YERVOY[™] (ipilimumab)

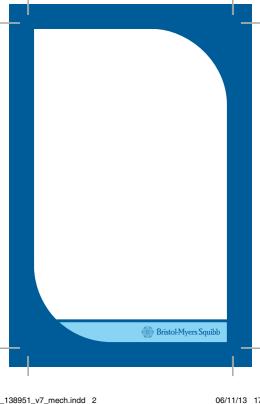
Patient Alert Card

ADR forms can be downloaded from www.medicinesauthority/adrportal and sent by post to 203,Level 3 Rue D'Argens Gzira or by email to postlicensing.medicinesauthority@gov.mt

YERVOYTM is subject to additional monitoring to quickly identify new safety information. You can help by reporting any side effects you may get.



Bristol-Myers Squibb



YERVOY™ (ipilimumab)

can cause serious side effects that need to be treated right away

Call us right away if you have any of these signs or symptoms

Report any of these symptoms to us right away

Symptoms that may appear mild can quickly worsen if left untreated¹

Signs and symptoms may be delayed and may occur weeks to months after your last injection¹

Therefore, do not feel embarrassed or that you are bothering us

BOWEL AND STOMACH¹

- diarrhoea (watery, loose or soft stools), vomiting or nausea
- an increased number of bowel movements than usual
- blood in your stools, or darker-coloured stools
- pain or tenderness in your stomach area, fever

LIVER1

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

SKIN¹

- skin rash with or without itching
- blisters and/or peeling of the skin, mouth sores
- dry skin

NERVE¹

- muscle weakness
- numbness or tingling in your hands or feet
- dizziness, loss of consciousness or difficulty waking up

HORMONE-PRODUCING GLANDS¹

- headaches
- blurry or double vision
- tiredness
- decreased sexual drive
- behavioural changes (e.g. being irritable or forgetful)

EYE1

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

IMPORTANT

 Tell us immediately if you have any of these signs or symptoms or if they worsen. Do not try to treat your symptoms with other medicines.¹

Even seemingly mild symptoms can lead to severe or even life-threatening conditions if not addressed.²

- Take this card with you if you go to the Emergency Room or if you must see another doctor.
- Be sure to tell all healthcare professionals you see that you are being treated with YERVOY™ and SHOW THEM THIS CARD.

Be aware of important symptoms of inflammation.

YERVOY™ acts on your immune system and may cause inflammation in parts of your body.

Inflammation may cause

serious damage to your body and some inflammatory conditions may be life-threatening. The side effects are sometimes delayed, and may develop weeks or monthsafter your last dose. These side effects may require special treatment.¹

For more information, consult YERVOY™ Package Leaflet including Information for the User at www.ema.europa.eu

My physician's contact information

Name of Physician	
Office Phone	
After-hours Phone	
My Name and Phone	
Name of Caregiver (in ca	se of emergency)

For Healthcare Providers IMPORTANT information

This patient is treated by YERVOY™, which is associated with inflammatory adverse reactions. Immune-related Adverse Reactions (irARs), which can be severe or life-threatening, may involve the gastrointestinal, liver, skin, nervous, endocrine, or other organ systems. While most irARs occurred during the induction period, onset months after the last dose of YERVOY™ has also been reported. Unless an alternate aetiology has been identified, diarrhoea, increased stool frequency, bloody stool, liver function test (LFT) elevations, rash and endocrinopathy must be considered inflammatory and YERVOY™-related. Early diagnosis and appropriate management are essential to minimise life-threatening complications. YERVOY™ specific management guidelines for irARs are available.²

Permanently discontinue YERVOY and initiate systemic high-dose corticosteroid therapy for severe irARs.²

Assess patients for signs and symptoms of enterocolitis, dermatitis, neuropathy and endocrinopathy and evaluate liver and thyroid function tests before initiation of YERVOY™ and during treatment.²

Please consult YERVOY™ Summary of Product Characteristics at www.ema.europa.eu or call Medical Information at +356 23976333 pv@ammangion.com.mt for more information.

1. YERVOY™ Package Leaflet.

2. YERVOY™ Summary of Product Characteristics.

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