

MEDICATION GUIDE
OPDIVO QVANTIG™ (op-DEE-voh cue-VAN-tig)
(nivolumab and hyaluronidase-nvhy)
injection, for subcutaneous use

Read this Medication Guide before you start receiving OPDIVO QVANTIG and before each injection. There may be new information. If your healthcare provider prescribes OPDIVO QVANTIG in combination with cabozantinib, also read the Patient Information that comes with cabozantinib. This Medication Guide does not take the place of talking with your healthcare provider about your medical condition or your treatment.

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. 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 QVANTIG is used in combination with another therapy.

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

Lung problems.

- cough
- shortness of breath
- chest pain

Intestinal problems.

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

Liver problems.

- yellowing of your skin or the whites of your eyes
- severe nausea or vomiting
- pain on the right side of your stomach area (abdomen)
- dark urine (tea colored)
- bleeding or bruising more easily than normal

Hormone gland problems.

- 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.

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

Skin problems.

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

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, 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 or tissue transplant that you have had.

Getting medical treatment right away may help keep these problems from becoming more serious. Your healthcare provider will check you for these problems during treatment with OPDIVO QVANTIG. Your healthcare provider may treat

you with corticosteroid or hormone replacement medicines. Your healthcare provider may also need to delay or completely stop treatment with OPDIVO QVANTIG, if you have severe side effects.

What is OPDIVO QVANTIG?

OPDIVO QVANTIG is a prescription medicine used to treat adults with:

- **a type of kidney cancer that has spread called advanced renal cell carcinoma (RCC).**
 - OPDIVO QVANTIG may be used alone as a first treatment in certain people with advanced RCC, after completing combination treatment with nivolumab given into the vein (intravenous nivolumab) and ipilimumab.
 - OPDIVO QVANTIG may be used in combination with cabozantinib as your first treatment for advanced RCC.
 - OPDIVO QVANTIG may be used alone when your cancer has spread after treatment with other cancer medicines.
- **a type of skin cancer called melanoma.**
 - OPDIVO QVANTIG may be used alone to treat melanoma that has spread or cannot be removed by surgery (advanced melanoma).
 - OPDIVO QVANTIG may be used alone to treat melanoma that has spread or cannot be removed by surgery (advanced melanoma), after completing combination treatment with intravenous nivolumab and ipilimumab.
 - OPDIVO QVANTIG may be used alone to help prevent Stage IIB, Stage IIC, Stage III, or Stage IV melanoma from coming back after it has been completely removed by surgery.
- **a type of lung cancer called non-small cell lung cancer (NSCLC).**
 - OPDIVO QVANTIG may be used in combination with chemotherapy that contains platinum and another chemotherapy medicine before you have surgery for early-stage NSCLC.
 - OPDIVO QVANTIG may be used in combination with chemotherapy that contains platinum and another chemotherapy medicine before you have surgery for early-stage NSCLC:
 - that does not have an abnormal EGFR or ALK gene, **and**
 - then OPDIVO QVANTIG may be continued alone after surgery to help prevent your lung cancer from coming back.
 - OPDIVO QVANTIG may be used alone when your lung cancer:
 - has spread, **and**
 - you have tried chemotherapy that contains platinum, and it did not work or is no longer working.
 - If your tumor has an abnormal EGFR or ALK gene, you should have also tried an FDA-approved therapy for tumors with these abnormal genes, **and** it did not work or is no longer working.
- **head and neck cancer (squamous cell carcinoma).**
 - OPDIVO QVANTIG may be used alone when your head and neck cancer:
 - has come back or spread, **and**
 - you have tried chemotherapy that contains platinum and it did not work or is no longer working.
- **cancer of the lining of the urinary tract (urothelial carcinoma).**
 - OPDIVO QVANTIG may be used alone to help prevent cancer of the urinary tract from coming back after it was removed by surgery.
 - OPDIVO QVANTIG may be used in combination with chemotherapy medicines cisplatin and gemcitabine as your first treatment when your urinary tract cancer has spread (metastatic) or cannot be removed by surgery.
 - OPDIVO QVANTIG may be used alone when your 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**
 - your cancer worsened within 12 months of treatment with chemotherapy that contains platinum, either before or after surgery to remove your cancer.
- **a type of colon or rectal cancer (colorectal cancer or CRC).**
 - OPDIVO QVANTIG may be used alone and after completing combination treatment with intravenous nivolumab and ipilimumab, when your colon or rectal cancer:
 - has spread to other parts of the body (metastatic CRC), **and**
 - is microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR), **and**
 - you 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 you have previously received treatment with sorafenib and after completing combination treatment with intravenous nivolumab and ipilimumab.
- **cancer of the tube that connects your throat to your stomach (esophageal cancer).**
 - OPDIVO QVANTIG may be used alone to help prevent your 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 that contains fluoropyrimidine and platinum as your first treatment when your esophageal cancer:
 - is a type called squamous cell carcinoma, **and**
 - cannot be removed with surgery, or has spread, **and**
 - your tumors are positive for PD-L1.
- OPDIVO QVANTIG may be used alone when your esophageal cancer:
 - is a type called squamous cell carcinoma, **and**
 - cannot be removed with surgery, and has come back or spread, **and**
 - 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 QVANTIG may be used in combination with chemotherapy that contains fluoropyrimidine and platinum when your gastric, gastroesophageal junction, or esophageal cancer:
 - cannot be removed with surgery, or has spread, **and**
 - your tumors are positive for PD-L1.

It is not known if OPDIVO QVANTIG is safe and effective in children.

Before receiving OPDIVO QVANTIG, tell your healthcare provider about all of your medical conditions, including if you:

- have immune system problems such as Crohn's disease, ulcerative colitis, or lupus
- have received an organ transplant, 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
- have a condition that affects your nervous system, such as myasthenia gravis or Guillain-Barré syndrome
- are pregnant or plan to become pregnant. OPDIVO QVANTIG can harm your unborn baby.

Females who 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 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.
- Tell your healthcare provider right away if you become pregnant or think you may be pregnant during treatment with OPDIVO QVANTIG.
- 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.

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

How will I receive OPDIVO QVANTIG?

- Your healthcare provider will give you OPDIVO QVANTIG as an injection under the skin, in the stomach area (abdomen) or thigh, over about 3 to 5 minutes.
- 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 will receive.
- Your healthcare provider will do blood tests to check you for side effects.
- 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.
- If you miss any appointments, call your healthcare provider as soon as possible to reschedule your appointment.

What are the possible side effects of OPDIVO QVANTIG?

OPDIVO QVANTIG can cause serious side effects, including:

- **See “What is the most important information I should know about OPDIVO QVANTIG?”**
- **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 QVANTIG. Your healthcare provider will monitor you for signs of complications if you have an allogeneic stem cell transplant.

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

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|--------------------------------------|---------------------------------|
| • pain in muscles, bones, and joints | • low thyroid hormone levels |
| • feeling tired | • diarrhea |
| • itchy skin | • cough |
| • rash | • stomach-area (abdominal) pain |

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

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

- | | | |
|--|--------------------------------------|-------------------------------------|
| • diarrhea | • mouth sores | • nausea |
| • feeling tired | • rash | • change in the sense of taste |
| • liver problems. See “What is the most important information I should know about OPDIVO QVANTIG?” | • high blood pressure | • stomach-area (abdominal) pain |
| | • low thyroid hormone levels | • cough |
| • rash, redness, pain, swelling or blisters on the palms of your hands or soles of your feet | • pain in muscles, bones, and joints | • upper respiratory tract infection |
| | • decreased appetite | |

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 | • feeling tired | • rash |
| • constipation | • decreased appetite | |

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

- | | | |
|--------------------------------------|----------------------|--|
| • nausea | • constipation | • vomiting |
| • feeling tired | • decreased appetite | • numbness, pain, tingling or burning in your hands and feet |
| • pain in muscles, bones, and joints | • rash | |

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 | • feeling tired | • vomiting |
| • numbness, pain, tingling, or burning in your hands or feet | • constipation | • stomach-area (abdominal) pain |
| • decreased appetite | • mouth sores | • pain in muscles, bones, and joints |
| | • diarrhea | |

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

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

General information about the safe and effective use of OPDIVO QVANTIG.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. You can ask your pharmacist or healthcare provider for information about OPDIVO QVANTIG that is written for health professionals.

What are the ingredients in OPDIVO QVANTIG?

Active ingredients: nivolumab and hyaluronidase-nvhy

Inactive ingredients: histidine, histidine hydrochloride monohydrate, methionine, pentetic acid, polysorbate 80, sucrose, and Water for Injection.

Manufactured by: Bristol-Myers Squibb Company, Princeton, NJ 08543 USA U.S. License No. 1713

Halozyme Therapeutics, Inc., 12390 El Camino Real, San Diego, CA 92130, U.S. License No. 2187

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For more information, call 1-855-673-4861 or go to www.Qvantig.com.

This Medication Guide has been approved by the U.S. Food and Drug Administration.

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