



# MEDICINES RECALL

## CLASS 3 MEDICINES RECALL

Action Within 5 Days  
Pharmacy/Wholesaler Level Recall

Date: 04 April 2024

EL (24)A/11

Our Ref: MDR 181-03/24

Dear Healthcare Professional,

### Bristol-Myers Squibb Pharmaceuticals Limited

**OPDIVO 10 mg/mL concentrate for solution for infusion  
(nivolumab)**

**PLGB 15105/0133**

**SNOMED Code** 29887611000001103

Batch No	Expiry Date	Pack Size	First Distributed
8053520	31/12/2025	1	10/11/2023

Active Pharmaceutical Ingredient: nivolumab

#### Brief description of the problem

Bristol-Myers Squibb Pharmaceuticals Limited has informed the MHRA that a potential product quality issue has been detected, relating to incomplete crimping of the metal crimp cap of OPDIVO 10mg/mL concentrate for solution for infusion (nivolumab) (1VLX10ML). Four thousand (4,000) units of the concerned batch, specified in the above table, was distributed in Great Britain (GB) between 10 November 2023 - 5 December 2023. This defect has been reported in vials manufactured from the same bulk batch in another market, although no defects have been reported in the UK market.

#### Advice for healthcare professionals

Stop using the above batches immediately. Quarantine all remaining stock and return it to your supplier using your supplier's approved process. No further action is required concerning product that has already been administered.

#### Advice for patients

No action is required by patients as this is a Pharmacy and Wholesaler level recall. This product is administered by healthcare professionals directly. If you have concerns about a medicine you may be using, please contact your healthcare professional.

Patients who experience adverse reactions or have any questions about the medication should seek medical attention. Any suspected adverse reactions should also be reported via the [MHRA Yellow Card scheme](#).

#### Further information

For medical information enquiries please contact the Bristol Myers Squibb Medical Information Department by phone (0800 731 1736) or email ([medical.information@bms.com](mailto:medical.information@bms.com)).



# Medicines & Healthcare products Regulatory Agency

Recipients of this Medicines Recall should bring it to the attention of relevant contacts by copy of this notice. NHS regional teams are asked to forward this to community pharmacists and dispensing general practitioners for information.

Yours faithfully

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