Patient Pocket Guide

A guide to identify signs and symptoms of potential side effects while on immunotherapy, including immune-mediated side effects



Detach the wallet card and keep on your person at all times

■ Fill out the treating oncologist's contact information



Read the information inside and use the Signs and Symptoms Checklist to recognize what to report immediately

- Call your treating oncologist right away if you experience anything unusual while on OPDIVO®, YERVOY®, Opdualag™, or OPDIVO Qvantig™
- Contact your oncologist immediately if you experience any symptoms listed on this Signs and Symptoms Checklist, or they get worse. Getting medical treatment right away may keep the problem from becoming more serious



Show this wallet card during any visits outside of your healthcare network

■ Tell the urgent care/emergency room staff that you are being treated with OPDIVO, YERVOY, Opdualag, or OPDIVO Qvantig and show them the important information for Doctors/Nurses section of this wallet card

Please see Important Safety Information for OPDIVO, YERVOY, Opdualag, or OPDIVO Qvantig on pages <u>11–19</u>, a full listing of indications on pages <u>5–10</u>, and the U.S. Full Prescribing Information and Medication Guide for <u>OPDIVO</u>, <u>YERVOY</u>, <u>Opdualag</u>, and <u>OPDIVO</u> <u>Ovantig</u>.

Please check the box to indicate which immunotherapy the patient is receiving.











Detach the wallet card and keep on your person at all times

- Fill out name of immunotherapy drug(s) prescribed by oncologist
- · Fill out patient name
- Fill out name and phone number of oncologist
- Keep card in patient's wallet

Be sure to tell all healthcare providers you visit that you are being treated with immunotherapy and SHOW THEM THIS CARD.

Show this wallet card during any urgent care/emergency room visit.













Please see Important Safety Information for OPDIVO®, YERVOY®, Opdualag™, and OPDIVO Qvantig™ on pages <u>11–19</u>, and the U.S. Full Prescribing Information and Medication Guide for <u>OPDIVO</u>, <u>YERVOY</u>, <u>Opdualag</u>, and <u>OPDIVO Ovantig</u>.

Keep this quide handy for your reference. This quide includes a helpful checklist of Signs and Symptoms for you to closely monitor. Call your Oncology Care Team if you have any of these signs or symptoms, or if they get worse.

These are not all of the possible side effects of OPDIVO® (nivolumab), YERVOY® (ipilimumab), Opdualag™ (nivolumab and relatlimab-rmbw), or OPDIVO Qvantig™ (nivolumab and hyaluronidase-nvhy). This is why you need to report any discomfort or changes in the way you are feeling to your Oncology Care Team.



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



- yellowing of your skin or the whites of vour eves
- 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



- 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



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, YERVOY, Opdualag or 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

YERVOY may be associated with eye problems with signs and symptoms that include blurry vision, double vision or other vision problems and eve pain or redness.



Hormone Glands

- headaches that will not go away or unusual headaches
- eve sensitivity to light
- eve problems
- ranid heartheat
- 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



- cough
- chest pain
- shortness of breath



Kidnevs

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



Severe Infusion-Related

Reactions

shortness of breath or wheezing

chills or shaking

feel like passing out

back or neck pain

itching or rash

flushing

dizziness

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

Do not treat symptoms yourself

Symptoms may occur anytime during treatment or even after your treatment has ended

Do not feel embarrassed or that you are bothering your oncologist

Complications, including graft-versus-host disease (GVHD), of bone marrow (stem cell) transplant that uses donor stem cells (allogeneic). These complications can be severe and can lead to death. These complications may happen if you underwent transplantation either before or after being treated with OPDIVO, YERVOY, Opdualag, or OPDIVO Qvantig. Your healthcare provider will monitor you for these complications.

Please see Important Safety Information for OPDIVO, YERVOY, Opdualag, and OPDIVO Ovantiq on pages <u>11-19</u>, and the U.S. Full Prescribing Information and Medication Guide for OPDIVO, YERVOY, Opdualag, and OPDIVO Ovantig.

Important Safety Information

OPDIVO® (nivolumab), YERVOY® (ipilimumab), Opdualag™ (nivolumab and relatlimab-rmbw) and OPDIVO Qvantig™ (nivolumab and hyaluronidase-nvhy) are medicines that may treat certain cancers by working with your immune system. OPDIVO, YERVOY, Opdualag 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 life-threatening and 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 is used in combination with YERVOY or another therapy. YERVOY can cause serious side effects in many parts of your body which can lead to death. These problems may happen anytime during treatment with YERVOY or after you have completed treatment.

OPDIVO® (nivolumab) and OPDIVO® + YERVOY® (ipilimumab) Indications



OPDIVO® (nivolumab) is a prescription medicine used to treat adults and children 12 years of age or older with a type of skin cancer called melanoma that has spread or cannot be removed by surgery (advanced melanoma).



OPDIVO® (nivolumab) is a prescription medicine used in combination with YERVOY® (ipilimumab) to treat adults and children 12 years of age or older with a type of skin cancer called melanoma that has spread or cannot be removed by surgery (advanced melanoma).



OPDIVO® (nivolumab) is a prescription medicine used to treat a kind of skin cancer called melanoma. It may be used alone in adults and children 12 years and older with Stage IIB, Stage IIC, Stage III or Stage IV melanoma to help prevent melanoma from coming back after it has been completely removed by surgery.



OPDIVO® (nivolumab) is a prescription medicine used in combination with chemotherapy that contains platinum and another chemotherapy medicine, before you have surgery, for adults with early-stage lung cancer (called non-small cell lung cancer).



OPDIVO® (nivolumab) is a prescription medicine used in combination with chemotherapy that contains platinum and another chemotherapy medicine, before you have surgery, for adults with early stage lung cancer (called non-small cell lung cancer) that does not have an abnormal EGFR or ALK gene and then may be continued alone after surgery to help prevent your lung cancer from coming back.



OPDIVO® (nivolumab) is a prescription medicine used in combination with YERVOY® (ipilimumab) as a first treatment for adults with a type of advanced stage lung cancer (called non-small cell lung cancer) when your lung cancer has spread to other parts of your body (metastatic) **and** your tumors are positive for PD-L1, but do not have an abnormal EGFR or ALK gene.



OPDIVO® (nivolumab) is a prescription medicine used in combination with YERVOY® (ipilimumab) and 2 cycles of chemotherapy that contains platinum and another chemotherapy medicine, as a first treatment for adults with a type of advanced stage lung cancer (called non-small cell lung cancer) when your lung cancer has spread or comes back, **and** your tumor does not have an abnormal EGFR or ALK gene.



OPDIVO® (nivolumab) is a prescription medicine used to treat adults with a type of advanced stage lung cancer (called non-small cell lung cancer) that has spread **and** you have received 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 received an EGFR or ALK inhibitor medicine and it did not work or is no longer working.



OPDIVO® (nivolumab) is a prescription medicine used in combination with YERVOY® (ipilimumab) as a first treatment for adults with a type of cancer that affects the lining of the lungs and chest wall called malignant pleural mesothelioma which cannot be removed by surgery.



OPDIVO® (nivolumab) is a prescription medicine used in combination with YERVOY® (ipilimumab) as a first treatment for certain adults with kidney cancer that has spread (advanced renal cell carcinoma).



OPDIVO® (nivolumab) is a prescription medicine used in combination with cabozantinib as a first treatment for adults with kidney cancer that has spread (advanced renal cell carcinoma). Please read the Patient Information that comes with cabozantinib.



OPDIVO® (nivolumab) is a prescription medicine used to treat people with kidney cancer (renal cell carcinoma) when your cancer has spread after treatment with other cancer medications.



OPDIVO® (nivolumab) is a prescription medicine used to treat people with head and neck cancer (squamous cell carcinoma) that has come back or spread **and** you have received chemotherapy that contains platinum and it did not work or is no longer working.



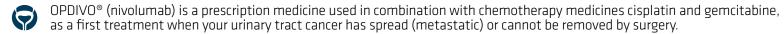
OPDIVO® (nivolumab) is a prescription medicine used to treat adults with cancer of the lining of the urinary tract (including the bladder, urethra, ureters, or renal pelvis) [urothelial carcinoma] when it has spread (locally advanced or metastatic) and you have received chemotherapy that contains platinum, 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 your cancer.

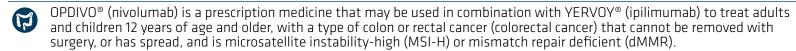


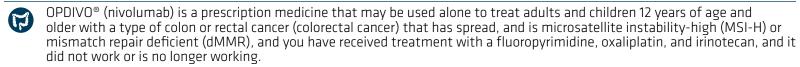
OPDIVO® (nivolumab) is a prescription medicine used to treat adults with cancer of the lining of the urinary tract (including the bladder, ureters, or renal pelvis) [urothelial carcinoma] to help prevent cancer of the urinary tract from coming back after it was removed by surgery.

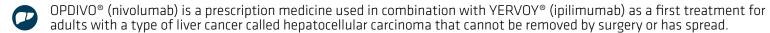
Please see Important Safety Information for OPDIVO, YERVOY, Opdualag, and OPDIVO Qvantig on pages <u>11-19</u>, and the U.S. Full Prescribing Information and Medication Guide for <u>OPDIVO</u>, <u>YERVOY</u>, <u>Opdualag</u>, and <u>OPDIVO</u> <u>Ovantig</u>.

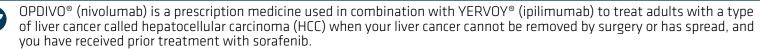
OPDIVO® (nivolumab) and OPDIVO® + YERVOY® (ipilimumab) Indications (cont'd)











- OPDIVO® (nivolumab) is a prescription medicine used to treat adults with cancer of the tube that connects your throat to your stomach (esophageal cancer) if your esophageal cancer is a type called squamous cell carcinoma, and cannot be removed with surgery, **and** has come back or spread after you have received chemotherapy that contains fluoropyrimidine and platinum.
- OPDIVO® (nivolumab) is a prescription medicine that may be used in adults to help prevent cancer of the tube that connects your throat to your stomach (esophageal cancer) or cancer where the esophagus joins the stomach (gastroesophageal junction cancer) from coming back after it 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® (nivolumab) is a prescription medicine used in combination with chemotherapy that contains fluoropyrimidine and platinum as a first treatment to treat adults with cancer of the tube that connects your throat to your stomach (esophageal cancer) when your 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® (nivolumab) is a prescription medicine used in combination with YERVOY® (ipilimumab) as a first treatment to treat adults with cancer of the tube that connects your throat to your stomach (esophageal cancer) when your cancer is a type called squamous cell carcinoma **and** cannot be removed with surgery (advanced) or has spread, **and** your tumors are positive for PD-L1.

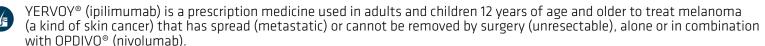


OPDIVO® (nivolumab) is a prescription medicine used in combination with chemotherapy that contains fluoropyrimidine and platinum to treat adults with cancer of the stomach (gastric cancer), cancer where the esophagus joins the stomach (gastroesophageal junction cancer), and with esophageal adenocarcinoma when your cancer cannot be removed with surgery or has spread, **and** your tumors are positive for PD-L1.

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.

YERVOY® (ipilimumab) Indications





YERVOY® (ipilimumab) is a prescription medicine used in adults to help prevent melanoma (a kind of skin cancer) from coming back after it and lymph nodes that contain cancer have been removed by surgery.

It is not known if YERVOY is safe and effective in children younger than 12 years of age.

Opdualag™ (nivolumab and relatlimab-rmbw) Indication



Opdualag™ (nivolumab and relatlimab-rmbw) is a prescription medicine used to treat adults and children 12 years of age or older with a type of skin cancer called melanoma that has spread or cannot be removed by surgery (advanced melanoma). It is not known if Opdualag is safe and effective when used in children younger than 12 years of age or older who weigh less than 88 pounds (40 kg), or in children younger than 12 years of age.

OPDIVO Qvantig™ (nivolumab and hyaluronidase-nvhy) Indications



OPDIVO Qvantig™ (nivolumab and hyaluronidase-nvhy) is a prescription medicine used alone as a first treatment for certain adults with kidney cancer that has spread (advanced renal cell carcinoma), after completing combination treatment with intravenous nivolumab and ipilimumab.

Please see Important Safety Information for OPDIVO, YERVOY, Opdualag, and OPDIVO Qvantig on pages <u>11-19</u>, and the U.S. Full Prescribing Information and Medication Guide for <u>OPDIVO</u>, <u>YERVOY</u>, <u>Opdualag</u>, and <u>OPDIVO Ovantia</u>.

OPDIVO Qvantig™ (nivolumab and hyaluronidase-nvhy) Indications (cont'd)

- OPDIVO Qvantig™ (nivolumab and hyaluronidase-nvhy) is a prescription medicine used in combination with cabozantinib as a first treatment for adults with kidney cancer that has spread (advanced renal cell carcinoma). Please read the Patient Information that comes with cabozantinib.
- OPDIVO Qvantig™ (nivolumab and hyaluronidase-nvhy) is a prescription medicine used to treat adults with kidney cancer (renal cell carcinoma) when your cancer has spread after treatment with other cancer medications.
- OPDIVO Qvantig™ (nivolumab and hyaluronidase-nvhy) is a prescription medicine used alone to treat adults with a type of skin cancer called melanoma that has spread or cannot be removed by surgery (advanced melanoma).
- OPDIVO Qvantig™ (nivolumab and hyaluronidase-nvhy) is a prescription medicine used alone to treat adults with a type of skin cancer called melanoma that has spread or cannot be removed by surgery (advanced melanoma), after completing combination treatment with intravenous nivolumab and ipilimumab.
- OPDIVO Qvantig™ (nivolumab and hyaluronidase-nvhy) is a prescription medicine used to treat a kind of skin cancer called melanoma. It may be used alone in adults with Stage IIB, Stage IIC, Stage III or Stage IV melanoma to help prevent melanoma from coming back after it has been completely removed by surgery.
- OPDIVO Qvantig™ (nivolumab and hyaluronidase-nvhy) is a prescription medicine used in combination with chemotherapy that contains platinum and another chemotherapy medicine, before you have surgery, for adults with early-stage lung cancer (called non-small cell lung cancer).
- OPDIVO Qvantig™ (nivolumab and hyaluronidase-nvhy) is a prescription medicine used in combination with chemotherapy that contains platinum and another chemotherapy medicine, before you have surgery, for adults with early stage lung cancer (called non-small cell lung cancer) that does not have an abnormal EGFR or ALK gene and then may be continued alone after surgery to help prevent your lung cancer from coming back.
- OPDIVO Qvantig™ (nivolumab and hyaluronidase-nvhy) is a prescription medicine used alone to treat adults with a type of advanced stage lung cancer (called non-small cell lung cancer) that has spread and you have received 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 received an FDA-approved therapy for tumors with these abnormal genes, and it did not work or is no longer working.
- OPDIVO Qvantig™ (nivolumab and hyaluronidase-nvhy) is a prescription medicine used alone to treat adults with head and neck cancer (squamous cell carcinoma) that has come back or spread and you have received chemotherapy that contains platinum and it did not work or is no longer working.

- OPDIVO Qvantig™ (nivolumab and hyaluronidase-nvhy) is a prescription medicine used alone to treat adults with cancer of the lining of the urinary tract (including the bladder, ureters, or renal pelvis) [urothelial carcinoma] to help prevent cancer of the urinary tract from coming back after it was removed by surgery.
- OPDIVO Qvantig™ (nivolumab and hyaluronidase-nvhy) is a prescription medicine used in combination with chemotherapy medicines cisplatin and gemcitabine, as a first treatment for adults whose urinary tract cancer has spread (metastatic) or cannot be removed by surgery.
- OPDIVO Qvantig™ (nivolumab and hyaluronidase-nvhy) is a prescription medicine used alone to treat adults with cancer of the lining of the urinary tract (including the bladder, urethra, ureters, or renal pelvis) [urothelial carcinoma] when it 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 your cancer.
- OPDIVO Qvantig™ (nivolumab and hyaluronidase-nvhy) is a prescription medicine used alone in adults to help prevent cancer of the tube that connects your throat to your stomach (esophageal cancer) or cancer where the esophagus joins the stomach (gastroesophageal junction cancer) from coming back after it 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™ (nivolumab and hyaluronidase-nvhy) is a prescription medicine used in combination with chemotherapy that contains fluoropyrimidine and platinum as a first treatment to treat adults with cancer of the tube that connects your throat to your stomach (esophageal cancer) when your 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™ (nivolumab and hyaluronidase-nvhy) is a prescription medicine used alone to treat adults with cancer of the tube that connects your throat to your stomach (esophageal cancer) if your esophageal cancer is a type called squamous cell carcinoma, and cannot be removed with surgery, and has come back or spread after you have received chemotherapy that contains fluoropyrimidine and platinum.
- OPDIVO Qvantig™ (nivolumab and hyaluronidase-nvhy) is a prescription medicine used in combination with chemotherapy that contains fluoropyrimidine and platinum to treat adults with cancer of the stomach (gastric), junction between the stomach and esophagus (gastroesophageal junction), and esophagus that is a type called esophageal adenocarcinoma and cannot be removed with surgery or has spread and your tumors are positive for PD-L1.

 It is not known if OPDIVO Qvantig™ (nivolumab and hyaluronidase-nvhy) is safe and effective in children.

Please see Important Safety Information for OPDIVO®, YERVOY®, Opdualag™, and OPDIVO Qvantig on pages <u>11-19</u>, and the U.S. Full Prescribing Information and Medication Guide for <u>OPDIVO</u>, <u>YERVOY</u>, <u>Opdualag</u>, and <u>OPDIVO Qvantig</u>.

Important Safety Information for OPDIVO® (nivolumab), YERVOY® (ipilimumab), and OPDIVO + YERVOY

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. These problems can sometimes become severe or life-threatening and 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 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 stomacharea (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 in your ankles; loss of appetite
- Skin problems: rash; itching; skin blistering or peeling; swollen lymph nodes; painful sores or ulcers in the mouth or nose, throat, or genital area; fever or flu-like symptoms
- **Eye problems:** blurry vision, double vision, or other vision problems; eye pain or redness.

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 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.

Getting medical help right away may help 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. Your healthcare team may also need to delay or completely stop your treatment if you have severe side effects.

Possible side effects of OPDIVO + YERVOY OPDIVO and OPDIVO + YERVOY can cause serious side effects, including:

- See "What is the most important information I should know about OPDIVO + YERVOY?"
- Severe infusion reactions. Tell your healthcare team right away if you get these symptoms during an infusion of OPDIVO or YERVOY: chills or shaking; itching or rash; flushing; shortness of breath or wheezing; dizziness; feel like passing out; fever; back or neck pain
- 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.

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; and urinary tract infection

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

The most common side effects of OPDIVO, when used in combination with YERVOY and a platinum-containing chemotherapy and another chemotherapy, include: feeling tired; pain in muscles, bones, and joints; nausea; diarrhea; rash; decreased appetite; constipation; and itching.

Please see Important Safety Information for <u>OPDIVO</u>, <u>YERVOY</u>, <u>Opdualag</u>™, and <u>OPDIVO Qvantig</u>™ continued on the following page.

11

Important Safety Information for OPDIVO® (nivolumab), YERVOY® (ipilimumab), and OPDIVO + YERVOY (continued)

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; and pain in muscles, bones, and joints.

The most common side effects of YERVOY include: feeling tired; diarrhea; nausea; itching; rash; vomiting; headache; weight loss; fever; decreased appetite; difficulty falling or staying asleep.

These are not all the possible side effects. For more information, ask your healthcare provider or pharmacist. You are encouraged to report side effects of prescription drugs to the FDA. Call 1-800-FDA-1088.

Before receiving OPDIVO or YERVOY, 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 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 with OPDIVO or YERVOY and for 5 months after the 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 and over-the-counter medicines, vitamins, and herbal supplements.

Important Safety Information for Opdualag™ (nivolumab and relatlimab-rmbw)

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

Opdualag is a medicine that may treat a type of skin cancer called melanoma by working with your immune system.

Opdualag can cause your immune system to attack normal organs and tissues in any area of your body and can affect the way they work. 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.

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

- Lung problems: new or worsening 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 in your ankles; loss of appetite
- **Skin problems:** rash; itching; skin blistering or peeling; painful sores or ulcers in the mouth or nose, throat, or genital area
- Heart problems: new or worse chest pain; irregular heartbeat or feel like your heart is racing; shortness of breath; tiredness; swelling in your ankles

Please see Important Safety Information for <u>OPDIVO</u>, <u>YERVOY</u>, <u>Opdualag</u>, and <u>OPDIVO Ovantia</u>™ continued on the following page.

Important Safety Information for Opdualag™ (nivolumab and relatlimab-rmbw) (continued)

Problems can also happen in other organs and tissues. These are not all of the signs and symptoms of immune system problems that can happen with Opdualag. Call or see your healthcare provider right away for any new or worsening signs or symptoms, which may include:

- 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

Getting medical help right away may help keep these problems from becoming more serious. Your healthcare team will check you for these problems during treatment with Opdualag. Your healthcare provider may treat you with corticosteroid or hormone replacement medicines. Your healthcare provider may also need to delay or completely stop your treatment with Opdualag if you have severe side effects.

Possible side effects of Opdualag

Opdualag can cause serious side effects, including:

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

- Severe infusion reactions. Tell your healthcare provider or nurse right away if you get these symptoms during an infusion of Opdualag: chills or shaking; itching or rash; flushing; shortness of breath; dizziness; feel like passing out; fever; back or neck pain
- Complications of stem cell transplant that uses donor stem cells (allogeneic). These complications can be severe and can lead to death. These complications may happen if you underwent transplantation either before or after being treated with Opdualag. Your healthcare provider will monitor you for signs of complications if you have an allogeneic stem cell transplant.

The most common side effects of Opdualag include: muscle and bone pain; tiredness; decreased red blood cell and white blood cell counts; increased liver function test results; rash; itching, diarrhea; decreased salt (sodium) in your blood.

These are not all the possible side effects of Opdualag. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

Before receiving Opdualag, tell your healthcare provider if you:

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

Females who are able to become pregnant:

- Your healthcare provider should do a pregnancy test before you start receiving Opdualag
- You should use an effective method of birth control during and for at least 5 months after the last dose of Opdualag.
 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 during treatment with Opdualag

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

Important Safety Information for OPDIVO Qvantig™ (nivolumab and hyaluronidase-nvhy)

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 of 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 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: 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; 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.

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 the 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.

Important Safety Information for OPDIVO Qvantig™ (nivolumab and hyaluronidase-nvhy) (continued)

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 and 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 the possible side effects of OPDIVO Qvantig. For more information, ask your healthcare provider or pharmacist. You are encouraged to report side effects of prescription drugs to FDA. Call 1-800-FDA-1088.

Before receiving OPDIVO Quantig, 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.
- 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.

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 Ovantig.

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

Please see Important Safety Information for OPDIVO®, YERVOY®, Opdualag™, and OPDIVO Qvantig on pages <u>11-19</u>, and the U.S. Full Prescribing Information and Medication Guide for <u>OPDIVO</u>, <u>YERVOY</u>, <u>Opdualag</u>, and <u>OPDIVO Ovantig</u>.

IMPORTANT Reminders for Patients

- Contact your oncologist immediately if you experience any symptoms listed on this Signs and Symptoms
 Checklist or if they get worse, or if you experience anything unusual while on OPDIVO® (nivolumab),
 YERVOY® (ipilimumab), Opdualag™ (nivolumab and relatlimab-rmbw), or OPDIVO Qvantig™ (nivolumab and
 hyaluronidase-nvhy) therapy. Getting medical treatment right away may keep the problem from becoming
 more serious
- These are not all of the possible side effects of OPDIVO, YERVOY, Opdualag, 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
- Do not treat Signs and Symptoms yourself without talking to your oncologist
- Your oncologist may decide to delay or completely stop OPDIVO, OPDIVO + YERVOY, YERVOY, Opdualag, or OPDIVO Qvantig, or give you other medicines to treat your symptoms

Live On-Demand Support Services for You and Your Patients

We're here to help you better understand your medication. These programs are for people who are prescribed OPDIVO, OPDIVO + YERVOY, Opdualag, or OPDIVO Qvantig and their loved ones. Signing up takes less than 5 minutes. Bristol Myers Squibb remains committed to responding to your needs within 24 hours or less.





1-855-OPDIVO-1

(1-855-673-4861)

FOR LIVE SUPPORT AND ASSISTANCE 8:00 AM to 8:00 PM ET, Monday-Friday

Responses provided between 8:00 AM to 8:00 PM ET, Monday-Friday

- Helpful information
- Details about support and advocacy groups

These support resources and more can be found on www.opdivo.com



Helpful Information

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

Support and Advocacy Groups

Injection for intravenous use | 480 mg/160 mg

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

Just call **1-855-OPDUALAG** (1-855-673-8252) 8:00 AM to 8:00 PM ET, Monday-Friday

These support resources and more can be found on www.Opdualag.com

Please see Important Safety Information for OPDIVO, YERVOY, Opdualag, and OPDIVO Qvantig on pages <u>11-19</u>, and the U.S. Full Prescribing Information and Medication Guide for <u>OPDIVO</u>, <u>YERVOY</u>, <u>Opdualag</u>, and <u>OPDIVO</u> <u>Ovantig</u>.

Bristol Myers Squibb

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Your Signs and Symptoms Checklist

Do you have any signs or symptoms?

- 1. If you notice any discomfort or changes in the way you are feeling, contact your Oncology Care Team immediately.
- 2. Getting medical treatment right away may help keep these problems from becoming more serious. Do not try to treat possible side effects yourself.
- 3. Your oncologist may decide to delay or completely stop OPDIVO® (nivolumab), YERVOY® (ipilimumab), Opdualag™ (nivolumab and relatlimab-rmbw), or OPDIVO Ovantig™ (nivolumab and hyaluronidase-nvhy) or give you other medicines to treat your symptoms.
- ► These are not all of the possible side effects of OPDIVO, YERVOY, Opdualag, 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. Signs or changes to look out for 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



Intestines

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



Lungs cough

- chest pain
- shortness of breath



rash

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

decrease in your

amount of urine

blood in your urine

Kidneys

swelling of

your ankles

loss of appetite

chills or shaking

itching or rash

shortness of

flushing

dizziness

fever

Severe Infusion-

Related Reactions

breath or wheezing

feel like passing out

back or neck pain

Hormone Glands

- headaches that will not go away or unusual headaches
- eve 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
- constipation
- your voice gets deeper
- dizziness or fainting
- changes in mood or behavior. such as decreased sex drive. irritability, or forgetfulness



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



Other Organs

- Problems can also happen in other organs and tissues. These are not all of the signs and symptoms of immune system problems that can happen with OPDIVO. YERVOY. Opdualag, or 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 evesight
- Persistent or severe muscle pain or weakness, muscle
- Low red blood cells, bruising

YERVOY may be associated with eye problems with signs and symptoms that include blurry vision, double vision, or other vision problems and eye pain or redness.

Complications, including graft-versus-host disease (GVHD), of bone marrow (stem cell) transplant that uses donor stem cells (allogeneic). These complications can be severe and can lead to death. These complications may happen if you underwent transplantation either before or after being treated with OPDIVO, YERVOY, Opdualag, or OPDIVO Ovantig. Your healthcare provider will monitor you for these complications.

If you experience a severe side effect, you may need to go to a hospital emergency department. If this happens, you need to:



- Bring the wallet card and a full list of your medications, including prescription and over-the-counter medicines, vitamins, and herbal supplements
- Tell doctors and nurses in the emergency department that you are on an immunotherapy treatment to treat vour condition
- · Make sure your Oncology Care Team is notified

Please see Important Safety Information for OPDIVO, YERVOY, Opdualaq, and OPDIVO Ovantiq on pages 11-19, and the U.S. Full Prescribing Information and Medication Guide for OPDIVO, YERVOY, Opdualag, and OPDIVO Ovantia.

Management of immunotherapy side effects may require a different approach than other cancer treatments. Do not wait to treat the patient if urgent care is required.



INATAOAMI session for Doctors/Nurses

TINATGODANI

Please call my oncologist.

I have received an immunotherapy called:

Drug Name(s):

Patient Name:

Oncologist Name:

Oncologist Phone Number:

Present this card every time you visit a healthcare provider.