OPDIVO QVANTIG™ COULD BE YOUR ANSWER TO FASTER* TREATMENT

FOR MORE ANSWERS, SEE FREQUENTLY ASKED QUESTIONS AND INFORMATION BELOW

Is OPDIVO Qvantig right for me?

It's important to talk to your doctor to discuss the most appropriate treatment for you. OPDIVO Qvantig (nivolumab and hyaluronidase-nvhy) is FDA-approved, and may be an alternative option to intravenous (IV) OPDIVO® (nivolumab) for certain patients. It is given through a subcutaneous (under-the-skin) injection. OPDIVO Qvantig received by injection could be an option for people who are on OPDIVO® treatment by itself (monotherapy). OPDIVO Qvantig could also be an option for people who are on OPDIVO® in combination with cabozantinib or chemotherapy. OPDIVO Qvantig cannot be prescribed in combination with YERVOY® (ipilimumab).

OPDIVO Qvantig is not approved for all the indications of OPDIVO® IV. Please see Full Prescribing Information for the list of indications. Please see the full list of indications for OPDIVO Qvantig on pages 5 and 6. Please see the full list of indications for OPDIVO® IV on pages 10 and 11.

What does it mean to get a subcutaneous injection?

When you receive OPDIVO Qvantig, it is injected subcutaneously under the skin in your stomach area (abdomen) or thigh area instead of into a vein. The injection will be given by a healthcare professional over a period of 3-5 minutes.*

While you might think of an injection as a "shot" like a flu shot, an injection to administer OPDIVO Qvantig is a bit different. It is given more gradually (in 3-5 minutes*) than an injection would be given for a flu shot or other type of vaccine.

What might be different if I switch from OPDIVO® IV to OPDIVO Qvantig?

With OPDIVO Qvantig, you could avoid needing access to a vein for your treatment, since OPDIVO Qvantig is injected under the skin. OPDIVO Qvantig includes a natural enzyme (hyaluronidase) which improves the way medicines are absorbed into the body when injected under the skin. Another difference is that the OPDIVO Qvantig injection takes 3-5 minutes* compared to about 30 minutes for OPDIVO® IV, so you will be finished with the administration faster.* For most people, the frequency of appointments will be the same. For example, if you currently receive an infusion of OPDIVO® IV every 4 weeks, you will most likely receive your injection with OPDIVO Qvantig every 4 weeks. Talk to your doctor to see if OPDIVO Qvantig is right for you.

Summary of Warnings and Precautions

OPDIVO QVANTIG, 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; 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. OPDIVO® is associated with severe infusion reactions.

*A 3-5 minute injection time of OPDIVO Qvantig compared to a 30-minute infusion time of OPDIVO®. This does not account for all aspects of treatment. Does not include observation time. Actual clinic time may vary.

Please see Important Facts about OPDIVO Qvantig, including serious side effects on pages 5-9, and Important Facts about OPDIVO®, including serious side effects on pages 10-13.

OPDIVO Qvantig™
nivolumab + hyaluronidase-nvhy
SUBCUTANEOUS INJECTION | 120 mg + 2,000 units / mL

FREQUENTLY ASKED QUESTIONS, AND INFORMATION, CONTINUED

Does OPDIVO Qvantig work as well as OPDIVO® IV?

Yes, a study of 495 people with advanced kidney cancer compared OPDIVO Qvantig and OPDIVO® IV by measuring the amount of medicine in the bloodstream. The results showed that there were no major differences in the amount of medicine that went into the bloodstream between OPDIVO Qvantig and OPDIVO® IV.

The active ingredient in OPDIVO Qvantig is the same as the active ingredient in OPDIVO® IV. OPDIVO Qvantig also includes a natural enzyme (hyaluronidase) which helps medicines absorb into the body when injected under the skin.

What if I've already started on OPDIVO® IV treatment? Can I switch?

Your doctor can help you decide at any time during your treatment if you can switch to OPDIVO Qvantig from OPDIVO® IV. You and your doctor can work together to decide if OPDIVO Qvantig may be right for you.

What can I expect at my appointment?

Your appointment will be similar to an OPDIVO® IV appointment. Depending on decisions that you and your healthcare team have made about your treatment plan, your OPDIVO Qvantig appointment will generally have a few parts.

Before your injection: Your healthcare team will do blood tests to check you for side effects

Receiving your injection: Injection time is 3-5 minutes,* though actual time in the clinic may vary

After your injection: Your healthcare team may monitor you for side effects

The time between treatments will vary from 2-4 weeks. Your healthcare team will decide the time between doses and how many treatments you will receive.

Summary of Warnings and Precautions

OPDIVO QVANTIG, 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; 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. OPDIVO® is associated with severe infusion reactions.

*A 3-5 minute injection time of OPDIVO Qvantig compared to a 30-minute infusion time of OPDIVO®. This does not account for all aspects of treatment. Does not include observation time. Actual clinic time may vary.

Please see Important Facts about OPDIVO Qvantig, including serious side effects on pages 5-9, and Important Facts about OPDIVO®, including serious side effects on pages 10-13.

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FREQUENTLY ASKED QUESTIONS, AND INFORMATION, CONTINUED

What should I wear to my appointment for my injection of OPDIVO Qvantig?

It'll be best for you and your healthcare team if you wear loose-fitting clothing and are comfortable. That way, your healthcare team can easily access your stomach area (abdomen) or thigh area to administer your injection. You may want to wear a large T-shirt, shorts, sweatpants, or something similar.

Will I need a port for treatment with OPDIVO Qvantig?

No, you will not need a port for OPDIVO Qvantig, since it is received by injection under the skin and not by infusion. However, if there are additional medications that you will receive (for example, chemotherapy), you may still need a port for those. Talk to your doctor for more details based on your individual treatment plan.

What kind of side effects are possible?

OPDIVO Qvantig can cause problems that can sometimes become severe or can lead to death. Serious side effects may include lung problems; intestinal problems; liver problems; hormone gland problems; kidney problems; skin problems; problems in other organs and tissues; and complications of stem cell transplant that uses donor stem cells (allogeneic). Call or see your healthcare provider right away for any new or worsening signs or symptoms. Please see the "Important Facts" section on pages 5-9 for additional information.

If I have side effects, when should I report them to my doctor?

Tell your doctor immediately about all side effects, including any changes in how you are feeling, so your doctor can help you address them right away. It's a good idea to keep a journal to write down anything unusual, and to help you and your doctor discuss potential symptoms of side effects. This side effects tracker may help. MedWatch can help you learn more about side effects and how to report them.

Summary of Warnings and Precautions

OPDIVO QVANTIG, 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; 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. OPDIVO® is associated with severe infusion reactions.

Please see Important Facts about OPDIVO Qvantig, including serious side effects on pages 5-9, and Important Facts about OPDIVO®, including serious side effects on pages 10-13.

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FREQUENTLY ASKED QUESTIONS, AND INFORMATION, CONTINUED

What are some questions I can ask my doctor?

- Is OPDIVO Qvantig approved for my type of cancer?
- Will I receive this treatment at an infusion center or a different location?
- How should I prepare for my injection appointment?
- How often will I receive treatment?
- Will this treatment affect my daily life in any way?
- How do I know if the treatment is working?
- What are potential side effects that I may experience?

Will my insurance cover switching treatments? What should I do next?

Please follow up with your insurance company about your coverage for OPDIVO Qvantig injections.

BMS Access Support® is committed to helping you access your prescribed BMS medications. We offer coverage assistance to support medication access as well as financial support options and educational resources to support you throughout your treatment journey. Upon your request, BMS Access Support® may be able to help you review your insurance benefits and understand your coverage for your medication. If your insurer requires prior authorization, BMS Access Support® may be able to provide you and your doctor information about this requirement.

To learn more, ask your doctor, visit **BMSAccessSupport**, or call BMS Access Support at **1-800-861-0048, 8 AM to 8 PM ET, Monday - Friday.**

Download **BMS Access Support brochure** for details.

ASK YOUR DOCTOR IF OPDIVO QVANTIG INJECTIONS COULD BE RIGHT FOR YOU

More questions about OPDIVO® IV? Click to visit Frequently Asked Questions about OPDIVO®

Summary of Warnings and Precautions

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Please see Important Facts about OPDIVO Qvantig, including serious side effects on pages 5-9, and Important Facts about OPDIVO®, including serious side effects on pages 10-13.

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nivolumab + hyaluronidase-nvhy
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Important Facts About OPDIVO Qvantig™
(nivolumab + hyaluronidase-nvhy)

This is a summary of important information that you need to know about OPDIVO Qvantig. 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 following icons as you read: Talk to your healthcare team | Call a healthcare provider right away | Helpful information to remember

What is OPDIVO Qvantig?

OPDIVO Qvantig is a prescription medicine given as a subcutaneous injection (under the skin) 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 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

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:

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

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**
- ✓ You 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

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

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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**
- ✓ You have received 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 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

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 has 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 QVANTIG 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.
- ✗ OPDIVO Qvantig may not be used in combination with ipilimumab.

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.

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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:

- 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 of your ankles
- loss of appetite

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

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

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nivolumab + hyaluronidase-nvhy
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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**
- **constipation**
- **decreased appetite**
- **rash**
- **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 your healthcare team for more information about side effects. 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**.

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.

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SUBCUTANEOUS INJECTION | 120 mg + 2,000 units / mL

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.

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:

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.

For more information, please see the U.S. Full Prescribing Information and Medication Guide for OPDIVO Qvantig. Talk to your healthcare provider for more information about this medication.

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nivolumab + hyaluronidase-nvhy
SUBCUTANEOUS INJECTION | 120 mg + 2,000 units / mL

Important Facts About OPDIVO® (nivolumab)

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 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).

Adults who have a type of **advanced stage lung cancer called non-small cell lung cancer (NSCLC)**.

OPDIVO is approved for adults when:

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

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 **kidney cancer (renal cell carcinoma)**:

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** when:

- ✓ Your 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**
- ✓ You 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:

- ✓ You 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 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.

OPDIVO is approved for adults when:

- ✓ Your urinary tract cancer 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.

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

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 the 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 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 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 your advanced or metastatic esophageal cancer.

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, **AND**
- ✓ Your cancer has come back or spread to other parts of the body (metastatic) after you have received chemotherapy that contains fluoropyrimidine and platinum.

OPDIVO alone is approved for adults whose esophageal cancer has come back or spread to other parts of the body after you have treatment with 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**
- ✓ You 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)**, and in adults with
- ✓ **Esophageal adenocarcinoma**.

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

- ✓ Your tumors are positive for PD-L1, **AND**
- ✓ Your cancer cannot be removed with surgery, **OR**
- ✓ Your cancer has spread to other parts of the 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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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. 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?

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
- 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 of your ankles
- loss of appetite

Skin problems – Things to look out for may include:

- rash
- itching
- skin blistering or peeling
- swollen lymph nodes
- painful sore 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 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

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?

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
- itching or rash
- flushing
- shortness of breath or wheezing
- 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.

Complications 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. Your healthcare provider will monitor you for these complications.

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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**
- **itching**
- **diarrhea**
- **nausea**
- **weakness**
- **cough**
- **shortness of breath**
- **constipation**
- **decreased appetite**
- **back pain**
- **upper respiratory tract infection**
- **fever**
- **headache**
- **stomach-area (abdominal) pain**
- **vomiting**
- **urinary tract infection**

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

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

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

- **diarrhea**
- **feeling tired or weak**
- **liver problems**
- **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 the sense of taste**
- **stomach-area (abdominal) pain**
- **cough**
- **upper respiratory tract infection**

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**
- **constipation**
- **mouth sores**
- **diarrhea**
- **vomiting**
- **stomach-area (abdominal) pain**
- **pain in muscles, bones, and joints**

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 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 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 and for 5 months after your 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 5 months after your 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.

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