

OPDIVO[®]

(nivolumab)

Injection for intravenous infusion

Patient Alert Card

Nivolumab is subject to additional monitoring to quickly identify new safety information. You can help by reporting any side effects you may get.

IMPORTANT - This card contains important safety information that you need to be aware of before and during treatment with nivolumab. Keep this card with you in your wallet and show it to any doctor involved in your treatment, not just your prescribing specialist doctor.



Bristol-Myers Squibb

My Oncologist's contact information

Name of Oncologist:

Contact number:

My name:

Contact number:

In case of an emergency, please contact:

IMPORTANT

Nivolumab can cause serious side effects that need to be treated right away

Call your Oncologist right away if you have any of these signs or symptoms

- **Problems with your lungs**, such as breathing difficulties or cough. These may be signs of inflammation of the lungs.
- **Diarrhoea**: watery, loose or soft stools or any symptoms of inflammation of the intestines (colitis), such as stomach pain and mucus or blood in stool.
- **Liver problems**: signs and symptoms may include eye or skin yellowing (jaundice), pain on the right side of your stomach area, or tiredness.
- **Inflammation or problems with your kidneys**: Signs and symptoms may include a decreased volume of urine.
- **Problems with your hormone producing glands** (including the thyroid and adrenal glands). Signs and symptoms that your glands are not working properly may include fatigue (extreme tiredness), weight change or headache and visual disturbances.
- Symptoms of **diabetes** which include excessive thirst, the passing of a greatly increased amount of urine, increased appetite with a loss of weight, feeling tired, drowsy, weak, depressed, irritable and generally unwell.
- **Rash**: skin rash and/or itchiness.

Also tell your doctor if you experience any other symptoms not listed on this card

Do **not** try to treat your symptoms with other medicines on your own

Symptoms may occur at any time during treatment or even after your treatment has ended

Like all medicines, this medicine can cause side effects, although not everybody gets them. Your doctor will discuss these with you and will explain the risks and benefits of your treatment. These signs and symptoms can occur at any time and are **sometimes delayed**, and may develop weeks or months after your last dose.

Getting medical treatment immediately may stop the problem from becoming more serious. Your doctor may decide to give you other medicines to prevent complications and reduce your symptoms, withhold the next dose or stop your treatment.

For further information please read the patient information leaflet, which can be found at [\[Insert EMA link to patient leaflet\]](#)

IMPORTANT Reminders for Patients

Nivolumab is a medicine to treat advanced (metastatic) melanoma, a type of skin cancer that has spread, or melanoma that cannot be removed by surgery.

Like all medicines, this medicine may cause side-effects, although not everybody gets them. It is important to tell your doctor **immediately** if you have any of the signs or symptoms listed on this card. You should also tell your Healthcare Professional if you:

- have an autoimmune disease
- have melanoma of the eye
- were previously given ipilimumab (YERVOY), another medicine for the treatment of melanoma, and experienced serious side effects
- are pregnant or planning to become pregnant
- are breast feeding
- are taking or have recently taken any other medicines

You should not start any other medicines during your treatment without talking to your doctor first.

If you have any further questions about your treatment or on the use of this medicine, please contact your doctor.

If you have any signs or symptoms listed on this card or if you notice any side effects not listed in this card contact your doctor immediately. Getting medical treatment early may stop the problem from becoming more serious.

It is important that you carry this card with you **at all times** whilst you are receiving treatment with this medicine. Please ensure you show this card to all Healthcare Professionals and doctors involved in your treatment, not just your prescribing doctor, and at any visits to the hospital.

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 <insert national reporting system details> for how to report side effects. Side effects should also be reported to Bristol-Myers Squibb Medical Information on <insert telephone number> or <insert email address>.

<Insert BMS disclaimer>
<Insert Date of Preparation>
<Insert Job Code>

IMPORTANT INFORMATION For Healthcare Providers

- This patient is being treated with nivolumab
- Nivolumab is associated with adverse reactions resulting from increased immune activity
- Alternate aetiology should be ruled out and use of immunosuppressive therapy should be considered
- Patients should be monitored continuously (at least up to 5 months after the last dose) as an adverse reaction with nivolumab may occur at any time during or even months after discontinuation of nivolumab therapy
- Treatment with nivolumab should be discontinued if a patient has Grade 3 or 4 pneumonitis, Grade 4 diarrhoea or colitis, Grade 3 or 4 elevation in aspartate aminotransferase, alanine transaminase, or total bilirubin, Grade 4 creatinine elevation, or Grade 4 rash
- Nivolumab should also be permanently discontinued for Grade 2 or 3 immune-related adverse reactions that persist despite treatment modifications or for inability to reduce corticosteroid dose to 10 mg prednisone or equivalent per day
- If immunosuppression with corticosteroids is used to treat an adverse reaction, a taper of at least 1 month duration should be initiated upon improvement
- Rapid tapering may lead to worsening of the adverse reaction
- Non-corticosteroid immunosuppressive therapy should be added if there is worsening or no improvement despite corticosteroid use
- Nivolumab should not be resumed while the patient is receiving immunosuppressive doses of corticosteroids or other immunosuppressive therapy
- Prophylactic antibiotics should be considered to prevent opportunistic infections in patients receiving immunosuppressive therapy

Please consult nivolumab's Summary of Product Characteristics at <insert BMS information>, or call Bristol-Myers Squibb < Insert BMS phone number> for more information.





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