

OPDIVO®/TM (nivolumab)

Patient Card

This Patient Card fulfills the conditions of the marketing authorisation and has been approved by
the Medicines Authority

Date of Health Authority approval: 6 January 2026
Local Approval Number: 1506-MT-2500001

Important Information for Patients

Carry this card with you at all times to inform healthcare professionals that you are receiving treatment with nivolumab, <nivolumab SC (or local generic name) for subcutaneous injection if required> or nivolumab in combination with YERVOY® (ipilimumab).

 Bristol Myers Squibb®

 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 <insert local patient labelling/package leaflet as appropriate>.

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 previous medical conditions, including if you have had a stem cell transplant that used donor stem cells (allogeneic).
- Early assessment and management of side-effects by your doctor reduces the likelihood that treatment with nivolumab, <nivolumab SC (or local generic name) if required> 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 **PIL** or call Medical Information on Tel - + 356 23976333

IMPORTANT Information for Healthcare Professionals

- This patient is treated with nivolumab, nivolumab SC (or local generic name) if required> 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 SmPC or call Medical Information on 00 356 23976333 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, <nivolumab SC (or local generic name) if required> 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):

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REPORTING OF ADVERSE REACTIONS

The safe use of pomalidomide is of paramount importance. As part of BMS' s ongoing safety monitoring, the company wishes to learn of Adverse Reactions that have occurred during the use of pomalidomide. *Healthcare professionals are asked to report any suspected adverse reactions via www.medicinesauthority.gov.mt/adrportal*

Please also report any suspected adverse reactions to AM Mangion Ltd on pv@ammangion.com or call + 356 23976333