OPDIVO® (NIVOLUMAB)

Injection for intravenous use

Patient Alert Card

Bristol-Myers Squibb

More information. This information can also be found at http://www.bms-arma.nl/opdivo/pacEN Please read the patient information leaflet for more information about your medicine. Visit your doctor or pharmacist with questions about your medication. This material is approved by the Dutch Medicines Evaluation Board (www.cbg-meb.nl).

▼ This medicine is subject to additional monitoring. This ensures that we are able to quickly identify new safety information about this medicine. Contact your doctor if you have an adverse event. Also contact your doctor in case of adverse events which are not described in the patient information leaflet. You can report adverse events via the Netherlands Pharmacovigilance Centre Lareb, website: www.lareb.nl

By reporting adverse events you help us collect more information about the safety of this medicine. Adverse events can also be reported at any time to the marketing authorisation holder of the product.

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150616LTRNP03718

Contact details of the treating physician

Name of your physician

Office phone

After hours phone

Contact details of the patient

Your name

Your phone number

Emergency contact (ICE)

OPDIVO (nivolumab)
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.

LUNGS
breathing difficulties, cough

BOWEL and STOMACH
diarrhoea (watery, loose or soft stools), blood or mucus in your 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, tiredness

KIDNEYS
decreased amount of urine

DIABETES/DIABETIC KETOACIDOSIS
excessive thirst, increased appetite with loss of weight, tiredness, weakness, drowsiness, depression, irritability, feeling unwell, increased amount of urine

SKIN
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 GLANDS
headaches, blurry or double vision, fatigue (extreme tiredness), weight changes, behavioural changes (e.g. less sex drive, irritability or forgetfulness)

HEART
chest pain, irregular heartbeat, palpitations

MUSCLES
muscle pain, stiffness, weakness, confusion, decreased amount of urine, dark urine, severe fatigue

OTHER ADVERSE EVENTS
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 nivolumab or nivolumab in combination with ipilimumab will need to be temporarily or permanently stopped
- Symptoms that may appear mild can quickly worsen if left untreated
- 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

IMPORTANT
information for healthcare professionals

- This patient is treated with **nivolumab or nivolumab in combination with ipilimumab**
- Immune-related adverse events (irAR's) 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

Healthcare professionals should consult the OPDIVO® Summary of Product Characteristics on **www.ema.europa.eu** or call Bristol-Myers Squibb Medical Information on **+31 (0)303002 222** for more information.