

Patient Pocket Guide

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

1

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

- Fill out the treating oncologist's contact information

2

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®, 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

3

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®, or OPDIVO Qvantig® and show them the important information for Doctors' /Nurses' section of this wallet card

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

☐ **OPDIVO Qvantig®**

☐ **OPDIVO®**

☐ **OPDIVO® + YERVOY®**

☐ **YERVOY®**

To obtain a copy of this pocket guide please contact Bristol Myers Squibb by phone: 03-5231021, fax: 03-9226896 or email: Office_IL@bms.com

Please see Important Safety Information for OPDIVO, YERVOY, and OPDIVO Qvantig on pages 8–17, and the Israeli Full Prescribing Information and Patient leaflet for OPDIVO and YERVOY, and the Information leaflet for OPDIVO Qvantig included in the package

Please see Important Safety Information for OPDIVO, YERVOY, and OPDIVO Qvantig on pages 8–17, and the Israeli Full Prescribing Information and Patient leaflet for OPDIVO and YERVOY, and the Information leaflet for OPDIVO Qvantig included in the package

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.

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נא להתקשר לאונקולוג שלי. Please call my oncologist.

קיבלתי טיפול אימונותרפי הנקרא: I have received an immunotherapy called:

שם התכשיר(ים): (ממין את המתיאים)	OPDIVO Qvantig® / OPDIVO® /YERVOY® /OPDIVO® + YERVOY®
שם המטופל/ת:	
שם האונקולוג:	
מספר טלפון של האונקולוג:	

Present this card **every time** you visit a healthcare provider

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חשוב מידע עבור רופאים/אחיות

הגישה לטיפול בתופעות לוואי הנגרמות מאימונותרפיה עשויה להיות שונה מטיפולים אחרים לסרטן

אין להמתין עם הענקת טיפול למטופל במקרה שנדרש טיפול דחוף



למידע נוסף יש לעיין בעלון לרופא הישראלי של אופדיבו ושל יירבוי ובעלון לרופא של אופדיבו קוונטיג המצורף לאריזת התכשיר. ניתן לדווח על תופעות לוואי למשרד הבריאות באמצעות הטופס המקוון לדיווח על תופעות לוואי שנמצא בדף הבית של אתר משרד הבריאות: [www.health.gov.il](https://sideeffects.health.gov.il) או על ידי כניסה לקישור: <https://sideeffects.health.gov.il>



Keep this guide handy for your reference. This guide 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), 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.

Please see Important Safety Information for OPDIVO, YERVOY and OPDIVO Qvantig on pages 8–17, and the Israeli Full Prescribing Information and Patient leaflet for OPDIVO and YERVOY, and the Information leaflet for OPDIVO Qvantig included in the package



Liver

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



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 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



Intestines

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



Lungs

- cough
- chest pain
- shortness of breath



Kidneys

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



Hormone Glands

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



Skin

- 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



Severe Infusion-Related Reactions

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

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.

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, or OPDIVO Qvantig. Your healthcare provider will monitor you for these complications.

Please see Important Safety Information for OPDIVO, YERVOY and OPDIVO Qvantig on pages 8–17, and the Israeli Full Prescribing Information and Patient leaflet for OPDIVO and YERVOY, and the Information leaflet for OPDIVO Qvantig included in the package

Important Safety Information

OPDIVO® (nivolumab), YERVOY® (ipilimumab) and OPDIVO Qvantig® (nivolumab and hyaluronidase - nvhy) are medicines that may treat certain cancers by working with your immune system.

OPDIVO, YERVOY and OPDIVO Qvantig can cause your immune system to attack normal organs and tissues in any area of your body and can affect the way they work. These problems can sometimes become severe or 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.

Please see Important Safety Information for OPDIVO, YERVOY, and OPDIVO Qvantig on pages 8–17, and the Israeli Full Prescribing Information and Patient leaflet for OPDIVO and YERVOY, and the Information leaflet for OPDIVO Qvantig included in the package

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), 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 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, or OPDIVO Qvantig, or give you other medicines to treat your symptoms

Please see Important Safety Information for OPDIVO, YERVOY, and OPDIVO Qvantig on pages 8–17, and the Israeli Full Prescribing Information and Patient leaflet for OPDIVO and YERVOY, and the Information leaflet for OPDIVO Qvantig included in the package

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 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; 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.

Please see Important Safety Information for OPDIVO, YERVOY, and OPDIVO Qvantig on pages 8–17, and the Israeli Full Prescribing Information and Patient leaflet for OPDIVO and YERVOY, and the Information leaflet for OPDIVO Qvantig included in the package

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

Please see Important Safety Information for OPDIVO, YERVOY, and OPDIVO Qvantig on pages 8–17, and the Israeli Full Prescribing Information and Patient leaflet for OPDIVO and YERVOY, and the Information leaflet for OPDIVO Qvantig included in the package

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

Very common side effects of OPDIVO, when used alone, include: feeling tired; weakness generally feeling unwell; fever; swelling (edema), including swelling of the hands, ankles or feet (peripheral edema); diarrhea; nausea; vomiting; stomach-area (abdominal) pain; constipation; dyspepsia; difficulty swallowing; rash; itching, including widespread itching; vitiligo, a disease in which light patches appear on the skin; erythema, manifested by skin redness and inflammation; pain in muscles, bones, and joints; headache; dizziness; upper respiratory tract infection; nasal congestion; pneumonia, including pneumonia involving the bronchi; cough, cough with phlegm; shortness of breath, shortness of breath upon exertion; decreased appetite; decreased weight; back pain; low thyroid hormone levels [hypothyroidism (decreased activity of the thyroid gland)] that can cause fatigue and weight gain; high thyroid hormone levels [hyperthyroidism (increased activity of the thyroid gland)] that can cause rapid heart rate, sweating and weight loss; thyroid gland problems, including thyroid gland inflammation (thyroiditis); abnormal renal function; urinary tract infection; liver inflammation (hepatitis); high blood pressure; high level of sugar in blood (hyperglycemia);

difficulty sleeping; numbness, pain, tingling or burning in the hands or feet (peripheral neuropathy); abnormal laboratory test results; infusion related reactions.

Very common side effects of OPDIVO, when used in combination with a platinum-containing chemotherapy and another chemotherapy, include: feeling tired; generally feeling unwell; swelling (edema); fever; nausea; constipation; vomiting; diarrhea; stomach-area (abdominal) pain; decreased appetite; rash; itching; hair loss; numbness, pain, tingling, or burning in your hands or feet (peripheral neuropathy); headache; pain in muscles, bones, and joints; urinary tract infection; low thyroid hormone levels [hypothyroidism (decreased activity of the thyroid gland)] that can cause fatigue and weight gain; abnormal renal function; blood in your urine; decreased weight; abnormal laboratory test results.

Very common side effects of OPDIVO, when used in combination with YERVOY, include: feeling tired; fever; swelling (edema); rash; itching, widespread itching; dry skin; diarrhea; nausea; vomiting; stomach-area (abdominal) pain; constipation; swollen stomach (abdomen) due to fluid accumulation (ascites); dry mouth; dyspepsia; difficulty

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

swallowing; sores or ulcers in the mouth (stomatitis); inflammation of the colon (colitis); pain in muscles, bones, and joints; cough, cough with phlegm; shortness of breath, shortness of breath upon exertion; pneumonia; upper respiratory tract infection; inflammation of the lung tissues (pneumonitis) characterized by coughing and difficulty breathing, shortness of breath and cough; decreased appetite; headache; dizziness; flu; flu-like illness; weakness, generally feeling unwell; chills; low blood pressure; low thyroid hormone levels [hypothyroidism (decreased activity of the thyroid gland)] that can cause fatigue and weight gain; high thyroid hormone levels [hyperthyroidism (increased activity of the thyroid gland)] that can cause rapid heart rate, sweating and weight loss; adrenal glands insufficiency (decrease in the level of hormones secreted by adrenal glands located above the kidneys); decreased weight; difficulty sleeping; abnormal laboratory test results.

Very common side effects of OPDIVO, when used in combination with YERVOY and a platinum-containing chemotherapy and another chemotherapy, include: feeling tired; fever; pain in muscles, bones, and joints;

nausea; diarrhea; constipation; vomiting; stomach-area (abdominal) pain; rash; itching, including widespread itching; hair loss; decreased appetite; cough; shortness of breath; low thyroid hormone levels [hypothyroidism (decreased activity of the thyroid gland)] that can cause fatigue and weight gain; headache; dizziness; abnormal laboratory test results.

Very common side effects of OPDIVO, when used in combination with cabozantinib, include: diarrhea; nausea; stomach-area (abdominal) pain; vomiting; dyspepsia; feeling tired or weak; liver problems; liver toxicity; rash, redness, pain, swelling or blisters on the palms of your hands or soles of your feet; sores or ulcers in the mouth (stomatitis); rash; itching; high blood pressure; low thyroid hormone levels [hypothyroidism (decreased activity of the thyroid gland)] that can cause fatigue and weight gain; pain in muscles, bones, and joints; decreased appetite; change in the sense of taste; headache; cough; voice disorders (difficulty speaking due to disorders of the pharynx, vocal cords, tongue or mouth); upper respiratory tract infection; abnormal laboratory test results.

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

Very common side effects of OPDIVO when used in combination with fluoropyrimidine and platinum-containing chemotherapy include: numbness, pain, tingling, or burning in your hands or feet (peripheral neuropathy); headache; nausea; diarrhea; vomiting; difficulty swallowing; stomach-area (abdominal) pain; constipation; sores or ulcers in the mouth (stomatitis); feeling tired; fever; swelling (edema); decreased appetite; decreased weight; pain in muscles, bones, and joints; rash; itching; hair loss; rash, redness, pain, swelling or blistering of the hands or feet; cough, cough with phlegm; upper respiratory tract infection; pneumonia; difficulty sleeping; abnormal laboratory test results.

Very common side effects of YERVOY include: feeling tired; diarrhea; nausea; itching; rash; vomiting; fever; decreased appetite; pain in muscles, bones, and joints; cough, cough with phlegm; shortness of breath, shortness of breath upon exertion; upper respiratory tract infection.

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 Ministry of Health.

Side effects can be reported to the Ministry of Health by clicking on the “Reporting side effects following drug treatment” link found on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects, or through the following link: <https://sideeffects.health.gov.il>

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

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 and for 3 months after the last dose of 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 and for 3 months after the last dose of 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.

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

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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 the mouth or nose, throat, or genital area; fever or flu-like symptoms.

Please see Important Safety Information for OPDIVO, YERVOY, and OPDIVO Qvantig on pages 8–17, and the Israeli Full Prescribing Information and Patient leaflet for OPDIVO and YERVOY, and the Information leaflet for OPDIVO Qvantig included in the package

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

Please see Important Safety Information for OPDIVO, YERVOY, and OPDIVO Qvantig on pages 8–17, and the Israeli Full Prescribing Information and Patient leaflet for OPDIVO and YERVOY, and the Information leaflet for OPDIVO Qvantig included in the package

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

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 observed with nivolumab given into the vein (intravenous nivolumab), which may be experienced with OPDIVO Qvantig, are listed in the Information leaflet included in the package

For more information concerning possible side effects, ask your healthcare provider or pharmacist. You are encouraged to report side effects of prescription drugs to the Ministry of Health.

Side effects can be reported to the Ministry of Health by clicking on the “Reporting side effects following drug treatment” link found on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects, or through the following link: <https://sideeffects.health.gov.il>

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

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

- have immune system problems such as Crohn’s disease, ulcerative colitis, or lupus.
- have received an organ transplant, including corneal transplant.
- have received or plan to receive a stem cell transplant that uses donor stem cells (allogeneic).
- have received radiation treatment to your chest area in the past.
- have a condition that affects your nervous system, such as myasthenia gravis or Guillain-Barré syndrome.
- are pregnant or plan to become pregnant. OPDIVO Qvantig can harm your unborn baby.
- 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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Females who are able to become pregnant:

- Your healthcare provider should do a pregnancy test before you start receiving OPDIVO Qvantig.
- You should use an effective method of birth control during treatment and for 5 months after your last dose of OPDIVO Qvantig. Talk to your healthcare provider about birth control methods that you can use during this time.
- Tell your healthcare provider right away if you become pregnant or think you may be pregnant during treatment with OPDIVO Qvantig.

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

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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), or OPDIVO Qvantig® (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, 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:**



Liver

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



Intestines

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



Lungs

- cough
- chest pain
- shortness of breath



Skin

- 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



Kidneys

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



Severe Infusion-Related Reactions

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



Hormone Glands

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



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 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 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, or OPDIVO Qvantig. 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, nutritional supplements and herbal supplements
- Tell doctors and nurses in the emergency department that **you are on an immunotherapy treatment** to treat your condition
- Make sure your Oncology Care Team is notified



Bristol Myers Squibb®

Please see Important Safety Information for OPDIVO, YERVOY, and OPDIVO Qvantig on pages 8-17, and the Israeli Full Prescribing Information and Patient leaflet for OPDIVO and YERVOY, and the Information leaflet for OPDIVO Qvantig included in the package