- dizziness
- back or neck pain

**Tell your healthcare team** right away if you get these symptoms during an infusion of OPDIVO.

**Complications of bone marrow (stem cell) transplant that uses donor stem cells (allogeneic).** These complications can be severe and can lead to death. These complications may happen if you underwent transplantation either before or after being treated with OPDIVO. Your healthcare provider will monitor you for these complications.

## What are the most common side effects of OPDIVO?

The most common side effects of OPDIVO when used alone include:

- feeling tired
- cough
- upper respiratory tract infection
- rash
- vomiting
- fever
- pain in muscles, bones, and joints
- shortness of breath
- headache
- itchy skin
- constipation
- stomach-area (abdominal) pain
- diarrhea
- decreased appetite
- urinary tract infection
- nausea
- back pain
- weakness

These are not all the possible side effects. **Talk to your healthcare team** or pharmacist for more information. You are encouraged to report side effects of prescription drugs to the FDA. Call 1-800-FDA-1088.

## What should I discuss with my healthcare team before receiving OPDIVO?

**Tell your healthcare provider about all your medical conditions, including if you:**

- have immune system problems such as Crohn’s disease, ulcerative colitis, or lupus
- have received radiation treatment to your chest area in the past and have received other medicines that are like OPDIVO
- have received an organ transplant
- have a condition that affects your nervous system, such as myasthenia gravis or Guillain-Barré syndrome
- have received or plan to receive a stem cell transplant that uses donor stem cells (allogeneic)
- are pregnant or plan to become pregnant. OPDIVO can harm your unborn baby.
- are breastfeeding or plan to breastfeed. It is not known if OPDIVO passes into your breast milk. Do not breastfeed during treatment with OPDIVO and for 5 months after the last dose of OPDIVO.



### Females who are able to become pregnant:

Your healthcare provider should do a pregnancy test before you start receiving OPDIVO.

- You should use an effective method of birth control during your treatment and for at least 5 months after the last dose of OPDIVO. Talk to your healthcare provider about birth control methods that you can use during this time.
- Tell your healthcare provider right away if you become pregnant or think you may be pregnant during treatment with OPDIVO.

**Tell your healthcare provider about all the medicines you take, including:**

- prescription medicines
- over-the-counter medicines
- vitamins
- herbal supplements

**For more information, please see [U.S. Full Prescribing Information and Medication Guide for OPDIVO](#), or talk to your healthcare team.**

## Financial Resources

### Patient Access, Reimbursement, and Co-Pay Support

Available through  
Bristol Myers Squibb Access Support®

Bristol Myers Squibb is committed to helping patients gain access to their prescribed BMS medications. That's why we offer the BMS Access Support program, which provides resources to help patients understand their insurance coverage and find information on sources of financial support, including co-pay assistance for eligible commercially insured patients.

For more information, ask your doctor, visit [BMS Access Support](#), or call BMS Access Support at **1-800-861-0048**, 8 AM to 8 PM ET, Monday–Friday.

## Other Patient Resources\*



### Bladder Cancer Advocacy Network

[bcan.org](http://bcan.org)

The preeminent national patient advocacy group for the bladder cancer community promotes and funds cutting-edge research programs and critical patient support and education services.



### American Bladder Cancer Society

[bladdercancer.ngo](http://bladdercancer.ngo)

The society provides free services such as a forum for sharing tips and stories, detailed information on the condition, and a treatment center finder.



### Cancer.Net for Bladder Cancer

[cancer.net/bladder](http://cancer.net/bladder)

This general resource has a robust section on bladder cancer that features statistics, medical illustrations, diagnosis and risk-factor information, and highlights on the latest research in the field.†



### CancerCare

[cancercares.org](http://cancercares.org)

CancerCare is the leading national organization providing free, professional support services and information to help people manage the emotional, practical, and financial challenges of cancer. These comprehensive services include counseling, support groups, educational workshops, publications, and financial and co-payment assistance.



### Cancer Support Community

[cancersupportcommunity.org](http://cancersupportcommunity.org)

This organization provides emotional and educational services for all people affected by cancer.

*\*Bristol Myers Squibb does not endorse these organizations. The information and links provided by Bristol Myers Squibb are meant for informational purposes only and are not meant to replace a physician's medical advice.*

*†Cancer.Net is a patient support resource and is a registered trademark of the American Society of Clinical Oncology, Inc. Used with permission. ASCO® does not endorse any company, product, service, or therapy.*

## From a leader in immunotherapy



Bristol Myers Squibb has been at the forefront of the battle against cancer since 1967, recently paving the way in the field of immuno-oncology.

With OPDIVO adjuvant therapy—the first and only adjuvant immunotherapy approved for people whose cancer in the lining of the urinary tract (urothelial carcinoma) was removed by surgery—we continue our commitment to helping patients.



Please see [Important Facts about OPDIVO, including serious side effects, on pages 7–8](#) and [U.S. Full Prescribing Information and Medication Guide](#).

# There may be more that can be done after surgery

And your doctors, healthcare team, friends, and family can help. Here's how:



Your doctors may recommend adjuvant therapy as part of your treatment plan. Surgery and adjuvant therapy can work together. Surgery removes the cancer, and after surgery, adjuvant therapy could reduce the risk of cancer coming back. Because there may still be cancer cells that remain "hidden" or hard to spot after surgery, it's important to ask your doctors if adjuvant therapy may be right for you.



Share any questions or concerns you have with your doctors, such as:

- What kind of follow-up visits or tests will I need after surgery?
- How will I know if cancer comes back—what should I look for?
- If I'm feeling stressed out, how should I handle it?



Lifestyle choices can make a difference, too. Find out if your doctors have any recommendations regarding everyday activities such as your diet and exercise.



Connect with other members of your healthcare team to share your thinking and get their input. Also, loop in your loved ones. The more informed everyone is, the better they may be able to support you and the decisions you make.

## Contact Information

Urologist \_\_\_\_\_ Phone \_\_\_\_\_  
 Medical Oncologist \_\_\_\_\_ Phone \_\_\_\_\_

**Remember, the information in this brochure is not a substitute for talking to your healthcare team, which is your best source of information about options after surgery for cancer of the lining of the urinary tract (urothelial carcinoma).**



## SIGN UP for *OPDIVO with You*.

*OPDIVO with You* means just that: we're here to help you better understand OPDIVO, whether you or a loved one are just considering OPDIVO or already have an OPDIVO prescription. This complimentary program includes the following resources. Sign up and you'll receive:



### Helpful Information

Get useful tips, tools, and educational materials that can help you learn more about OPDIVO and may help support your care.



### Support and Advocacy Groups

We can direct you to organizations that may be helpful for the challenges you may face.



### A Care Counselor as Close as Your Phone

If you are prescribed OPDIVO and sign up for this additional resource, you'll be able to speak with a registered nurse. This personal Care Counselor can answer questions about treatment and help you to be a more informed partner with your doctor. Care Counselors cannot provide medical advice. Your healthcare professional is the best source of information about your health.

If you'd like to sign up for the *OPDIVO with You* program, or if you have general questions about OPDIVO, call **1-855-OPDIVO-1** (1-855-673-4861) 8 AM to 8 PM ET, Monday to Friday, or visit [www.OPDIVOwithYou.com](http://www.OPDIVOwithYou.com)



For more information, call **1-855-OPDIVO-1**  
or visit [www.OPDIVO.com](http://www.OPDIVO.com)



Please see **Important Facts about OPDIVO**, including serious side effects, on pages 7-8 and **U.S. Full Prescribing Information** and **Medication Guide**.

Bristol Myers Squibb is committed to helping patients throughout their treatment.



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(nivolumab)  
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