

YERVOY[®]

(ipilimumab)

Patient Information Guide

- This guide has Important Safety Information about ipilimumab treatment.
- This document is approved by The Executive Directorate of Pharmacovigilance, at SFDA.

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[®]

- ▶ Refer instead to the OPDIVO[®] (nivolumab) Patient Information Guide and Patient Alert Card.

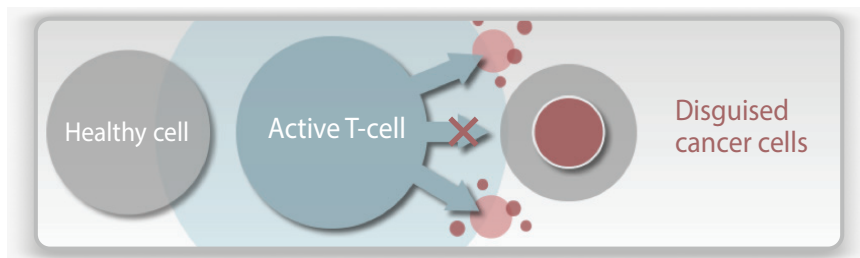
Introduction

- 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 signs and symptoms, to help make sure that these signs and symptoms do not worsen and you are treated as quickly and effectively as possible.
- 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 local Patient leaflet which can be found in the product pack.

About YERVOY®

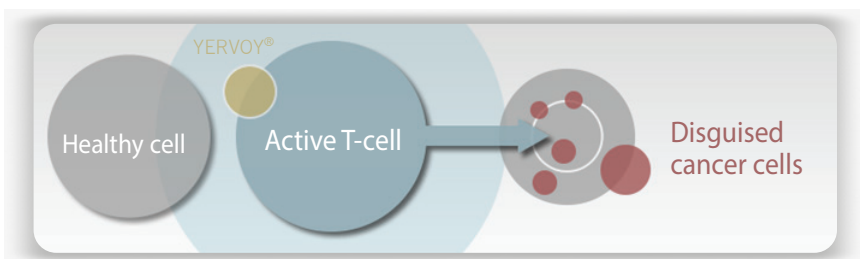
YERVOY® contains the active substance ipilimumab, a protein that helps your immune system to attack and destroy cancer cells.

Cancer and your immune system



Your immune system consists of a variety of cells (including white blood cells called T-cells) that act as the body's natural defense system. T-cells detect and destroy things that the body considers to be 'foreign', such as: bacteria, viruses, and cancer cells. Sometimes, cancer can find ways to escape the immune system's defense (for example, by blocking T-cell activity). This allows the cancer to spread and grow.

How does YERVOY® work on cancer cells?



YERVOY® is a medicine that helps to activate your immune system so that T-cells can fight 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)
- if you have had a stem cell transplant that uses donor stem cells (allogeneic)
- liver function tests (LFTs)
- thyroid function tests
- if you have an autoimmune disease (a condition where the body attacks its own cells)
- if you have or have ever had a chronic viral infection of the liver, including:
 - hepatitis B (HBV)
 - hepatitis C (HCV)
- if you have human immunodeficiency virus (HIV) infection or acquired immune deficiency syndrome (AIDS)
- 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

Although they may not be experienced by every patient, 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:

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- 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 reduces the likelihood that YERVOY® treatment will need to be temporarily or permanently stopped, allowing you to get the maximum benefit from treatment.

POSSIBLE SIDE EFFECTS



BOWEL AND STOMACH

- diarrhea (watery, loose or soft stools), bloody or dark-colored stools.
- more frequent bowel movements than usual.
- pain or tenderness in your stomach or abdomen area, nausea, vomiting.



LIVER

- eye or skin yellowing (jaundice).
- pain on the right side of your stomach area.
- dark urine.



SKIN

- skin rash with or without itching, dry skin.
- blisters and/or peeling of the skin, mouth sores.
- swelling of the face or lymph glands.



EYE

- redness in the eye.
- pain in the eye.
- vision problems or blurry vision.



NERVE

- muscle weakness.
- numbness or tingling in legs, arms or face.
- dizziness, loss of consciousness or difficulty waking up.



GENERAL

- fever, headache, tiredness.
- bleeding.
- behavioral changes (e.g. less sex drive, being irritable or forgetful).
- dehydration, low blood pressure, shock.

Other important side effects:

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

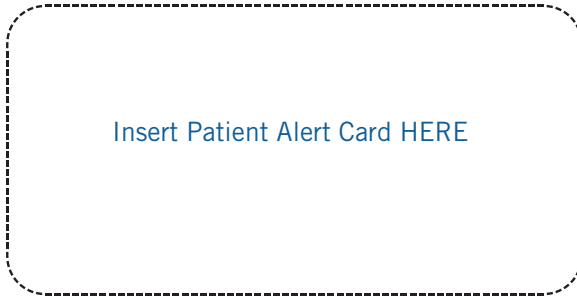
- Donated stem cells contain T cells that can attack your own body cells if they see them as foreign. These complications can be severe and can lead to death.
- **Inform your doctor if treated with an allogeneic stem cell transplant in order for your doctor to monitor you for signs of complications (e.g.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

Severe infusion reactions

- Reactions to infusing YERVOY® into the bloodstream might occur, usually during 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®: chills or shaking; itching or rash; flushing; difficulty breathing; dizziness; fever; and feeling like passing out.**

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 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.



My Doctor's Contact Information (<i>who prescribed YERVOY®</i>)	
Name of Doctor:	
Office Phone:	
After-hours Phone:	

For more information, consult the YERVOY® local patient information which can be found in the product pack.

**For reporting any suspected adverse reactions
via the national reporting system :**

Bristol Myers Squibb, Saudi Arabia:
At: medinfo.saudiarabia@bms.com
or call: 800 844 7710

The national Pharmacovigilance and Drug safety Center :
At: <https://ade.sfda.gov.sa/Home/Report>
Email: npc.drug@sfda.gov.sa
Toll free number: 19999

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