OPDIVO® (nivolumab) Patient Alert Card

IMPORTANT - This card contains important safety information that you need to be aware of before, during and after treatment with nivolumab or nivolumab in combination with ipilimumab (Yervoy®). Keep this card with you in your wallet and show it to any healthcare professional involved in your treatment, not just your prescribing specialist doctor. It is important that you keep this card for at least 5 months after completing your treatment.

Date of Preparation: December 2017
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This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See www.mhra.gov.uk/yellowcard for how to report side effects or search for MHRA Yellow Card in the Google Play or Apple App Store. Side effects should also be reported to Bristol-Myers Squibb Medical Information on 0800 731 1736 or medical.information@bms.com
This card contains important information. 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 ipilimumab.

Tell your doctor right away if you have any of these symptoms or any other symptoms:

**LUNGS¹**
- Breathing difficulties, cough

**BOWEL and STOMACH¹**
- Diarrhoea (watery, loose or soft stools), blood or mucus in your stools, dark-coloured stools, pain or tenderness in your stomach or abdominal area

**LIVER¹**
- Eye or skin yellowing (jaundice), pain on the right side of your stomach area, tiredness

**KIDNEYS¹**
- Decreased amount of urine

**DIABETES/DIABETIC KETOACIDOSIS¹**
- Excessive thirst, increased appetite with a loss of weight, tiredness, weakness, drowsiness, depression, irritability, feeling unwell, increased amount of urine

**SKIN¹**
- Severe skin reactions, like skin rash with or without itching, blisters and/or peeling of the skin (possibly fatal), ulcers, dry skin, skin nodules

**HORMONE-PRODUCING GLANDS²**
- Headaches, blurry or double vision, fatigue (extreme tiredness), weight changes, behavioural changes (e.g. less sex drive, irritability or forgetfulness)

**HEART¹**
- Chest pain, irregular heartbeat, palpitations

**MUSCLES¹**
- Muscle pain, stiffness, weakness, confusion, decreased amount of urine, dark urine, severe fatigue

**OTHER¹**
- Eye pain or redness, blurry vision, or other vision problems; upper abdominal pain, decreased appetite, nausea or vomiting; indigestion or heartburn; tingling or numbness in arms and legs, or difficulty walking; fever, swollen lymph nodes; signs or symptoms of inflammation of the brain, which may include headache, fever, seizures, stiff neck, tiredness, confusion, weakness or drowsiness

**TELL YOUR DOCTOR BEFORE YOU START RECEIVING NIVOLUMAB IF YOU:**

- Know you are allergic to nivolumab or any other medicine or medicine ingredients
- Have an autoimmune disease
- Have melanoma of the eye
- Have experienced side effects with another drug, such as ipilimumab
- Have been told your cancer has spread to your brain
- Have taken medicine to suppress your immune system

- Have received a transplant (nivolumab may cause rejection of transplanted organs; e.g. kidney, liver, heart, cornea, or skin)
- Have any history of inflammation of the lungs
- Are pregnant or planning to become pregnant, or are breast-feeding
- Are taking or have taken any other medicines
- Are on a low salt diet

For further information, consult the Opdivo Package Leaflet, which can be found at www.medicines.org.uk/emc or call Bristol-Myers Squibb Medical Information on 0800 731 1736
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. Nivolumab-specific management guidelines for irARs are available.

Consultation with an Oncologist or other medical specialist may be helpful for management of organ-specific irARs.

For further information, please consult the Opdivo (nivolumab) Summary of Product Characteristics and Opdivo Important Safety Information To Minimise The Risks Of Immune-Related Adverse Reactions, both located at www.medicines.org.uk/emc. You may also contact the Bristol-Myers Squibb Medical Information Department (telephone: 0800 731 1736; email: medical.information@bms.com) for further information.