

YERVOY® (ipilimumab)

Patient Information Guide

If you have been prescribed **ipilimumab alone**

▶ Refer to this guide and the ipilimumab Patient Alert Card.

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

▶ Refer instead to the nivolumab Patient Alert Card.

Reporting of side effects: If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in the package leaflet. You can also report side effects directly via HPRC Pharmacovigilance at www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine. Side effects should also be reported to Bristol-Myers Squibb Medical Information on 1 800 749 749 or medical.information@bms.com.

Date of HPRC Approval: NOV 2020
Local Approval Number: 7311E2005685-01
Date of Preparation: November 2020

Introduction

- This guide provides you with information about treatment with ipilimumab and describes potential signs and symptoms of side effects 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.
- Ipilimumab can cause serious side effects in various parts of the body that can be life-threatening. Thus, they 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 ipilimumab is available in the Package Leaflet.

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 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

Ipilimumab helps to activate your immune system to fight cancer cells. 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. 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. Signs and symptoms that may appear mild can quickly worsen if left untreated.

- **DO NOT** treat any signs and symptoms yourself.

Please note:

- The following signs and symptoms are NOT all of the possible signs and symptoms of side effects from treatment with ipilimumab.
- 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 ipilimumab treatment will need to be temporarily or permanently stopped.

POSSIBLE SIDE EFFECTS



BOWEL AND STOMACH

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



EYE

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



LIVER

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



NERVES

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



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



GENERAL

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

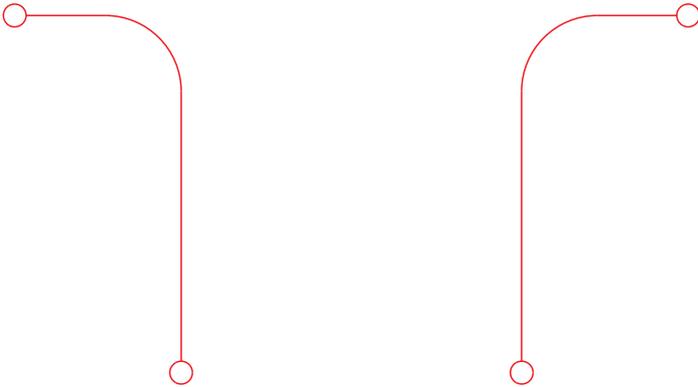
Other important side effects:

Severe infusion reactions

- Reactions to infusing ipilimumab 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 ipilimumab: 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 your doctor/nurse. It also contains the contact details of the treating physician and will make other healthcare professionals aware that you are treated with ipilimumab.
- The healthcare professional treating you with ipilimumab 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 (*who prescribed ipilimumab*)

Name of Doctor:

Office Phone:

After-hours Phone:

For more information, read the ipilimumab Package Leaflet at www.medicines.ie or call Medical Information on 1 800 749 749

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