Opdualag™ ▼

(nivolumab and relatlimab)

Patient Card

This Patient Card has been approved by the Health Products Regulatory Authority.

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Bristol Myers Squibb™

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 nivolumab and relatlimab.

IMPORTANT

Nivolumab and relatlimab 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. The side effects need to be addressed immediately, some can be life-threatening.

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.

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 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 nivolumab and relatlimab 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 nivolumab and relatlimab. Signs and symptoms that may appear mild can quickly worsen if left untreated.
- 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 nivolumab and relatlimab if you develop severe side effects.
- **YOU SHOULD** also read the nivolumab and relatlimab package leaflet via www.ema.europa.eu/en/medicines/human/EPAR/opdualag (under Product Information), or call Bristol-Myers Squibb Medical Information on 1 800 749 749.

▼This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. 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 report side effects directly via HPRA Pharmacovigilance at www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine. Side effects should also be reported to Bristol-Myers Squibb Medical Information on 1 800 749 749 or medical.information@bms.com.

IMPORTANT Information for Healthcare Professionals

- This patient is being treated with nivolumab and relatlimab, 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 nivolumab and relatlimab Summary of Product Characteristics (SmPC) via www.ema.europa.eu/en or call Bristol-Myers Squibb Medical Information on 1 800 749 749 for further information.

Doctor's Contact Details (who prescribed nivolumab and relatlimab)
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: _____