▼Opdualag™
(nivolumab and relatlimab)

Patient Card

This Patient Card is part of the marketing authorisation *and has been approved by the Medicines Authority.*

Date of Health Authority Approval: *15 December 2022*
Document Version Number: *1425-MT-2200001*

▼This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side affects you may get.

Bristol Myers Squibb™

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Information for Patients

Please carry this card with you at all times to inform any healthcare professionals treating you (e.g. doctor, nurse, pharmacist, emergency department personnel) that you are receiving treatment with Opdualag.

IMPORTANT

Opdualag can cause serious immune-related side effects that can affect different parts of the body. These side effects can occur at any time, may be delayed and may occur weeks to months after your last dose of treatment. Some of the following side effects can be life-threatening and need to be addressed immediately:

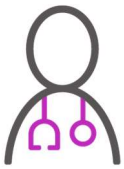
Body Part	**Possible Side Effects**
Lung	New or worsening cough, shortness of breath, breathing difficulties or chest pain.
Stomach and bowel (gut)	Diarrhoea (watery, loose or soft stools) or more frequent bowel movements than usual; stools that are black, tarry, sticky or have blood or mucus; or stomach area (abdomen) pain or tenderness.
Liver	Yellowing of the skin or the whites of the eyes (jaundice), nausea or vomiting, pain in the right side of stomach area (abdomen), dark urine, tiredness, bleeding or bruising more easily than usual.
Hormone glands (including diabetes and diabetic ketoacidosis)	Headaches, increased sweating, weight gain or loss, increased tiredness, increased hunger or thirst, needing to urinate more often, hair loss, feeling cold, constipation, changes in voice, dizziness or fainting, changes in mood or behaviour, sensitivity to light, eye problems, rapid heartbeat, having difficulty thinking clearly, breath that smells sweet or fruity, a sweet or metallic taste in your mouth, a different odour to your urine or sweat, feeling sick or being sick, stomach (abdomen) pain, and deep or fast breathing.
Kidneys	Decrease in amount of urine, swelling in the ankles, loss of appetite or blood in urine.
Skin	Rash, itching, blistering or peeling skin; painful sores or ulcers in the mouth.
Heart	New or worsening chest pain, irregular and/or rapid heartbeat, fatigue, swelling in the ankles or shortness of breath.
General/Other	Confusion, sleepiness, memory problems, stiff neck, balance problems, tingling or numbness of the arms or legs, double vision, eye pain, changes in eyesight, persistent or severe muscle pain or weakness, muscle cramps or swollen lymph glands.

If you experience any of the signs or symptoms listed above, or if symptoms persist or worsen, tell your doctor or nurse or seek other medical attention **immediately**.

Immune-related side effects can also occur in other organs and tissues. This Patient Card does not describe all the signs and symptoms of problems associated with Opdualag treatment. If you get any side effects, even those not listed in this card or the package leaflet, talk to your doctor, nurse or pharmacist.

MORE INFORMATION

- Tell your doctor of any previous or current medical conditions or past/current treatments. This includes if you have received or plan to receive a stem cell transplant using donor stem cells (allogeneic) or have had an organ transplant.
- Early identification and management of side effects are important to help ensure the safe use of Opdualag. Signs and symptoms that may appear mild can quickly worsen if left untreated.
- **DO NOT** attempt to treat any symptoms yourself. It is very important that you reach out to your doctor or nurse for advice.
- If you have any side effects, you may need other medicines to reduce your symptoms or prevent them from worsening. Your doctor may also need to delay or completely stop treatment with Opdualag if you develop severe side effects.
- For more information, read the Opdualag package leaflet *https://www.ema.europa.eu/en/documents/product-information/opdualag-epar-product-information_en.pdf* or call Bristol Myers Squibb Medical Information on *00 356 2397 6333.*



IMPORTANT Information for Healthcare Professionals

- This patient is being treated with Opdualag, which can cause serious immune-related adverse reactions (irARs) that can affect various organ systems and lead to death.

- irARs can occur at any time, may be delayed and may appear weeks to months after treatment discontinuation.
- Early diagnosis and appropriate management of irARs are essential to help 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 Opdualag SmPC *https://www.ema.europa.eu/en/documents/product-information/opdualag-epar-product-information_en.pdf* or call Bristol Myers Squibb Medical Information on *00 356 2397 6333* for further information.

REPORTING OF ADVERSE REACTIONS: Suspected adverse reactions and medication errors should be reported at ADR Reporting, The Medicines Authority, Post-Licensing Directorate, Sir Temi Zammit Buildings, Malta Life Sciences Park, San Gwann SGN 3000, Malta
Website: www.medicinesauthority.gov.mt
e-mail: postlicensing.medicinesauthority@gov.mt OR ADR Reporting: www.medicinesauthority.gov.mt/adrportal
Adverse reactions could also be reported to Bristol-Myers Squibb Medical Information at 00 356 2397 6333 or pv@ammangion.com.

Doctor's Contact Details (who prescribed Opdualag)
Please complete in CAPITAL LETTERS.

Name of Doctor: _____

Office Phone: _____

Out-of-Hours Phone: _____

My Contact Details
Please complete in CAPITAL LETTERS.

My Name: _____

My Phone Number: _____

Emergency Contact: Name: _____

Phone Number: _____