

Pr **YERVOY**<sup>®</sup>  
(ipilimumab for injection)

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## Patient Information Guide

**If you have been prescribed YERVOY alone**

- Refer to this guide and the YERVOY (ipilimumab) Patient Alert Card.

**If you have been prescribed YERVOY in combination with OPDIVO (nivolumab)**

- Refer instead to the OPDIVO Patient Information Guide and Patient Alert Card.

This material was developed by Bristol-Myers Squibb  
as part of the risk minimization plan for YERVOY.  
This material is not intended for promotional use.

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## Introduction

- This guide provides you with information about treatment 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 side effects as they can quickly worsen if left untreated.
- 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 Patient Alert Card with you and show it to any healthcare professional you consult (for example, if your regular doctor is unavailable or you are travelling).
- Additional information concerning YERVOY is available in the Patient Medication/ Consumer Information leaflet at [https://www.bms.com/assets/bms/ca/documents/productinformation/YERVOY\\_EN\\_PIL.pdf](https://www.bms.com/assets/bms/ca/documents/productinformation/YERVOY_EN_PIL.pdf).

## About YERVOY

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

With YERVOY, there is a risk that your activated immune system can harm healthy cells in your body, which may cause potentially serious or even life-threatening side effects.

## What to check with your doctor before treatment

Before starting the treatment, you should inform your doctor of any previous treatment you received and any medical conditions you may have experienced or you are experiencing.



### In addition, your doctor will check for the following before the treatment:

- if you take corticosteroids or other treatments that affect the immune system
- if you take any medicines that stop your blood from clotting (anticoagulants)
- liver function tests (LFTs)
- thyroid function tests
- if you had an organ transplant
- if you have an autoimmune disease (a condition where the body attacks its own cells)
- if you have hepatitis
- if you are pregnant, breast-feeding or planning to become pregnant
- your general physical condition to determine whether you are suitable for treatment

# The main side effects of your treatment

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 persist or 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.

### Please note:

- The following signs and symptoms are NOT all of the possible signs and symptoms of side effects from treatment with YERVOY.
- 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).

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



## Possible side effects:

### General

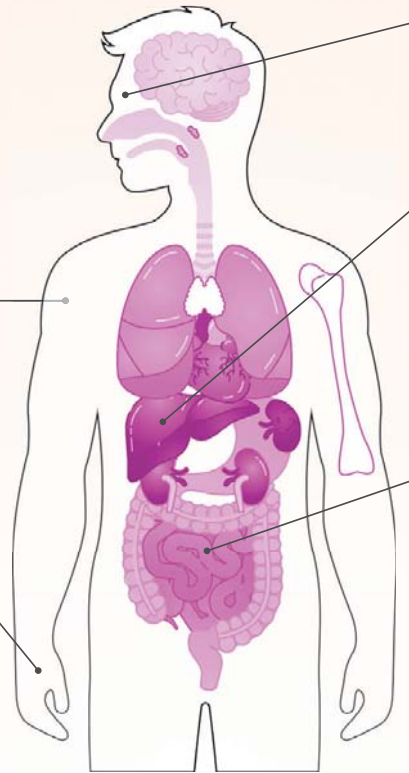
- headaches or unusual tiredness or sleepiness
- changes in behaviour such as less sex drive, being irritable or forgetful, dizziness or fainting

### Nerves

- weakness of legs, arms or face, numbness or tingling in hands or feet

### Skin

- rash on your skin, mouth blisters or peeling skin



### Eye

- blurry vision, double vision or other vision problems, eye pain or redness

### Liver

- yellowing of your skin or the white of your eyes (jaundice), dark urine, tiredness, nausea or vomiting, loss of appetite, pain on the right side of your stomach or bruise easily

### Bowel and stomach

- diarrhea (loose stools) or more bowel movements than usual
- constipation
- blood in stools, or dark, tarry, sticky stools
- stomach pain (abdominal pain) or tenderness

## Other important side effects:

### Complications of stem cell transplant that uses donor stem cells (allogeneic)

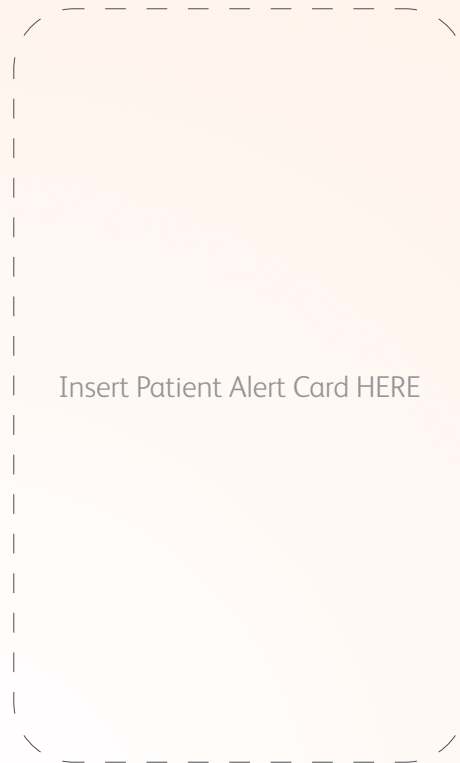
- Donated stem cells contain T cells that can attack your own body cells if they see them as foreign. These complications can be severe and can lead to death.
- **Inform your doctor if treated with an allogeneic stem cell transplant in order for your doctor to monitor you for signs of complications (e.g.,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

### Severe infusion reactions

- Reactions to infusing YERVOY into the bloodstream might occur, usually during the infusion or within 24 hours of receiving a dose.
- **Tell your doctor or nurse right away if you get these symptoms during an infusion of YERVOY: shortness of breath or trouble breathing, cough, chest tightness; dizziness, fainting, rapid or weak heartbeat; itching, hives or feeling warm; swelling of the throat, tongue or face; hoarse voice, throat tightness or trouble swallowing.**

# Patient Alert Card

- Always carry your Patient Alert Card with you and show it to any healthcare professional you consult (for example, if your regular doctor is unavailable or you are travelling).
- The Patient Alert Card reminds you about key symptoms that need to be reported immediately to the doctor/nurse. It also contains the contact details of the treating physician and will make other healthcare professionals aware that you are being treated with YERVOY.
- The healthcare professional treating you with YERVOY should complete the 'My Doctor's Contact Information' section of this Patient Alert Card and also fill in the doctor's contact details below.



**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 YERVOY)	
Name of Doctor:	
Office Phone:	
After-Hours Phone:	

# Reporting suspected side effects

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- Online at [www.healthcanada.gc.ca/medeffect](http://www.healthcanada.gc.ca/medeffect)
- By calling 1-866-234-2345 (toll-free)
- By completing a Patient Side Effect Reporting Form and sending it by:
  - Fax to 1-866-678-6789 (toll-free), or
  - Mail to: Canada Vigilance Program  
Health Canada, Postal Locator 1908C  
Ottawa, ON  
K1A 0K9

Postage-paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Website at [www.healthcanada.gc.ca/medeffect](http://www.healthcanada.gc.ca/medeffect).

*NOTE: Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance program does not provide medical advice.*

For more information, consult the YERVOY patient medication information leaflet [https://www.bms.com/assets/bms/ca/documents/productinformation/YERVOY\\_EN\\_PIL.pdf](https://www.bms.com/assets/bms/ca/documents/productinformation/YERVOY_EN_PIL.pdf) or call Medical Information at 1866-463-6267.

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