

OPDIVO[®]

(nivolumab)

OPDIVO[®] + YERVOY[®]
(nivolumab) (ipilimumab)

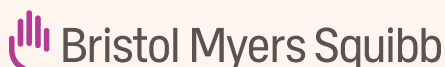
Patient Information Guide

This material was developed by Bristol-Myers Squibb
as part of the risk minimization plan for OPDIVO.

This material is not intended for promotional use.

Date of internal approval: September 2020

Local Approval Number:
7356CA2000182



Introduction

- This guide provides you with information about treatment with OPDIVO or OPDIVO in combination with YERVOY and describes potential signs and symptoms that you might experience.
- It also provides important advice on what you should do if you experience signs and symptoms as they can quickly worsen if left untreated.
- OPDIVO or OPDIVO in combination with YERVOY can cause serious side effects in various parts of the body that need to be addressed immediately, regardless of their severity, to avoid their worsening.
- **This guide includes a Patient Alert Card.** Remember to always carry your OPDIVO Patient Alert Card with you and to inform healthcare professionals that you are receiving treatment with OPDIVO or OPDIVO in combination with YERVOY.
- The healthcare professional treating you with OPDIVO or OPDIVO in combination with YERVOY should complete the 'My Doctor's Contact Information' section of the Patient Alert Card.

Please note: Contact your doctor if you need advice, information and support.

An online version of this Patient Information Guide is available at the following website address: www.BMSpatientsafetyinfo123.ca

What is OPDIVO?

OPDIVO helps your immune system to attack and destroy cancer cells.

OPDIVO may be given in combination with YERVOY. YERVOY is a different medicine which also helps your immune system attack and destroy cancer cells. OPDIVO given with YERVOY can produce a combined effect on your immune system when taken together.

Receiving treatment

What does OPDIVO treatment involve?

OPDIVO or OPDIVO in combination with YERVOY is a doctor-prescribed medicine that is slowly injected over time (infused) directly into the bloodstream. You will receive the medicine(s) at a treatment centre where you will have a needle placed in a vein, usually in your arm or the back of your hand.

OPDIVO or OPDIVO with YERVOY will be infused through this needle, and the actual time you will spend in the treatment centre may vary. Your doctor will discuss with you what treatments you will receive.



It is important that you:

- Tell your doctor before receiving OPDIVO or OPDIVO in combination with YERVOY if you
 - have any medical conditions, including an auto-immune disease (a condition where the body attacks its own cells or any history of inflammation of the lungs)
 - are pregnant, planning to become pregnant, or breastfeeding
 - take corticosteroids or any other treatment that affects the immune system
 - take or have taken any other medicines (including prescribed and over-the-counter products, and herbal and vitamin supplements)
 - have received a stem cell transplant that uses donor stem cells (allogeneic)
 - have received an organ transplant (e.g., kidney, liver, heart, cornea, or skin)
- Talk to your healthcare team **immediately** about any new or worsening signs and symptoms you experience.
- Do NOT breastfeed, and tell your doctor **immediately** if you become pregnant during your treatment with OPDIVO or OPDIVO in combination with YERVOY.
- Re-schedule any missed appointments right away.

Signs and symptoms of your treatment

OPDIVO or OPDIVO in combination with YERVOY can cause serious or even life-threatening side effects. Signs and symptoms of side effects may happen any time during treatment or even months after your treatment has ended.



What to do if you suspect a side effect:

- Call your doctor **immediately** if you experience any signs or symptoms, or if they get worse. Signs and symptoms that may appear mild can quickly worsen if left untreated.
- **DO NOT** treat any signs and symptoms yourself.
- **DO NOT** feel embarrassed or worry that you are bothering your doctor.

The following are NOT all of the possible signs and symptoms of side effects from treatment with OPDIVO or OPDIVO in combination with YERVOY. For more information, ask your doctor or nurse and/or read the OPDIVO patient medication information leaflet available at https://www.bms.com/assets/bms/ca/documents/productinformation/OPDIVO_EN_PIL.pdf

(and also, if relevant, the YERVOY patient medication information leaflet available at https://www.bms.com/assets/bms/ca/documents/productinformation/YERVOY_EN_PIL.pdf).

Please note: Some signs and/or symptoms occurring in one part of your body may be related to a side effect in another part of your body (for example, yellow skin may represent a liver problem).

Signs and symptoms to look out for include:

General

- Changes in mood or behaviour, such as decreased sex drive, irritability, forgetfulness, or depression
- Confusion and memory problems
- Feeling unwell
- Fever
- Headaches
- Increased or decreased appetite
- Nausea or vomiting
- Seizures (fits)
- Seeing things that are not really there (hallucinations)
- Swelling in extremities
- Swollen lymph nodes
- Excessive thirst
- Hunger
- Sensation of paralysis
- Pain on the right side of your stomach (abdomen)
- Tiredness
- Weight gain or loss
- Tingling and/or numbness (e.g., in your fingers or toes)
- Sleepiness or drowsiness

Skin

- Bruising easily
- Dry skin
- Itching
- Raised skin lumps/bumps (skin nodules)
- Severe skin reaction or rash
- Skin blistering/peeling
- Skin yellowing (jaundice)

Eyes

- Eyesight changes (e.g., blurry vision, other vision problems)
- Eye pain or redness
- Yellowing of the whites of your eyes

Mouth, nose, and throat

- Ulcers in the mouth or other mucous membranes

Chest

- Chest pain
- Breathing difficulties
- Cough (new or worsening)
- Irregular heartbeat, palpitations (being more aware of heartbeat than normal)

Muscles and bones

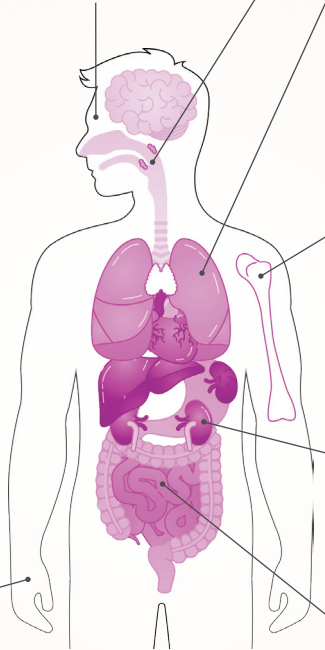
- Difficulty walking
- Numbness in arms and/or legs
- Muscle or joint pains
- Muscle weakness or stiffness
- Stiff neck

Kidneys and bladder

- Decreased or increased amount of urine
- Darker urine than normal (tea-coloured)

Stomach and bowel (gut)

- Dark, tarry, or sticky stools
- Blood or mucous in your stools
- Diarrhea (watery, loose or soft stools) or more bowel movements than usual
- Heartburn or indigestion
- Pain or tenderness in your stomach or abdominal area



Other important side effects

Severe infusion reaction

- Reactions to infusing OPDIVO or OPDIVO in combination with YERVOY into the bloodstream might occur, usually during or within 24 hours of receiving a dose.
- **Tell your doctor or nurse right away if you get these symptoms during an infusion of OPDIVO or OPDIVO in combination with YERVOY: chills or shaking; itching or rash; flushing; difficulty breathing; dizziness; fever; and feeling like passing out.**

Complications of stem cell transplant that uses donor stem cells (allogeneic) after treatment with OPDIVO

- Donated stem cells contain T cells that can attack your own body cells if they see them as foreign. These complications can be severe and can lead to death.
- **Inform your doctor if you underwent an allogeneic stem cell transplant either before or after being treated with OPDIVO, in order for your doctor to monitor you for signs of complications (e.g., skin rash, liver inflammation, abdominal pain, and diarrhea).**

Rejection of a transplanted organ

- People who have had an organ transplant may have an increased risk of organ transplant rejection if they are treated with OPDIVO.
- **Please tell your doctor before treatment if you have had an organ transplantation.**

Monitoring signs and symptoms



Signs and symptoms that appear mild can quickly worsen if left untreated.

Do not try to treat any signs and symptoms yourself.

Always carry your Patient Alert Card with you.

Contact your cancer specialist doctor (oncologist) immediately if you experience any of the symptoms previously described, if they get worse, or if you experience anything unusual while on OPDIVO or OPDIVO in combination with YERVOY.

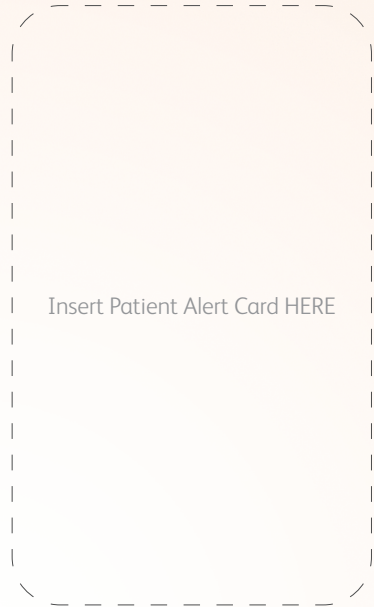
These are not all of the possible side effects of treatment, so you should report any discomfort or changes in the way you are feeling to your Oncology Care Team. Some side effects may occur many months after treatment.

Getting medical treatment right away may help keep the problem from becoming more serious.

Early treatment of side effects may reduce the likelihood that treatment with OPDIVO or OPDIVO in combination with YERVOY will need to be temporarily or permanently stopped.

Patient Alert Card

- A Patient Alert Card is available to help remind you about side effects that could occur during or after treatment with OPDIVO or OPDIVO in combination with YERVOY, and what to do if you suspect you have a problem.
- You should always keep the Patient Alert Card with you since it contains important information about your cancer treatment.
- Show the Patient Alert Card to any healthcare professional involved in your medical treatment, not just to your oncologist.
- You must keep this card with you for at least 5 months after completing your treatment because there may be active drug remaining in your body.



Please ensure that the doctor who is treating you completes the My Doctor's Contact Information on the Patient Alert Card and below.

My Doctor's Contact Information (who prescribed OPDIVO or OPDIVO in combination with YERVOY)	
Name of Doctor:	
Office Phone:	
After-Hours Phone:	

Reporting side effects

You can report any suspected side effects associated with the use of Health Products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

For more information, consult the OPDIVO patient medication information leaflet https://www.bms.com/assets/bms/ca/documents/productinformation/OPDIVO_EN_PIL.pdf or call Medical Information at 1-866-463-6267.

Reference: 1. OPDIVO Product Monograph dated August 6, 2020.

OPDIVO and YERVOY are registered trademarks of Bristol-Myers Squibb Company used under license by Bristol-Myers Squibb Canada Co.
©2020 Bristol-Myers Squibb Company. All rights reserved.

Date of Internal Approval: September 2020
Local Approval Number: 7356CA2000182
1422219