OPDIVO® (nivolumab)

Patient Alert Card

Date of UK Health Authority Approval: 18 October 2022
Date of Irish Health Authority Approval: 24 October 2022
Local Approval Number: 1506-GB-2200414
Date of Preparation: September 2022

Bristol Myers Squibb™

Important Information for Patients

Please 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). It is important that you keep this card for at least 5 months after completing your treatment.

If you have any signs or symptoms, tell your doctor right away.

IMPORTANT

- Nivolumab treatment may increase the risk of serious or even life-threatening immune-related side-effects, which may affect different parts of the body, for example:

  - **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
  - **Skin:** rash, itching, blisters and/or peeling of the skin (possibly fatal), ulcers, dry skin, skin nodules
  - **Hormone-producing glands (including Diabetes):** headaches, blurry or double vision, fatigue (tiredness), weight changes, behavioural changes (e.g. lower sex drive, irritability or forgetfulness), excessive thirst, increased appetite with weight loss, weakness, drowsiness, depression, irritability, feeling unwell, change in amount and/or frequency of urine
  - **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

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)**

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 or nivolumab in combination with ipilimumab will need to be temporarily or permanently stopped.
- **DO NOT** try to treat these symptoms yourself.
- Signs and symptoms that may appear mild can quickly worsen if left untreated.
- Signs and symptoms 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 (Great Britain - UK), www.emcmedicines.com/en-gb/northernireland/ (Northern Ireland - UK), www.medicines.ie (Ireland)]** or call Bristol-Myers Squibb Medical Information on 0800 731 1736 **(UK);** 1 800 749 749 **(Ireland).**

My Doctor's Contact Information ***(who prescribed nivolumab or nivolumab in combination with ipilimumab)***

Name of Doctor: _____

Office Phone: _____

Out-of-Hours Phone: _____

My Contact Information

My Name: _____

My Phone Number: _____

Emergency Contact (name and phone number):

_____

IMPORTANT Information for Healthcare Professionals

- This patient is treated with **nivolumab** or **nivolumab in combination with ipilimumab.**
- Immune-related adverse reactions (irARs) 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 irARs.
- Healthcare professionals should refer to the nivolumab Summary of Product Characteristics (SmPC) [via www.medicines.org.uk/emc **(Great Britain - UK)**, www.emcmedicines.com/en-gb/northernireland/ **(Northern Ireland - 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 Alert Card.