Your guide to YERVOY[®] (ipilimumab)

Patient Information Guide

This guide has been designed to help you to identify any side effects that you may experience while you are on ipilimumab treatment.

If you have been prescribed **ipilimumab alone**, used for treating advanced melanoma (a type of skin cancer) in adults and adolescents 12 years of age and older ► Refer to this guide and the YERVOY[®] (ipilimumab) Patient Alert Card.

If you have been prescribed **ipilimumab in combination with nivolumab**

- ▶ Refer instead to the OPDIVO[®] (nivolumab) Patient Alert Card.
 - Ipilimumab 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.
 - Symptoms may include diarrhoea, eye or skin yellowing, skin rash with or without itching, blurry vision, pain in the eye, muscle weakness, numbness or tingling in legs, arms, or face, or headache.
 - Before receiving the treatment, inform your doctor of all known medical conditions and any medicines you are taking or have recently taken.
 - Call your doctor immediately if you develop any of the symptoms mentioned in this guide, or any other symptoms, or if the symptoms persist or get worse.
 - Always carry the Patient Alert Card with you and show it to any doctor you consult.
 - Additional information concerning ipilimumab is available in the Package Leaflet.

Healthcare professionals are asked to report any suspected adverse reactions via WWW.medicinesauthority.gov.mt/adrportal Adverse reactions should also be reported to Bristol-Myers Squibb Medical Information at 00 356 23976417or pv@ammangion.com

Introduction

This guide includes a Patient Alert Card.

Always carry your Patient Alert Card with you and show it to any doctor 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 your treating doctor and will make other doctors aware that you are treated with ipilimumab.

Patient Alert Card HERE

Contact your doctor at this number Name of Physician: Phone number: Name of Nurse: Phone number:

The main side effects of your treatment

It is important to tell your doctor immediately if you have, or develop, any side effects such as those listed below.

Early treatment of side effects reduces the likelihood that ipilimumab treatment will need to be temporarily or permanently stopped, allowing you to get the maximum benefit from treatment.

Tell your doctor also if side effects worsen, even if they do not seem serious or you are not sure.¹

If side effects occur, they usually do so in the first 12 weeks of treatment. However, side effects may be delayed, and develop weeks or months after the last dose. This requires attention to side effects even after the end of your treatment.¹

BOWEL AND STOMACH ¹	EYE ¹
 diarrhoea (watery, loose or soft stools), 	 redness in the eye
bloody or dark-coloured stools	 pain in the eye
 more frequent bowel movements than 	 vision problems or blurry vision
usual	
 pain or tenderness in your stomach or 	
abdomen area, nausea, vomiting	
	NERVES ¹
 eye or skin yellowing (jaundice) 	 muscle weakness
• pain on the right side of your stomach area	 numbness or tingling in legs, arms or
• dark urine	face
	 dizziness, loss of consciousness or
	difficulty waking up
SKIN ¹	GENERAL ¹
 skin rash with or without itching, dry skin 	 fever, headache, tiredness
 blisters and/or peeling of the skin, mouth 	 bleeding
sores	 behavioural changes (e.g. less sex
 swelling of the face or lymph glands 	drive, being irritable or forgetful)

- Under no circumstances should you attempt to treat these side effects yourself. You should seek medical assistance as soon as possible.
- Always take your Patient Alert Card with you and show it to any doctor you consult (for example, if your regular doctor is unavailable or you are travelling).

What to expect with your treatment

Before the treatment, your doctor will check:

- 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)
- your general physical condition to determine whether you are suitable for treatment

Please also tell your doctor if you are pregnant, breast-feeding or planning to become pregnant.¹

1. YERVOY[®] Package Leaflet.

Where to find further information

For more information:

- Consult the YERVOY[®] Package Leaflet including Information for the User at <u>www.ema.europa.eu</u>
- Call Bristol-Myers Squibb Medical Information at 00 356 2397 6505