

OPDIVO[®]

(nivolumab)

Patient Card

This Patient Card fulfils the conditions of the marketing authorisation and has been approved by the Medicines and Healthcare products Regulatory Agency (MHRA) and Health Products Regulatory Authority (HPRA).

Date of MHRA Approval: APR 2026 Date of HPRA Approval: MAR 2026

Local Approval Number: 1506-GB-2500229 Date of Preparation: April 2026



IMPORTANT Information for Patients

Carry this card with you at all times to inform healthcare professionals that you are receiving treatment with nivolumab, or nivolumab in combination with YERVOY[®] (ipilimumab).



Nivolumab can increase the risk of serious or even life-threatening side effects, which may affect different parts of the body. If you have any signs or symptoms, tell your doctor right away. This includes any possible side effects not included in this card or in the nivolumab package leaflet.

POSSIBLE SIDE EFFECTS



Chest (heart and lungs)

Breathing difficulties, cough, wheeze, chest pain, irregular heartbeat, palpitations (increased awareness of your heartbeat)



Gut (stomach and bowels)

Diarrhoea (watery, loose, or soft stools), blood or mucus in stools, dark-coloured stools, pain or tenderness in your stomach or abdominal area



Liver

Eye or skin yellowing (jaundice), pain on the right side of your stomach area



Kidneys

Change in amount and/or frequency of urine



Hormone-producing glands (including diabetes)

Headaches, blurry or double vision, fatigue (tiredness), weight changes, behavioural changes (eg, lower sex drive, irritability, or forgetfulness), excessive thirst, increased appetite with weight loss, weakness, drowsiness, depression, feeling unwell, change in amount and/or frequency of urine



Skin

Rash, itching, blisters and/or peeling of the skin (possibly fatal), ulcers, dry skin, skin nodules



Other

Weakness, fatigue (tiredness), decreased appetite, nausea, vomiting, tingling or numbness in arms and legs, difficulty walking, fever, swollen lymph nodes, headache, seizures, stiff neck, confusion, drowsiness, muscle pain, stiffness, dark urine, eye pain or redness, blurry vision, or other vision problems

IMPORTANT

- Tell your doctor of any previous medical conditions, including if you have had a stem cell transplant that uses donor stem cells (allogeneic).
- Early assessment and management of side effects by your doctor reduces the likelihood that treatment with nivolumab, or nivolumab in combination with ipilimumab will need to be temporarily or permanently stopped.
- Signs and symptoms that may appear mild can quickly worsen if left untreated.

• **DO NOT** try to treat these symptoms yourself.

• Signs and symptoms can appear during treatment or may be delayed and may occur weeks to months after your last injection.

For more information, read the nivolumab package leaflet [via www.medicines.org.uk/emc (UK), www.medicines.ie (Ireland)] or call Bristol-Myers Squibb Medical Information on 0800 731 1736 (UK); 1 800 749 749 (Ireland).

IMPORTANT Information for Healthcare Professionals

- This patient is treated with nivolumab, or nivolumab in combination with ipilimumab.
- Immune-related adverse reactions may appear at any time during treatment or months after its discontinuation.
- Early diagnosis and appropriate management are essential to minimise life-threatening complications.
- Consultation with an oncologist or other medical specialist may be helpful for management of organ-specific immune-related adverse reactions.

- Healthcare professionals should refer to the nivolumab Summary of Product Characteristics (SmPC) [via www.medicines.org.uk/emc (UK), www.medicines.ie (Ireland)] or call Bristol-Myers Squibb Medical Information on 0800 731 1736 (UK); 1 800 749 749 (Ireland) for more information.

The healthcare professional treating this patient with nivolumab, or nivolumab in combination with ipilimumab should complete the 'My Doctor's Contact Information' section of this Patient Card.

My Doctor's Contact Information

(who prescribed nivolumab, or nivolumab in combination with ipilimumab)

Name of Doctor: _____

Office Phone: _____

After-Hours Phone: _____

My Contact Information

My Name: _____

My Phone Number: _____

Emergency Contact (name and phone number):

Reporting of side effects:

By reporting side effects, you can help provide more information on the safety of this medicine.

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in the package leaflet. You can also report side effects directly.

UK - see www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store for how to report side effects.

Ireland - via HPRA Pharmacovigilance at www.hpra.ie

Side effects should also be reported to Bristol-Myers Squibb via medical.information@bms.com or 0800 731 1736 (UK); 1 800 749 749 (Ireland).

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