Your guide to YERVOY® (ipilimumab) Patient Information Guide

YERVOY® (ipilimumab) contains the active substance ipilimumab, a protein which helps your immune system to attack and destroy cancer cells by your immune cells. This guide has been designed to help you to identify any side effects that you may experience while you are on ipilimumab treatment.

You have been prescribed ipilimumab, a drug which is used to treat advanced melanoma (a type of skin cancer).

- ipilimumab can cause serious side effects in various parts of the body that need to be addressed immediately, regardless of their severity.
- 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.
- Call your doctor immediately if you develop any of the symptoms mentioned in this card, 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.

This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects that you may get to your Doctor or on www.medicinesauthority.gov.mt/adrportal

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).

Patient Alert Card HERE

Contact your doctor at this number

Name of Physician:

Phone number: Name of Nurse: Phone number:

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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 dose¹.

BOWEL AND STOMACH ¹	GENERAL ¹
 diarrhoea (watery, loose or soft stools), 	 fever, headache, tiredness
bloody or dark-colored stools	bleeding
 more frequent bowel movements than 	• behavioural changes (e.g. less sex
usual	drive, being irritable or forgetful)
 pain or tenderness in your stomach or 	
abdomen area, vomiting or nausea	
LIVER ¹	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	EYE ¹
 skin rash with or without itching, dry skin 	• redness in the eye
 blisters and/or peeling of the skin, mouth 	pain in the eye
sores	 vision problems or blurry vision
swelling of the face or lymph glands	

- Under no circumstances should you attempt to treat these side effects yourself. You should seek medical assistance.
- 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)
- your general physical condition to determine whether you are suitable for treatment
- if you have or have ever had a chronic viral infection of the liver, including:
 - o hepatitis B (HBV)
 - hepatitis C (HCV)
- if you have human immunodeficiency virus (HIV) infection or acquired immune deficiency syndrome (AIDS)

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 www.ema.europa.eu or call medical information at 00 356 23976505