

# YERVOY™ (ipilimumab)

## Patient Alert Card

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

YERVOY™ 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



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# 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 untreated<sup>1</sup>

Signs and symptoms may be delayed and may occur weeks to months after your last injection<sup>1</sup>

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

### BOWEL AND STOMACH<sup>1</sup>

- 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

### LIVER<sup>1</sup>

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

### SKIN<sup>1</sup>

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

### NERVE<sup>1</sup>

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

### HORMONE-PRODUCING GLANDS<sup>1</sup>

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

### EYE<sup>1</sup>

- redness in the eye
- 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.**<sup>1</sup> Even seemingly mild symptoms can lead to severe or even life-threatening conditions if not addressed.<sup>2</sup>
- 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 months after your last dose. These side effects may require special treatment.<sup>1</sup>

For more information, consult YERVOY™ Package Leaflet including Information for the User at [www.ema.europa.eu](http://www.ema.europa.eu)

## My physician's contact information

Name of Physician

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.....

Office Phone

.....  
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After-hours Phone

.....  
.....

My Name and Phone

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Name of Caregiver (in case of emergency)

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## 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.<sup>2</sup>

Permanently discontinue YERVOY™ and initiate systemic high-dose corticosteroid therapy for severe irARs.<sup>2</sup>

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.<sup>2</sup>

Please consult YERVOY™ Summary of Product Characteristics at [www.ema.europa.eu](http://www.ema.europa.eu) or call Medical Information at +356 23976333 [pv@ammangion.com.mt](mailto:pv@ammangion.com.mt) for more information.

1. YERVOY™ Package Leaflet.

2. YERVOY™ Summary of Product Characteristics.

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