

Opdivo[®] ▼ (nivolumab)

Patient Alert Card

Date: November 2018
1506UK1800878-02



Bristol-Myers Squibb



This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. 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 Freepost, HPRA
Pharmacovigilance, Earlsfort Terrace,
IRL - Dublin 2; Tel:+353 1 6764971;
Fax:+353 1 6762517. Website: www.hpra.ie;
E-mail: medsafety@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)

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Opdivo®

This card contains important information about your treatment. It is important that you keep this card for at least 5 months after completing your treatment.

Please carry this card with you at all times to inform healthcare professionals that you are receiving treatment with Opdivo® or Opdivo® in combination with Yervoy® (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 loss of weight, tiredness, weakness, drowsiness, depression, irritability, feeling unwell, increased amount of urine

SKIN¹

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 GLANDS¹

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

IMPORTANT

- Early management of side effects by your doctor reduces the likelihood that treatment with Opdivo® or Opdivo® in combination with Yervoy® will need to be temporarily or permanently stopped.
- Symptoms that may appear mild can quickly worsen if left untreated.¹
- Don't try to treat these symptoms yourself.
- Report any of these symptoms or any other symptoms to your doctor right away.
- Signs and symptoms may be delayed, and may occur weeks to months after your last injection.¹
- Carry this card with you at all times to inform healthcare professionals that you are receiving treatment with Opdivo® or Opdivo® in combination with Yervoy®.



TELL YOUR DOCTOR BEFORE YOU START RECEIVING OPDIVO® IF YOU:

- Know you are allergic to Opdivo® or any other medicine or medicine ingredients
- Have an autoimmune disease (a condition where the body attacks its own cells) such as arthritis, Crohn's disease
- Have melanoma of the eye
- Have experienced side effects with another drug, such as Yervoy®
- Have been told your cancer has spread to your brain
- Have taken medicine to suppress your immune system
- Have received a transplant (Opdivo® may cause rejection of transplanted organs; e.g. kidney, liver, heart, cornea, or skin)
- Have received a bone marrow or stem cell transplant from another person (allogeneic)
- 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

If you are receiving treatment with Opdivo® alone, please consult the Opdivo® Package Leaflet for further information. If you are receiving treatment with Opdivo® in combination with Yervoy®, please refer to both the Opdivo® and the Yervoy® Package Leaflet for further information. Both Package Leaflets can be found at www.medicines.org.uk/emc (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

Name of Doctor:

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Office Phone:

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After-Hours Phone:

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My Contact Information

My Name and Phone Number:

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Emergency Contact (in case of emergency):

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IMPORTANT Information for Healthcare Professionals

- This patient is treated with **Opdivo®** or **Opdivo® in combination with Yervoy®**.
- 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. Opdivo®- specific management guidelines for irARs are available.
- Consultation with an Oncologist or other medical specialist may be helpful for management of organ-specific irARs.

Healthcare professionals should consult the Opdivo® Summary of Product Characteristics (SmPC) and the Opdivo® Important Risk Minimisation Information for Healthcare Professionals.

For **UK**, the Opdivo® SmPC and Opdivo® Important Risk Minimisation Information for Healthcare Professionals can be viewed online via www.medicines.org.uk/emc.

For **Ireland**, the Opdivo® SmPC can be viewed online via www.medicines.ie. The Opdivo® Important Risk Minimisation Information for Healthcare Professionals can be viewed online via www.medicines.ie or www.hpra.ie/homepage/medicines/medicines-information/find-a-medicine.

You may also contact the Bristol-Myers Squibb Medical Information Department via medical.information@bms.com or 0800 731 1736 (UK); 1 800 749 749 (Ireland) for further information or hard copies of the above educational materials.

1. Opdivo® Package Leaflet