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.

Mercury code: 1506MT15NP08693-01 Approval date: 11.12.2015

[Page 2, as seen when opened on left hand side]

My Oncologist's contact information

Name of Oncologist:

.....

Contact number

.....

My name

.....

Contact number

.....

In case of an emergency, please contact:

.....

[Page 2, as seen when opened in centre and right hand sections]

Important

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

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

- **Problems with your lungs,** such as breathing difficulties or cough. These may be symptoms 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 may include a decreased volume of urine.
- **Problems with your hormone producing glands** (including the pituitary, 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.

It is important to be aware of the symptoms of inflammation. Nivolumab acts on your immune system and may cause inflammation in parts of your body. Inflammation may cause serious damage to your body and some inflammatory conditions may be life-threatening. Please speak with your Healthcare Professional for further information.

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.

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

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 www.medicinesauthority.gov.mt

Important
Reminders for Patients

Nivolumab is a medicine to treat adults with:

- advanced (metastatic) melanoma, a type of skin cancer that has spread, or melanoma that cannot be removed by surgery
- advanced squamous non-small cell lung cancer (a type of lung cancer) in adults

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
- have been told that your cancer has spread to your brain
- have any history of inflammation of the lungs
- have been taking medicine to suppress your immune system
- are pregnant or planning to become pregnant

- are breast-feeding
- are taking or have recently taken any other medicines
- are on a low-sodium (low-salt) diet

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 www.medicinesauthority.gov.mt/pub/adr for how to report side effects. Side effects should also be reported to Bristol-Myers Squibb Medical Information on 00 356 2397 6333 or pv@ammangion.com.mt

IMPORTANT information

For Healthcare Providers

- This patient is being treated with nivolumab
- Nivolumab is associated with adverse reactions resulting from increased immune activity
- For suspected immune-related adverse reactions, adequate evaluation should be performed to confirm aetiology or exclude other causes
- 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 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 www.medicinesauthority.gov.mt or call Bristol-Myers Squibb at AM Mangion Ltd on 00 356 23976333 for more information.