

Staying on Top of Side Effects?

This booklet may help.



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

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

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Tips on how to view this PDF

To help make it easier to find what you need in this PDF, you can click the numbers in the table of contents above to bring you to the pages you need if you are viewing this PDF on the internet.

You can also print this PDF. Make sure to print front and back, and in black and white, to save paper and ink.



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What is OPDIVO® (nivolumab)? 🝺

INDICATIONS

OPDIVO is a prescription medicine used to treat:

- Adults and children 12 years of age and older who have a type of **skin cancer called melanoma** when:
 - ✓ Your melanoma has spread or cannot be removed by surgery (advanced melanoma).

OPDIVO can be used alone or in combination with YERVOY (OPDIVO + YERVOY).

Adults who have a type of **advanced stage lung cancer called non-small cell lung cancer (NSCLC)**: OPDIVO + YERVOY is approved as a first treatment for adults when:

✓ Your lung cancer has spread to other parts of the body (metastatic), AND

✓ Your tumors are positive for PD-L1 but do not have an abnormal EGFR or ALK gene.

OPDIVO + YERVOY in combination with 2 cycles of chemotherapy that contains platinum and another chemotherapy medicine (OPDIVO + YERVOY + chemo) is approved as a first treatment for adults when:

- ✓ Your lung cancer has spread (metastatic) or comes back (recurrent), AND
- ✓ Your tumors do not have an abnormal EGFR or ALK gene.

OPDIVO is approved for adults when:

- ✓ Your lung cancer has spread, AND
- Vou have tried chemotherapy that contains platinum, and it did not work or is no longer working, **AND**
- Vour tumor has an abnormal EGFR or ALK gene, and you have also tried an FDA-approved therapy for tumors with these abnormal genes and it did not work or is no longer working.

Select Important Facts About OPDIVO and OPDIVO + YERVOY

OPDIVO and YERVOY 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; eye problems; problems in other organs and tissues; severe infusion reactions; and 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.



What is OPDIVO® (nivolumab)? (continued)

INDICATIONS (continued)

🖄 Adults with a type of early-stage lung cancer called non-small cell lung cancer (NSCLC):

OPDIVO, in combination with chemotherapy that contains platinum and another chemotherapy medicine, is approved for adults with early-stage NSCLC before you have surgery. If your early-stage lung cancer does **not** have an abnormal EGFR or ALK gene, OPDIVO alone may be continued after surgery to help prevent your lung cancer from coming back.

Adults who have a type of cancer called **malignant pleural mesothelioma**, which affects the lining of your lungs and chest wall:

OPDIVO + YERVOY may be used as your first treatment for malignant pleural mesothelioma that cannot be removed by surgery.

Adults who have kidney cancer (renal cell carcinoma):

OPDIVO + YERVOY is approved as a first treatment for certain adults when:

✓ Your cancer has spread (advanced RCC).

OPDIVO in combination with cabozantinib is approved as a first treatment for adults when:

✓ Your cancer has spread (advanced RCC).

Please read the Patient Information that comes with cabozantinib.

OPDIVO is approved for adults when:

Your kidney cancer (RCC) has spread after treatment with other cancer medicines.

Adults who have a type of **blood cancer called classical Hodgkin lymphoma (cHL)** when:

Vour classical Hodgkin lymphoma has come back or spread after a type of stem cell transplant that uses your own stem cells (autologous stem cell transplant), **AND**

✓ You have used the medicine brentuximab vedotin before or after the stem cell transplant, **OR**

Vou have received at least 3 kinds of treatment including an autologous stem cell transplant.

OPDIVO was approved based on response rate. There is ongoing evaluation of clinical benefit of OPDIVO for this use.

Adults who have head and neck cancer called squamous cell carcinoma of the head and neck (SCCHN) when:

Vou have received chemotherapy that contains platinum, but your head and neck cancer has returned or spread after treatment.

Adults who have cancer of the lining of the urinary tract (including the bladder, urethra, ureters, or renal pelvis) **(urothelial carcinoma)**:

OPDIVO is approved to help prevent cancer from coming back in adults when:

You have had cancer of the urinary tract (including the bladder, ureters, or renal pelvis), AND

You have had surgery to remove the cancer.

OPDIVO may be used in combination with chemotherapy medicines cisplatin and gemcitabine as the first treatment when urinary tract cancer has spread (metastatic) or cannot be removed by surgery.





What is OPDIVO[®] (nivolumab)? (continued)

INDICATIONS (continued)

OPDIVO is approved for adults when:

- Vour urinary tract cancer that has spread (locally advanced or metastatic), AND
- You have received chemotherapy that contains platinum, and it did not work or is no longer working, **OR**

Your cancer worsened within 12 months of treatment with chemotherapy that contains platinum, either before or after surgery to remove the cancer.

🔀 Adults and children 12 years of age and older who have colorectal cancer (a type of colon or rectal cancer).

OPDIVO + YERVOY is approved for adults and children 12 years of age and older when:

- You have colorectal cancer that cannot be removed with surgery, or has spread to other parts of your body (metastatic),
 AND
- You have a tumor that is microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR).

OPDIVO is approved for adults and children 12 years of age and older when:

- You have colorectal cancer that has spread to other parts of your body (metastatic), AND
- You have a tumor that is microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR), AND
- You have received treatment with a fluoropyrimidine, oxaliplatin, and irinotecan, and it did not work or is no longer working.

Adults with a type of liver cancer called hepatocellular carcinoma (HCC):

OPDIVO + YERVOY is approved for adults when:

You have liver cancer that cannot be removed with surgery, or has spread to other parts of your body (metastatic).

OPDIVO + YERVOY is approved for adults when:

You have liver cancer that cannot be removed with surgery, or has spread to other parts of your body (metastatic), AND
 You have previously received treatment with sorafenib.

Adults and children 12 years of age and older who have a type of skin cancer called melanoma:

✓ To help prevent Stage IIB or Stage IIC melanoma from coming back after it has been completely removed by surgery, OR

To help prevent Stage III or Stage IV melanoma from coming back after it has been completely removed by surgery.

OPDIVO, when used alone, is approved for adults and children 12 years of age and older to help prevent melanoma from coming back after surgery

Adults who have **cancer of the tube that connects the throat to the stomach (esophageal cancer).** OPDIVO + YERVOY is approved for adults when:

- Your esophageal cancer is a type called squamous cell carcinoma, AND
- Your cancer cannot be removed with surgery (advanced), or has spread (metastatic), AND
- Your tumors are positive for PD-L1, AND
- As a first treatment for your advanced or metastatic esophageal cancer.





What is OPDIVO® (nivolumab)? (continued)

INDICATIONS (continued)

OPDIVO with chemotherapy that contains fluoropyrimidine and platinum is approved for adults when:

- ✓ Your esophageal cancer is a type called squamous cell cancer, AND
- Your cancer cannot be removed with surgery (advanced), or has spread (metastatic), AND
- ✓ Your tumors are positive for PD-L1, AND

As a first treatment for their advanced or metastatic esophageal cancer.

 $igcar{1}$ Adults who have cancer of the tube that connects the throat to the stomach (esophageal cancer) when:

- ✓ Your esophageal cancer is a type called squamous cell carcinoma, AND
- ✓ Your cancer cannot be removed with surgery, or has spread, AND
- Your cancer has come back or spread after they have received chemotherapy that contains fluoropyrimidine and platinum.

Adults who have cancer of the tube that connects the throat to the stomach (esophageal cancer) or cancer where the esophagus joins the stomach (gastroesophageal junction cancer) when:

✓ You have been treated with chemoradiation, AND THEN

Vou have had surgery to completely remove the cancer, **but** some cancer cells were still present in the removed tumor or lymph nodes.

OPDIVO may be used to help prevent the esophageal or gastroesophageal junction cancer from coming back.

Adults who have:

Cancer of the stomach (gastric cancer).

Cancer where the esophagus joins the stomach (gastroesophageal junction cancer).

Esophageal adenocarcinoma.

OPDIVO may be used with chemotherapy that contains fluoropyrimidine and platinum in adults whose gastric, gastroesophageal junction, or esophageal cancer when:

Your tumors are positive for PD-L1, AND



Your cancer has spread to other parts of your body.

It is not known if OPDIVO is safe and effective in children younger than 12 years of age with melanoma or MSI-H or dMMR metastatic colorectal cancer.

It is not known if OPDIVO is safe and effective in children for the treatment of any other cancers.





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

What is OPDIVO Qvantig[™] (nivolumab + hyaluronidase-nvhy)?

OPDIVO Qvantig is a prescription medicine given as a subcutaneous injection (under the skin) used to treat adults with:

INDICATIONS



A type of kidney cancer that has spread, called advanced renal cell carcinoma (RCC).

OPDIVO Qvantig may be used alone in certain people after completing combination treatment with nivolumab given into the vein (intravenous nivolumab) and ipilimumab, when:

Kidney cancer has spread (advanced RCC), AND

This is your first treatment for advanced RCC

OPDIVO Qvantig may be used in combination with cabozantinib when:

- ✓ Kidney cancer has spread (advanced RCC), AND
- ✓ This is your first treatment for advanced RCC

OPDIVO Qvantig may be used alone when:

✓ Kidney cancer (RCC) has spread after treatment with other cancer medicines

Select Important Facts About OPDIVO Qvantig

OPDIVO Qvantig 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; eye problems; problems in other organs and tissues; and 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.



What is OPDIVO Qvantig? (continued)

INDICATIONS (continued)



A type of skin cancer called melanoma:

OPDIVO Qvantig may be used alone when:

Melanoma has spread or cannot be removed by surgery (advanced melanoma)

OPDIVO Qvantig may be used alone after completing combination treatment with intravenous nivolumab and ipilimumab, when:



OPDIVO Qvantig may be used alone to help prevent melanoma from coming back when:

🗸 Stage IIB, Stage IIC, Stage III, or Stage IV melanoma has been completely removed by surgery

A type of early stage lung cancer called non-small cell lung cancer (NSCLC):

OPDIVO Qvantig may be used in combination with chemotherapy medicines that contain platinum, and another chemotherapy medicine **before** you have surgery for early-stage NSCLC.

OPDIVO Qvantig may then be continued alone to help prevent lung cancer from coming back after you have surgery if:

Early-stage lung cancer does **not** have an abnormal EGFR or ALK gene

A type of advanced stage lung cancer called non-small cell lung cancer (NSCLC):

OPDIVO Qvantig may be used alone when:

- ✓ Lung cancer has spread, AND
- Vou have tried chemotherapy that contains platinum, and it did not work or is no longer working, AND
- You have tried an FDA-approved therapy for tumors with abnormal genes that did not work or is no longer working,
 IF the tumor has an abnormal EGFR or ALK gene

💦 Head and neck cancer called squamous cell carcinoma of the head and neck (SCCHN):

OPDIVO Qvantig may be used alone when:

- Head and neck cancer has come back or spread, AND
- 🖌 You have been treated with chemotherapy that contains platinum, and it did not work or is no longer working



What is OPDIVO Qvantig? (continued)

INDICATIONS (continued)

ᠵ Cancer of the lining of the urinary tract (including the bladder, urethra, ureters, or renal pelvis) (urothelial carcinoma):

OPDIVO Qvantig may be used alone to help prevent cancer from coming back when:

✓ Cancer of the urinary tract has been removed by surgery

OPDIVO Qvantig may be used in combination with chemotherapy medicines cisplatin and gemcitabine as your first treatment when:

- Urinary tract cancer has spread (metastatic), OR
- Cancer cannot be removed by surgery

OPDIVO Qvantig may be used alone when:

- ✓ Urinary tract cancer has spread (locally advanced or metastatic), AND
- You have tried chemotherapy that contains platinum, and it did not work or is no longer working, **OR**
- Cancer worsened within 12 months of treatment with chemotherapy that contains platinum, either before or after surgery to remove the cancer

A type of colon or rectal cancer (colorectal cancer [CRC]):

OPDIVO QVANTIG may be used alone, after completing combination treatment with intravenous nivolumab and ipilimumab when:

- Colon or rectal cancer cannot be removed with surgery, or has spread, **AND**
- ✓ Cancer is microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR)

OPDIVO Qvantig may be used alone when:

- ✓ Colon or rectal cancer has spread to other parts of the body (metastatic CRC), AND
- Cancer is microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR), AND
- Vou have tried treatment with a fluoropyrimidine, oxaliplatin, and irinotecan, and it did not work or is no longer working

A type of liver cancer called hepatocellular carcinoma (HCC):

OPDIVO QVANTIG may be used alone if:

- \checkmark You have completed combination treatment with intravenous nivolumab and ipilimumab, AND
- ✓ Your liver cancer cannot be removed with surgery, **OR**
- ✓ Your liver cancer has spread

OPDIVO QVANTIG may be used alone after completing combination therapy with intravenous nivolumab and ipilimumab when:

- ✓ Your liver cancer cannot be removed with surgery, OR
- Your liver cancer has spread, AND
- You have received prior treatment with sorafenib





What is OPDIVO Qvantig? (continued)

INDICATIONS (continued)



Cancer of the tube that connects the throat to the stomach (esophageal cancer):

OPDIVO Qvantig may be used alone to help prevent esophageal or gastroesophageal junction cancer from coming back when:

- Your esophageal or gastroesophageal junction cancer has been treated with chemoradiation followed by surgery to completely remove the cancer. BUT
- Some cancer cells were still present in the removed tumor or lymph nodes

OPDIVO Qvantig may be used in combination with chemotherapy medicines that contain fluoropyrimidine and platinum as your first treatment when esophageal cancer:

- Is a type of cancer called squamous cell carcinoma, **AND**
- Tumors are positive for PD-L1, AND
- Cannot be removed with surgery (advanced), OR
- ✓ Has spread to other parts of the body (metastatic)

OPDIVO Qvantig may be used alone when esophageal cancer:

- Is a type of cancer called squamous cell carcinoma, **AND**
- Cannot be removed with surgery (advanced), AND
- Has come back or spread to other parts of the body (metastatic), after you have received chemotherapy that contains fluoropyrimidine and platinum

Cancer of the stomach (gastric cancer), cancer where the esophagus joins the stomach (gastroesophageal junction cancer), and a type of cancer in the esophagus called esophageal adenocarcinoma:

OPDIVO Ovantig may be used with chemotherapy that contains fluoropyrimidine and platinum when gastric. gastroesophageal junction, or esophageal cancer:

- Tumors are positive for PD-L1, AND
- Cannot be removed with surgery, OR has spread
- 🗙 It is not known if OPDIVO Qvantig is safe and effective in children.
- X OPDIVO Qvantig may not be used in combination with ipilimumab.

Please see Important Facts About OPDIVO + YERVOY on pages 18-20 and Important Facts About OPDIVO Qvantig on pages 21-25. Please see accompanying U.S. Full Prescribing Information and Medication Guide for OPDIVO. For more information, please see accompanying U.S. Full Prescribing Information and Medication Guide for YERVOY. For more information, please see the accompanying U.S. Full Prescribing Information and Medication Guide for OPDIVO Qvantig.



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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
- A built-in stand for easy access that also gives you the option of keeping it closed for privacy

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



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.**

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.

Side effects may occur

OPDIVO, YERVOY, and OPDIVO Qvantig 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. Some of these problems may happen more often when OPDIVO or OPDIVO Qvantig is used in combination with another therapy.



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 of the members of your support network.



If you haven't already registered for your personal Care Counselor, visit **www.OPDIVOwithYou.com** or call **1-855-OPDIVO-1** (1-855-673-4861) to request a registration form.

How to use your daily check-in 📴

Be aware of what to look out for Use the list of potential side effects on pages 16–17 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:



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 OPDIVO with You at 1-855-OPDIVO-1 (1-855-673-4861).



Your Daily Check-In: Week 1 and 2

Date	Any Side Effects (Circle "Yes" or "No")	? How Severe? (Circle one)			Any Side Effects? (Circle "Yes" or "No")			w Sev ircle o		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			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		Y	N	1	2	3	Tracking Complete
		WEEK 1					w	ЕЕК	2 -	

Your Daily Check-In: Week 3 and 4

Date	Any Side Effects? (Circle "Yes" or "No")		How Severe? (Circle one)				Date	(Circle	Any Side Effects? (Circle "Yes" or "No")		v Sev rcle o		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			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	Complete		Y	N	1	2	3	Tracking Complet
	L		WE	ЕК	3 -					WE	ЕК	4 -	

Please see Important Facts About OPDIVO + YERVOY on <u>pages 18-20</u> and Important Facts About OPDIVO Qvantig on <u>pages 21-25</u>. Please see accompanying <u>U.S. Full Prescribing Information</u> and <u>Medication Guide</u> for <u>OPDIVO</u>. For more information, please see accompanying <u>U.S. Full Prescribing Information</u> and <u>Medication Guide</u> for <u>YERVOY</u>. For more information, please see the accompanying <u>U.S. Full Prescribing Information</u> and <u>Medication Guide</u> for <u>OPDIVO</u> Qvantig.

OPDIVO. OPDIVO (nivolumab) (nivolumab)





Your Daily Check-In: Week 5 and 6

Date	Any Side Effects? (Circle "Yes" or "No")	How Severe? (Circle one)			"Yes"		w Sev ircle o		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			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	Complete		Y	N	1	2	3	Tracking Complete
	L	WEEK 5					WE	ЕЕК	6 -	

Your Daily Check-In: Week 7 and 8

Date	Any Side Effects? (Circle "Yes" or "No")		(Circle "Yes"		How Severe? Name and Describe (Circle one) Side Effects Date (Circle "Yes" or "No")		e "Yes"		v Sev rcle o		Name and Describe Side Effects	
	Y	N	1	2	3		Y	Ν	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	
	Y	N	1	2	3		Y	N	1	2	3	
	Y	N	1	2	З		Y	N	1	2	3	
	Y	N	1	2	3	Tracking Complete	Y	N	1	2	3	Tracking Complete
			WE	ЕК	7 •				WE	ЕК	8	

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OPDIVO. OPDIVO (nivolumab) (nivolumab)





Your Daily Check-In: Week 9 and 10

Date	Any Side Effects? (Circle "Yes" or "No")	How Severe? (Circle one)	now Severe: Name and Describe Date		Any Side Effects? (Circle "Yes" or "No")	How Severe? (Circle 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			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		Y N	1 2 3	Tracking Complete
		WEEK 9				WEEK 10 -	

Your Daily Check-In: Week 11 and 12

Date	Any Side Effects? (Circle "Yes" or "No")		How Severe? (Circle one)			Date	Any Side (Circle or "	How Severe? (Circle one)			Name and Describe Side Effects		
	Y	Ν	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			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	Complete		Y	N	1	2	3	Trackir Comple
	L		WE	ΕК	11 -			I L		WE	ΕK	12 -	

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OPDIVO. (nivolumab)

(nivolumab)



OPDIVO Qvantig[®] nivolumab + hyaluronidase-nvhy 14 SUBCUTANEOUS INJECTION 120 mg + 2,000 units / ml.

Your Daily Check-In: Week ____ and ____ You can print out this page if you need additional charts.

Date	Any Side Effects? Date (Circle "Yes" or "No")			v Sev rcle o		Name and Describe Side Effects	Date	(Circle	e Effects? e "Yes" No")		v Sev rcle o		Name and Describe Side Effects
	Y	N	1	2	3			Y	Ν	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	
	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	Complete		Y	N	1	2	3	Tracking Complete
	WEEK							L		WE	ЕК		

Your Daily Check-In: Week and

Any Side Effects? (Circle "Yes" or "No")		How Severe? (Circle one)				Date	Any Side Effects? (Circle "Yes" or "No")		How Severe? (Circle 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			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	C Tracking Complete		Y	N	1	2	3	Complet
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Please see Important Facts About OPDIVO + YERVOY on pages 18-20 and Important Facts About OPDIVO Qvantig on pages 21-25. Please see accompanying U.S. Full Prescribing Information and Medication Guide for OPDIVO. For more information, please see accompanying U.S. Full Prescribing Information and Medication Guide for YERVOY. For more information, please see the accompanying U.S. Full Prescribing Information and Medication Guide for OPDIVO Qvantig.

OPDIVO (nivolumab)

(nivolumab)





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.

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



See the following pages for more potential Adverse Events.



Please see Important Facts About OPDIVO + YERVOY on pages 18-20 and Important Facts About OPDIVO Qvantig on pages 21-25. Please see accompanying U.S. Full Prescribing Information and Medication Guide for OPDIVO. For more information, please see accompanying U.S. Full Prescribing Information and Medication Guide for YERVOY. For more information, please see the accompanying U.S. Full Prescribing Information and Medication Guide for OPDIVO Qvantig.





What are possible side effects? (continued)

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

Rejection of a transplanted organ or tissue. Your healthcare provider should tell you what signs and symptoms you should report and monitor you depending on the type of organ or tissue transplant that you have had.

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 severe and can lead to death. These complications may happen if you underwent transplantation either before or after being treated with OPDIVO, OPDIVO + YERVOY, or OPDIVO Qvantig. Your healthcare provider will monitor you for signs of complications if you have an allogeneic stem cell transplant.

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



Please see Important Facts About OPDIVO + YERVOY on <u>pages 18-20</u> and Important Facts About OPDIVO Qvantig on <u>pages 21-25</u>. Please see accompanying <u>U.S. Full Prescribing Information</u> and <u>Medication Guide</u> for <u>OPDIVO</u>. For more information, please see accompanying <u>U.S. Full Prescribing Information</u> and <u>Medication Guide</u> for <u>YERVOY</u>. For more information, please see the accompanying <u>U.S. Full Prescribing Information</u> and <u>Medication Guide</u> for <u>OPDIVO</u> Qvantig.





Important Facts About OPDIVO[®] (nivolumab) and OPDIVO + YERVOY[®] (ipilimumab)

This is a summary of important information that you need to know about OPDIVO and OPDIVO + YERVOY. Your healthcare team can work with you to help answer any questions you may have about these medications. 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:



healthcare team

Call a healthcare provider right away



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

OPDIVO and YERVOY are medicines that may treat certain cancers by working with your immune system. OPDIVO and YERVOY 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 may happen more often when OPDIVO is used in combination with another therapy.

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 and OPDIVO + YERVOY?

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 ou	t for may include:		
• cough	 shortness of breath 	 chest pain 	
Intestinal problems – Things to look of	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-are pain or tenderness 	
Liver problems – Things to look ou	t for may include:		
the whites of your eyes	 pain on the right side of your stomach area (abdomen) dark urine (tea colored) 	 bleeding or bruising more easily than no 	
Hormone gland problems – Things	to look out for may include:		
away or unusual headaches • eye sensitivity to light • eye problems	 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:		
	blood in your urineswelling of your ankles	 loss of appetite 	
Skin problems – Things to look out	for may include:		
	skin blistering or peelingswollen lymph nodes	 painful sore or ulcer or genital area fever or flu-like sym 	rs in mouth or nose, throat,

Eye problems – Things to look out for may include:

Please see Important Facts About OPDIVO + YERVOY on pages 18-20 and Important Facts About OPDIVO Qvantig on pages 21-25. Please see accompanying U.S. Full Prescribing Information and Medication Guide for OPDIVO. For more

information, please see accompanying U.S. Full Prescribing Information and

U.S. Full Prescribing Information and Medication Guide for OPDIVO Qvantig.

- blurry vision, double vision, or other vision problems
- eye pain or redness
- ever of hu-like symptoms

(nivolumah)

(ipilimumab)





Important Facts About OPDIVO[®] (nivolumab) and OPDIVO + YERVOY[®] (ipilimumab) (continued)

What are the serious side effects of OPDIVO and OPDIVO + YERVOY? (continued)

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 and YERVOY. 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

Rejection of a transplanted organ or tissue. Your healthcare provider should tell you what signs and symptoms you should report and monitor you depending on the type of organ transplant that you have had.

What are the possible side effects of OPDIVO + YERVOY?

OPDIVO and OPDIVO + YERVOY can cause serious side effects, including: See the previous section, "What is the most important information I should know about OPDIVO + YERVOY?"

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

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

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

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

What are the most common side effects?

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

diarrhea

• cough

feeling tired

bones, and joints

• rash • pain in muscles,

itching

- nausea weakness
- constipation decreased appetite
- back pain
 - upper respiratory tract
- infection shortness of breath

- fever
- headache
- stomach-area (abdominal) pain

constipation

decreased weight

- vomiting
- urinary tract infection
- The most common side effects of OPDIVO when used in combination with YERVOY include:
- feeling tired pain in muscles, decreased appetite shortness of headache low thyroid diarrhea bones, and joints • vomiting breath
- upper respiratory hormone levels dizziness rash fever stomach-area tract infection itching • cough (abdominal) pain (hypothyroidism)
- nausea

The most common side effects of OPDIVO when used in combination with YERVOY and chemotherapy include:

feeling tired

bones, and joints

- pain in muscles,
- nausea diarrhea
- rash decreased appetite
- constipation
 - itching



Please see Important Facts About OPDIVO + YERVOY on pages 18-20 and Important Facts About OPDIVO Qvantig on pages 21-25. Please see accompanying U.S. Full Prescribing Information and Medication Guide for OPDIVO. For more information, please see accompanying U.S. Full Prescribing Information and Medication Guide for YERVOY. For more information, please see the accompanying U.S. Full Prescribing Information and Medication Guide for OPDIVO Qvantig.





Important Facts About OPDIVO[®] (nivolumab) and OPDIVO + YERVOY[®] (ipilimumab) (continued)

What are the most common side effects? (continued)

• rash

rash

The most common side effects of OPDIVO when used in combination with chemotherapy include:

- nausea
- constipation decreased appetite
- feeling tired pain in muscles,
- bones, and joints

The most common side effects of OPDIVO when used in combination with cabozantinib include:

- diarrhea
- feeling tired or weak

or soles of your feet

- high blood pressure
- rash, redness, pain, swelling, or blisters on
 - bones, and joints

constipation

mouth sores

- vomiting numbness, pain, tingling, or
 - burning in your hands and feet

- liver problems
- low thyroid

mouth sores

- hormone levels
- the palms of your hands pain in muscles,
- nausea • change in the sense of taste

decreased appetite

- stomach-area
- (abdominal) pain

The most common side effects of OPDIVO when used in combination with fluoropyrimidine- and platinum-containing chemotherapy include:

- nausea
- numbness, pain, tingling, or burning in your hands or feet
- decreased appetite feeling tired
 - diarrhea vomiting
 - stomach-area

cough

- (abdominal) pain
- pain in muscles, bones, and joints

upper respiratory

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.

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

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



Females who are able to become pregnant:

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

- You should use an effective method of birth control during your treatment and for 5 months after the last dose of OPDIVO or YERVOY. 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 or YERVOY. You or your healthcare provider should contact Bristol Myers Squibb at 1-844-593-7869 as soon as you become aware of a pregnancy.



- Tell your healthcare provider about all the medicines you take, including:
- prescription medicines • over-the-counter medicines
 - vitamins
 - herbal supplements

YFRV

For more information, please see accompanying U.S. Full Prescribing Information and Medication Guide for OPDIVO and for YERVOY, or talk to your healthcare team.

Please see Important Facts About OPDIVO + YERVOY on pages 18-20 and Important Facts About OPDIVO Qvantig on pages 21-25. Please see accompanying U.S. Full Prescribing Information and Medication Guide for OPDIVO. For more information, please see accompanying U.S. Full Prescribing Information and Medication Guide for YERVOY. For more information, please see the accompanying U.S. Full Prescribing Information and Medication Guide for OPDIVO Qvantig.





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

Look out for the fo	llowing
icons as you read:	



Call a healthcare provider right away

Helpful information to remember

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

OPDIVO Qvantig is a medicine that may treat certain cancers by working with your immune system. OPDIVO Qvantig 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 may happen more often when OPDIVO Qvantig is used in combination with another therapy.

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 Qvantig?

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:

cough

shortness of breath

Intestinal problems – Things to look out for may include:

• diarrhea (loose stools) or more stools that are black, tarry, sticky, or have blood or mucus frequent bowel movements than usual

Liver problems – Things to look out for may include:

- yellowing of your skin or the • pain on the right side of your stomach whites of your eyes area (abdomen)
- 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
- eye sensitivity to light
- eve 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

- bleeding or bruising more easily than normal
- constipation

chest pain

- your voice gets deeper
- dizziness or fainting

(ipilimumab)

 changes in mood or behavior, such as decreased sex drive, irritability, or forgetfulness





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severe stomach-area (abdominal)

pain or tenderness

What is the most important information I should know about OPDIVO Qvantig? (continued)

Kidney problems – Things to look out for may include:

- decrease in your amount of urine • swelling of your ankles
- blood in your urine

Skin problems – Things to look out for may include:

- rash
- itching

- skin blistering or peeling swollen lymph nodes
- painful sores or ulcers in the mouth or nose, throat, or genital area
- fever and flu-like symptoms

loss of appetite

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 OPDIVO Qvantig.

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 eyesight
- Persistent or severe muscle pain or weakness, muscle cramps
- Low red blood cells or bruising

Rejection of a transplanted organ or tissue. Your healthcare provider should tell you what signs and symptoms you should report and monitor you depending on the type of organ transplant that you have had.

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 OPDIVO Qvantig. Your healthcare provider will monitor you for signs of complications if you have an allogeneic stem cell transplant.

What are the most common side effects of OPDIVO Qvantig?

The most common side effects of OPDIVO Qvantig when used alone in people with renal cell carcinoma include:

- pain in muscles, bones, and joints
- rash
- low thyroid hormone levels
- cough
- stomach area (abdominal) pain

 feeling tired itchy skin

- diarrhea
- The most common side effects observed with nivolumab given into the vein (intravenous nivolumab), which may be experienced with OPDIVO Qvantig, are shown below.

The most common side effects of intravenous nivolumab when used alone include:

- feeling tired or weak
- rash
- pain in muscles, bones, and joints
- itchy skin
- diarrhea
- nausea

- constipation decreased appetite
 - back pain

 weakness cough

shortness of breath

- upper respiratory tract infection
- fever
- headache
- stomach-area (abdominal) pain
- vomiting
- urinary tract infection

Please see Important Facts About OPDIVO + YERVOY on pages 18-20 and Important Facts About OPDIVO Qvantig on pages 21-25. Please see accompanying U.S. Full Prescribing Information and Medication Guide for OPDIVO. For more information, please see accompanying U.S. Full Prescribing Information and Medication Guide for YERVOY. For more information, please see the accompanying U.S. Full Prescribing Information and Medication Guide for OPDIVO Qvantig.

(nivolumab)



What are the most common side effects of OPDIVO Qvantig? (continued)

The most common side effects of intravenous nivolumab when used in combination with cabozantinib as the first treatment for advanced RCC include:

- diarrhea
- feeling tired
- liver problems. See "What is the most important information I should know about OPDIVO Qvantig?"
- rash, redness, pain, swelling, or blisters on the palms of your hands or soles of your feet
- mouth sores
- rash
- high blood pressure
- low thyroid hormone levels
- pain in muscles, bones, and joints
- decreased appetite

• nausea

- change in sense of taste
- stomach area (abdominal) pain
- cough
- upper respiratory tract infection

The most common side effects of intravenous nivolumab when used in combination with platinum-containing chemotherapy and another chemotherapy medicine before having surgery for NSCLC include:

• nausea

constipation

- feeling tired
- decreased appetite

• rash

The most common side effects of intravenous nivolumab when used in combination with cisplatin and gemcitabine to treat urothelial cancer include:

- nausea
- feeling tired
- pain in muscles, bones, and joints
- decreased appetite
 rash

constipation

- vomiting
 - numbness, pain, tingling, or burning in your hands or feet

The most common side effects of intravenous nivolumab when used in combination with fluoropyrimidine and platinum-containing chemotherapy to treat esophageal cancer and gastric cancer include:

- nausea
- numbness, pain, tingling, or burning in your hands or feet
- decreased appetite

- feeling tired
- constipation
- mouth sores
- diarrhea

- vomiting
- stomach area (abdominal) pain
- pain in muscles, bones, and joints

These are not all of the possible side effects of OPDIVO Qvantig.

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







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

Talk to your healthcare team 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, including corneal transplant
- have received or plan to receive a stem cell transplant that uses donor stem cells (allogeneic)
- have received radiation treatment to your chest area in the past and have received other medicines that are like OPDIVO Qvantig
- have a condition that affects your nervous system, such as myasthenia gravis or Guillain-Barré syndrome

Talk to your healthcare team about all the medicines you are taking, including:

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

These are not all the topics you should discuss with your healthcare team. Talk to your healthcare team about anything you might be unsure of before starting treatment.

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. OPDIVO Qvantig can harm your unborn baby.

If you are able to become pregnant, your healthcare provider should do a pregnancy test **before** you start receiving OPDIVO Qvantig.

You should use an effective method of birth control **during your treatment and for 5 months after** your last dose of OPDIVO Qvantig. Talk to your healthcare provider about birth control methods that you can use during this time.

Call your healthcare provider right away if you become pregnant or think you may be pregnant during treatment
with OPDIVO Qvantig.

You are breastfeeding or plan to breastfeed: It is not known if OPDIVO Qvantig passes into your breast milk. Do not breastfeed during treatment and for 5 months after your last dose of OPDIVO Qvantig.

How will I receive OPDIVO Qvantig?

OPDIVO Qvantig is given as an injection under the skin by your healthcare provider. An injection under the skin is sometimes called a **subcutaneous injection**. The injection is usually given in the stomach area (abdomen) or thigh, over about 3-5 minutes.





How will I receive OPDIVO Qvantig? (continued)

There are 3 parts to an **OPDIVO Qvantig** appointment:

Before your injection:

Your healthcare provider will do blood tests to check you for side effects.

Your healthcare provider may delay or stop treatment with OPDIVO Qvantig, if you have severe side effects.

Receiving your injection:

Injection time is **3-5 minutes**, though actual time in the clinic may vary.

After your injection:



igvee Your healthcare provider may monitor you for side effects after your injection.

For a type of kidney cancer called advanced renal cell carcinoma, your healthcare provider may also prescribe you cabozantinib. Take cabozantinib exactly as your healthcare provider tells you.



OPDIVO Qvantig is usually given every 2, 3, or 4 weeks, depending on the dose you are receiving. Your healthcare provider will decide how many treatments you need.

What should I do if I miss an appointment?

Call your healthcare provider right away to reschedule your appointment.







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	Nurse
Phone number	Phone number
Email address	Email address
Primary Care Physician	Health Insurance Provider
Phone number	
Email address	
Caregiver	
Phone number	
Email address	

OPDIVO (10 mg/mL) and YERVOY (5 mg/mL) are injections for intravenous use.

Ull Bristol Myers Squibb

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