

OPDIVO® (NIVOLUMAB)

Patient Alert Card

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.

 Bristol Myers Squibb™

Bristol Myers Squibb B.V.

Phone number: 030 - 3002 222

E-mail: medischeafdeling@bms.com

More information.

This information can also be found at

www.bms-arma.nl/opdivo/pac-EN. 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).

Contact details of your treating physician

Name of your physician

Office phone

After hours phone

Contact details of the patient

Your name

Your phone number

Emergency contact (name and phone number)

Important information for patients

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.



If you have any signs or symptoms, tell your doctor right away.



IMPORTANT OPDIVO® treatment may increase the risk of serious or even life threatening immune-related side-effects, which may affect different parts of the body, for example:

CHEST (heart and lungs):

- breathing difficulties
- cough
- wheeze
- chest pain
- irregular heartbeat
- palpitations (increased awareness of your heartbeat)

GUT (bowel and stomach)

- diarrhea (watery, loose or soft stools)
- blood or mucus in 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

KIDNEYS

- change in amount and/or frequency of urine

HORMONE PRODUCING GLANDS (including Diabetes):

- headaches
- blurry or double vision

- fatigue (tiredness)
- weight changes
- behavioural changes (e.g. lower sex drive, irritability or forgetfulness)
- excessive thirst
- increased appetite with weight loss
- weakness
- drowsiness
- depression
- irritability
- feeling unwell
- change in amount and/or frequency of urine

SKIN

- rash
- itching
- blisters and/or peeling of the skin (possibly fatal)
- ulcers
- dry skin
- skin nodules

OTHER ADVERSE EVENTS

- weakness
- fatigue (tiredness)
- decreased appetite

- nausea
- vomiting
- tingling or numbness in arms and legs
- difficulty walking
- fever
- swollen lymph nodes
- headache
- seizures
- stiff neck
- confusion
- drowsiness
- muscle pain
- stiffness
- dark urine
- eye pain or redness
- blurry vision, or other vision problems



IMPORTANT

- Tell your doctor of previous medical conditions, including if you have had a stem cell transplant that used donor stem cells (allogeneic)
- Early assessment and 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
- Signs and symptoms that may appear mild can quickly worsen if left untreated
- Do not try to treat these symptoms yourself
- Signs and symptoms may be delayed and may occur weeks to months after your last injection with nivolumab or nivolumab and ipilimumab

For more information, read the nivolumab Package Leaflet or call Medical Information on **030 - 3002 222**.



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
- Consultation with an oncologist or other medical specialist may be helpful for management of organ-specific irARs
- Healthcare professionals should consult the nivolumab Summary of Product Characteristics on www.ema.europa.eu or call Bristol Myers Squibb Medical Information on +31 (0)303002 222 for more information



IMPORTANT

The healthcare professional treating this patient with nivolumab or nivolumab in combination with ipilimumab should complete the 'Contact details of your treating physician' section of this Patient Alert Card.