

Staying on Top of Side Effects?

This booklet may help.



Opdualag[™]
(nivolumab and relatlimab-rmbw)
Injection for intravenous use | 480 mg/160 mg

Information 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.

Important stuff!
Use this to help
understand potential
side effects.



Please see Important Facts on pages [15–20](#) and accompanying U.S. Full Prescribing Information and Medication Guide for [Opdualag](#).



What is Opdualag?

INDICATION

What is Opdualag?

Opdualag is a premixed combination of nivolumab and relatlimab that is prepared and given through intravenous (IV) infusions. Opdualag is a prescription medicine used to treat:

- ✓ Adults who have a type of skin cancer called melanoma that has spread or cannot be removed by surgery (advanced melanoma).
- ✓ Children who are 12 years of age and older, who have melanoma that has spread or cannot be removed by surgery (advanced melanoma).

It is not known if Opdualag is safe and effective when used in children younger than 12 years of age or in children 12 years and older weighing less than 88 pounds (40 kg) or for the treatment of any other cancers.

Select Important Safety Information

Opdualag can cause problems that can sometimes become serious or life-threatening and can lead to death. Serious side effects may include: lung problems; intestinal problems; liver problems; hormone gland problems; kidney problems; skin problems; heart problems; problems in other organs and tissues; severe infusion reactions; complications of stem cell transplant, including graft-versus-host disease (GVHD), that uses donor stem cells (allogeneic). Call or see your healthcare provider right away for any new or worsening signs or symptoms.



Please see additional Important Facts on pages [15–20](#) and accompanying U.S. Full Prescribing Information and Medication Guide for [Opdualag](#).

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Contact Information



Talk to your doctor, nurse, and other caregivers in advance about the best way to contact them. Write the information below. It will make it easy to reach out to your healthcare team.

Oncologist _____

Phone number _____

Email address _____

Nurse _____

Phone number _____

Email address _____

Primary Care Physician

Phone number _____

Email address _____

Health Insurance Provider

Phone number _____

Caregiver _____

Phone number _____

Email address _____



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How Can You Play an Active Role?



Reporting side effects early is important

Talking to your healthcare team about how you are feeling can help them become aware of side effects early. **Treating certain side effects early may help keep them from becoming more serious.**



Side effects may occur

Opdualag 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 can lead to death. These problems 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.



Play an active role in communication

Don't feel like you're bothering your healthcare team by getting in touch, even if you are not sure that what you're feeling is a side effect.

Do not treat possible side effects yourself. Your healthcare team is the best source of medical help.



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Utilize Your Support Network



Play an active role in your treatment by paying attention to how you're feeling. No matter how minor a side effect may seem, don't be embarrassed to talk about it with all the members of your support network.

Your Healthcare Team

Contact your oncologist, nurse, or other clinic staff if you notice any side effects.



Advocacy and support groups

Use them to share information and experiences with other patients and caregivers.



Caregivers and community

Family and friends can help you monitor and report any changes.



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Your Daily Side Effects Check-In



You have a lot on your mind, so it may be difficult to remember any changes in how you're feeling over time. Use this Daily Side Effects Check-In to help you:

- Keep track of how you're doing on treatment
- Communicate the details of how you're feeling to your healthcare team

It includes:

- Bi-weekly pages to make a daily record of any side effects you notice
- A list of potential side effects to refer to on page 8

Use them together to start a daily **3-step routine** of:



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How To Use Your Daily Check-In



1 Be aware of what to look out for

Use the list of potential side effects **on page 8** to help you identify and describe how you're feeling.

2 Make a habit of keeping track

Make an entry in your Daily Check-In chart at the same time every day. Here's an example:

Date	Any Side Effects (Click "Yes" or "No")	How Severe? (Click one)	Name and Describe Side Effects
11/27	<input checked="" type="radio"/> Y <input type="radio"/> N	<input type="radio"/> 1 <input checked="" type="radio"/> 2 <input type="radio"/> 3	Diarrhea

Indicate whether or not you've noticed any side effects that day by clicking "Yes" or "No."

Score the side effect severity as:
1 = mild
2 = moderate
3 = severe

Use the last column to name your side effects.



Mark every week you complete.

Over time, you and your doctor will be able to see if side effects increase, decrease, or stay the same. All side effects, even those that may seem mild, should be discussed with your healthcare team right away. This may help keep your side effects from becoming more serious.

For additional charts, please call *Opdualag with You* at 1-855-OPDUALAG (1-855-673-8252).




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What Are Possible Side Effects?

It's important to notice any changes in your body after you begin treatment and to report them to your healthcare team right away.

 Working with your doctor, use this chart to write down how you are feeling as you start treatment. The descriptions under each organ of the body can help you put your thoughts into words. After treatment begins, use your chart as a "baseline" for comparison. It may help you become more aware of changes that could be the result of side effects.

If you are taking Opdualag in combination with another medicine, consult your healthcare professional about the potential side effects of that medicine.

Complications, including graft-versus-host disease (GVHD), 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 Opdualag. Your healthcare provider will monitor you for these complications.

These are not all of the possible side effects of Opdualag. This is why you need to report any discomfort or changes in the way you are feeling to your Oncology Care Team.



Heart:

- new or worse chest pain
- irregular heartbeat or feel like your heart is racing
- shortness of breath
- tiredness
- swelling in your ankles



Liver:

- 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



Intestines:

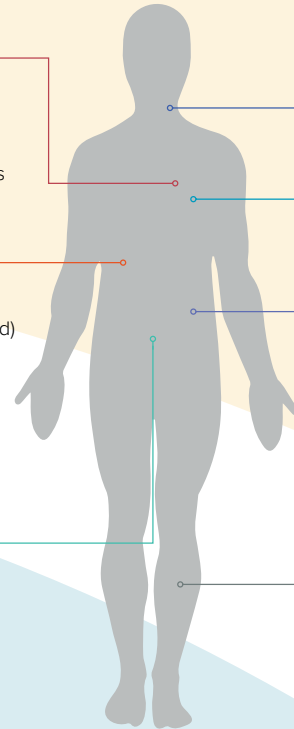
- diarrhea (loose stools) or more frequent bowel movements than usual
- stools that are black, tarry, sticky, or have blood or mucus
- severe stomach-area (abdominal) pain or tenderness



Other Organs:

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



Hormone Glands:

- 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



Lungs:

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



Kidneys:

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



Skin:

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



Severe Infusion Reactions:

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



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Your Daily Check-In: Week 1 and 2

Date	Any Side Effects (Click "Yes" or "No")		How Severe? (Click one)			Name and Describe Side Effects
	Y	N	1	2	3	
	Y	N	1	2	3	
	Y	N	1	2	3	
	Y	N	1	2	3	
	Y	N	1	2	3	
	Y	N	1	2	3	
	Y	N	1	2	3	Tracking Complete

WEEK 1

Date	Any Side Effects (Click "Yes" or "No")		How Severe? (Click one)			Name and Describe Side Effects
	Y	N	1	2	3	
	Y	N	1	2	3	
	Y	N	1	2	3	
	Y	N	1	2	3	
	Y	N	1	2	3	
	Y	N	1	2	3	
	Y	N	1	2	3	Tracking Complete

WEEK 2



Make a habit of clicking the *Tracking Complete* box at the end of every week to show that you've completed your regular Daily Check-Ins.



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Your Daily Check-In: Week 3 and 4

Date	Any Side Effects (Click "Yes" or "No")		How Severe? (Click one)			Name and Describe Side Effects
	Y	N	1	2	3	
	Y	N	1	2	3	
	Y	N	1	2	3	
	Y	N	1	2	3	
	Y	N	1	2	3	
	Y	N	1	2	3	
	Y	N	1	2	3	Tracking Complete

WEEK 3

Date	Any Side Effects (Click "Yes" or "No")		How Severe? (Click one)			Name and Describe Side Effects
	Y	N	1	2	3	
	Y	N	1	2	3	
	Y	N	1	2	3	
	Y	N	1	2	3	
	Y	N	1	2	3	
	Y	N	1	2	3	
	Y	N	1	2	3	Tracking Complete

WEEK 4



Make a habit of clicking the *Tracking Complete* box at the end of every week to show that you've completed your regular Daily Check-Ins.



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Your Daily Check-In: Week 5 and 6

Date	Any Side Effects (Click "Yes" or "No")		How Severe? (Click one)			Name and Describe Side Effects
	Y	N	1	2	3	
	Y	N	1	2	3	
	Y	N	1	2	3	
	Y	N	1	2	3	
	Y	N	1	2	3	
	Y	N	1	2	3	
	Y	N	1	2	3	Tracking Complete

WEEK 5

Date	Any Side Effects (Click "Yes" or "No")		How Severe? (Click one)			Name and Describe Side Effects
	Y	N	1	2	3	
	Y	N	1	2	3	
	Y	N	1	2	3	
	Y	N	1	2	3	
	Y	N	1	2	3	
	Y	N	1	2	3	
	Y	N	1	2	3	Tracking Complete

WEEK 6



Make a habit of clicking the *Tracking Complete* box at the end of every week to show that you've completed your regular Daily Check-Ins.



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Your Daily Check-In: Week 7 and 8

Date	Any Side Effects (Click "Yes" or "No")		How Severe? (Click one)			Name and Describe Side Effects
	Y	N	1	2	3	
	Y	N	1	2	3	
	Y	N	1	2	3	
	Y	N	1	2	3	
	Y	N	1	2	3	
	Y	N	1	2	3	
	Y	N	1	2	3	Tracking Complete

WEEK 7

Date	Any Side Effects (Click "Yes" or "No")		How Severe? (Click one)			Name and Describe Side Effects
	Y	N	1	2	3	
	Y	N	1	2	3	
	Y	N	1	2	3	
	Y	N	1	2	3	
	Y	N	1	2	3	
	Y	N	1	2	3	
	Y	N	1	2	3	Tracking Complete

WEEK 8



Make a habit of clicking the *Tracking Complete* box at the end of every week to show that you've completed your regular Daily Check-Ins.



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Your Daily Check-In: Week 9 and 10

Date	Any Side Effects (Click "Yes" or "No")		How Severe? (Click one)			Name and Describe Side Effects
	Y	N	1	2	3	
	Y	N	1	2	3	
	Y	N	1	2	3	
	Y	N	1	2	3	
	Y	N	1	2	3	
	Y	N	1	2	3	
	Y	N	1	2	3	Tracking Complete

WEEK 9

Date	Any Side Effects (Click "Yes" or "No")		How Severe? (Click one)			Name and Describe Side Effects
	Y	N	1	2	3	
	Y	N	1	2	3	
	Y	N	1	2	3	
	Y	N	1	2	3	
	Y	N	1	2	3	
	Y	N	1	2	3	
	Y	N	1	2	3	Tracking Complete

WEEK 10



Make a habit of clicking the *Tracking Complete* box at the end of every week to show that you've completed your regular Daily Check-Ins.



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Your Daily Check-In: Week ____ and ____

Date	Any Side Effects (Click "Yes" or "No")		How Severe? (Click one)			Name and Describe Side Effects
	Y	N	1	2	3	
	Y	N	1	2	3	
	Y	N	1	2	3	
	Y	N	1	2	3	
	Y	N	1	2	3	
	Y	N	1	2	3	
	Y	N	1	2	3	Tracking Complete

WEEK ____

Date	Any Side Effects (Click "Yes" or "No")		How Severe? (Click one)			Name and Describe Side Effects
	Y	N	1	2	3	
	Y	N	1	2	3	
	Y	N	1	2	3	
	Y	N	1	2	3	
	Y	N	1	2	3	
	Y	N	1	2	3	
	Y	N	1	2	3	Tracking Complete

WEEK ____



Make a habit of clicking the *Tracking Complete* box at the end of every week to show that you've completed your regular Daily Check-Ins.




Please see additional Important Facts on pages 15–20 and accompanying U.S. Full Prescribing Information and Medication Guide for Opdualag.


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Important Facts About Opdualag™ (nivolumab and relatlimab-rmbw)

This is a summary of important information that you need to know about Opdualag. Your healthcare team can work with you to help answer any questions you may have about this medication. 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 Opdualag?

 Opdualag is a premixed combination of nivolumab and relatlimab that is prepared and given through intravenous (IV) infusions. Opdualag is a prescription medicine used to treat:


- ✓ Adults who have a type of skin cancer called melanoma that has spread or cannot be removed by surgery (advanced melanoma).
- ✓ Children who are 12 years of age and older, who have melanoma that has spread or cannot be removed by surgery (advanced melanoma).

It is not known if Opdualag is safe and effective when used in children younger than 12 years of age or in children 12 years and older weighing less than 88 pounds (40 kg) or for the treatment of any other cancers.

 An IV infusion is when medicine is given directly into the bloodstream through a needle placed in a vein by a healthcare professional – usually in the arm or hand.

What is the most important information I should know about Opdualag?

Opdualag can cause serious side effects any time during and after treatment. A **serious side effect** is a side effect that can sometimes become life-threatening and can lead to death. Serious side effects may happen anytime during treatment or even after your treatment has ended. You may experience more than one side effect at the same time.

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

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Important Facts About Opdualag™ (continued)

Immune system-related side effects

Opdualag is a medicine that may treat melanoma that has spread or cannot be removed by surgery by working with your immune system. Opdualag can cause your immune system to attack normal organs and tissues in any area of your body and can affect the way they work. Some of these problems can sometimes become severe and can lead to death.

This is a list of some possible immune system-related side effects of Opdualag. You may experience other side effects that are not listed. You may experience side effects anytime during treatment or even after treatment has ended.



Call or see your healthcare provider right away if you develop any new or worsening 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
- pain on the right side of your stomach area (abdomen)
- bleeding or bruising more easily than normal
- severe nausea or vomiting
- dark urine (tea colored)

Hormone gland problems — Things to look out for may include:

- headaches that will not go away or unusual headaches
- weight gain or weight loss
- constipation
- eye sensitivity to light
- feeling more hungry or thirsty than usual
- your voice gets deeper
- eye problems
- urinating more often than usual
- dizziness or fainting
- rapid heartbeat
- hair loss
- changes in mood or behavior, such as decreased sex drive, irritability, or forgetfulness
- increased sweating
- feeling cold

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Important Facts About Opdualag™ (continued)

Immune system-related side effects (continued)

Kidney problems — Things to look out for may include:

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

Skin problems — Things to look out for may include:

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

Heart problems — Things to look out for may include:

- new or worse chest pain
- shortness of breath
- swelling in your ankles
- irregular heartbeat or feel like your heart is racing
- tiredness

Immune system-related side effects can also happen in **other organs and tissues** with Opdualag™ (nivolumab and relatlimab-rmbw), including:

Brain and nerve problems — Things to look out for may include:

- confusion
- changes in mood or behavior
- tingling or numbness of the arms or legs
- sleepiness
- stiff neck
- memory problems
- balance problems

Eye or vision problems — Things to look out for may include:


- double vision
- sensitivity to light
- changes in eyesight
- blurry vision
- eye pain

Muscle problems — Things to look out for may include:

- persistent or severe muscle pain or weakness
- muscle cramps

Blood problems — Things to look out for may include:

- low red blood cells
- bruising

 **Call or see your healthcare provider right away** if you develop any new or worsening signs or symptoms. **(Continued on page 18)**

 Please see additional Important Facts on pages [15–20](#) and accompanying U.S. Full Prescribing Information and Medication Guide for [Opdualag](#).


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Important Facts About Opdualag™ (continued)

What are some other serious side effects of Opdualag?

Severe Infusion Reactions

Opdualag™ (nivolumab and relatlimab-rmbw) is given through intravenous (IV) infusions. The medicine is put directly into your bloodstream through a needle that a healthcare professional places in a vein, usually in your arm or hand.

Things to look out for during an infusion of Opdualag may include:

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



Tell your healthcare team right away if you get these symptoms during or after an infusion of Opdualag.

Stem Cell Transplant Complications

You may experience complications if you receive donor stem cells (allogeneic stem cell transplant) before or after treatment with Opdualag. These complications can be severe and can lead to death. Your healthcare team will monitor you for signs of complications if you have an allogeneic stem cell transplant.

What are the most common side effects?

The most common side effects of Opdualag include:

- muscle and bone pain
- tiredness
- decreased red blood cell and white blood cell counts
- increased liver function test results
- rash
- itching
- diarrhea
- decreased salt (sodium) in your blood

These are not all the possible side effects.



Talk to your healthcare team for more information. You are encouraged to report side effects of prescription drugs to the FDA by visiting www.fda.gov/medwatch or calling 1-800-FDA-1088.

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What should I discuss with my healthcare team about pregnancy, birth control, and breastfeeding?



Talk to your healthcare team if:



You are **pregnant or **plan to become pregnant** – Opdualag can harm your unborn baby**

If you are able to become pregnant, your healthcare team should do a pregnancy test before you start receiving Opdualag. You should use an effective method of birth control during treatment and for at least 5 months after your last dose of Opdualag.



Talk to your healthcare team about **birth control methods** that you can use during this time.



Tell your healthcare team right away if you become pregnant or think you are pregnant during treatment with Opdualag.



You are **breastfeeding or **plan to breastfeed****

It is not known if Opdualag passes into your breast milk. Do not breastfeed during treatment with Opdualag and for 5 months after the last dose of Opdualag.

What should I discuss with my healthcare team before starting treatment?



Talk to your healthcare team about **all your health problems or concerns**, including if you:

- have immune system problems such as Crohn's disease, ulcerative colitis, or lupus
- have had an organ transplant
- have had or plan to have 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



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

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

These are not all the topics you should discuss with your healthcare team. Ask your healthcare team about anything you may be unsure about before starting treatment.

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How will I receive Opdualag?


Opdualag is a premixed prescription medication (12 mg/mL nivolumab and 4 mg/mL relatlimab) that is prepared and given as intravenous (IV) infusions by your healthcare team.


 An IV infusion is when medicine is given directly into the bloodstream through a needle placed in a vein by a healthcare professional – usually in the arm or hand.

Dosage:

 **Talk to your healthcare team** to learn more about the dosing for Opdualag.

Receiving Opdualag:

 IV infusion time is about **30 minutes**, though actual time in clinic or place of infusion may vary.

 Opdualag is usually given **every 4 weeks**. Your healthcare provider will decide how many treatments you will receive and do blood tests to monitor your health and check for side effects.

 **Call your healthcare team** as soon as possible to reschedule if you miss any of your appointments.

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