

PLEASE READ

**IMPORTANT MEDICINE
SAFETY INFORMATION**

APPROVED
BY THE



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

SEP 2026

Dear Healthcare Professional,

RE: Opdualag (nivolumab
and relatlimab fixed dose
combination) - Patient
Card Update

Opdualag® ▼ is indicated for the first-line treatment of advanced (unresectable or metastatic) melanoma in adults and adolescents 12 years of age and older with tumour cell PD-L1 expression < 1%.

As part of BMS's commitment to patient safety and to fulfil the requirements of the marketing authorisation for nivolumab and relatlimab fixed dose combination (FDC), BMS introduced a nivolumab and relatlimab FDC Patient Card as an additional risk minimisation material, two copies of which are enclosed.

The **Patient Card**, which has been approved by the Health Products Regulatory Authority (HPRA), **has been updated**. The main update is the **addition of "(both possibly fatal)" to the following description of side effects in the skin section of the Patient Card: "Rash, itching; blistering or peeling skin (both possibly fatal); painful sores or ulcers in the mouth."**

Please discard any previous versions of the Patient Card that you may have. We also kindly request that you share the information in this letter with other relevant healthcare professionals involved in the care of patients receiving nivolumab and relatlimab FDC, and provide them with a copy of the updated Patient Card.

Updated Patient Card - to be distributed by Healthcare Professionals to the patient

- The Patient Card provides important information to support patient awareness on the signs and symptoms of the important identified risks of immune-related adverse reactions and the need to seek immediate medical attention if these signs or symptoms occur, persist, or worsen. Please explain the card to the patient and their carers.
- All patients prescribed nivolumab and relatlimab FDC should be given an updated Patient Card to carry with them at all times, including after stopping treatment.

Date of Preparation: SEP 2026, Date of HPRA Approval: SEP 2026,
1425-GB-2600067

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Resources

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

Call for reporting

▼ This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. 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

Company Contact Point

Should you have any questions or require further information regarding nivolumab and relatlimab FDC, please contact BMS Medical Information on 1 800 749 749 or medical.information@bms.com

Yours sincerely,

**Hartridge-
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