PLEASE READ

IMPORTANT MEDICINE SAFETY INFORMATION

APPROVED BY THE HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Bristol Myers Squibb®

September 2025

Updates to the Yervoy® (ipilimumab) Additional Risk Minimisation Measures (ARMM)

Dear Healthcare Professional,

The purpose of this letter is to inform you of the following updates to the Yervoy (ipilimumab) patient educational materials that are additional risk minimisation measures (ARMM):

1. **Patient Card (previously called 'Patient Alert Card') - *Updated***
   The Patient Card has been updated with the following key changes:
   - New sections 'Hormone glands' and 'Lungs' have been added, with appropriate descriptions of the main symptoms.
   - The section 'General' has been removed, and symptoms previously listed under this category have been redistributed to sections by body organ or removed.
     - The symptoms of fever, tiredness, headache, and behavioural changes (e.g., less sex drive, being irritable or forgetful) were added to the 'Hormone glands' section.
     - The symptom of bleeding was added to the 'Liver' section.
     - The symptoms of dehydration and low blood pressure were removed.
   - A new section 'Severe infusion reactions' (previously included in the Patient Information Guide) has been added, with appropriate descriptions of the main symptoms.
   - The following statement has been added before the text "If you have any signs or symptoms, tell your doctor right away":
     "Ipilimumab treatment may increase the risk of serious or even life-threatening immune-related side effects, which may affect different parts of the body."

2. **Patient Information Guide - *Retired***
   The Patient Information Guide has been retired. The updated Patient Card now covers all relevant and important sections to mitigate the important identified risks of immune-related adverse reactions (irARs) and severe infusion reactions. This allows the Patient Card to serve as a single document that replaces the previously available patient educational materials.

Please discard previous versions of the Patient Alert Card and Patient Information Guide that you may have.

In agreement with the Health Products Regulatory Authority (HPRA) and under the terms of the marketing authorisation, the following ARMM is available for Yervoy:

- **Patient Card – to be distributed by the Healthcare Professional to patients**
  The purpose of this educational material is to ensure that patients are aware of the severe inflammatory adverse reactions, and understand the importance of their early recognition and appropriate management. The safety concerns addressed by the

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This is a non-promotional letter intended for Healthcare Professionals in Ireland only.

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Patient Card include the important identified risks of irARs and severe infusion reactions.

Enclosed with this letter are 3 hard copies of the updated Patient Card. We kindly request that you disseminate this updated Patient Card to other relevant colleagues to ensure that all healthcare professionals involved in the care of patients receiving Yervoy are aware of these updates.

Reporting adverse events

Reporting of suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via HPRA Pharmacovigilance at www.hpra.ie.

Adverse reactions should also be reported to Bristol-Myers Squibb Medical Information on 1 800 749 749 or medical.information@bms.com.

When reporting please provide as much information as possible, including information about medical history, any concomitant medication, onset, treatment dates and product brand name.

Resources

Electronic copies of the Yervoy Summary of Product Characteristics (SmPC), Patient Information Leaflet (PIL), and Patient Card can be viewed and/or downloaded via:

- https://www.medicines.ie/
- https://www.hpra.ie/

Hard copies of the Yervoy SmPC, PIL and Patient Card can be ordered by contacting BMS Medical Information on 1 800 749 749 or medical.information@bms.com.

Company Contact Point

Should you have any questions or require further information regarding the use of Yervoy, please contact BMS Medical Information on 1 800 749 749 or medical.information@bms.com.

Yours sincerely,

Hartridge-Lambert, Sidonie (00408945) Digitally signed by Hartridge-Lambert, Sidonie (00408945) Date: 2025.08.20 13:50:45 +01'00'

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