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EPAR summary for the public

Nivolumab BMS

nivolumab

This is a summary of the European public assessment report (EPAR) for Nivolumab BMS. It explains how the Agency assessed the medicine to recommend its authorisation in the EU and its conditions of use. It is not intended to provide practical advice on how to use Nivolumab BMS.

For practical information about using Nivolumab BMS, patients should read the package leaflet or contact their doctor or pharmacist.

What is Nivolumab BMS and what is it used for?

Nivolumab BMS is a cancer medicine used to treat adults with a type of lung cancer called squamous non-small cell lung cancer (NSCLC). It is used in patients whose disease has spread locally or to other parts of the body and who have previously been treated with other cancer medicines (chemotherapy).

The medicine contains the active substance nivolumab.

How is Nivolumab BMS used?

Nivolumab BMS can only be obtained with a prescription and treatment must be started and supervised by a doctor experienced in the treatment of cancer.

The medicine is available as a concentrate for making up a solution for infusion (drip) into a vein. The recommended dose is 3 mg of nivolumab per kilogram body weight given into a vein over 60 minutes, every two weeks for as long as the patient continues to benefit from it. Doses may need to be delayed or treatment stopped altogether if the patient develops certain severe side effects. For further information, see the package leaflet.

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How does Nivolumab BMS work?

The active substance in Nivolumab BMS is a monoclonal antibody. A monoclonal antibody is an antibody (a type of protein) that has been designed to recognise and attach to a specific structure (called an antigen) that is found in certain cells in the body.

The antigen to which nivolumab has been designed to attach is a receptor called 'programmed cell death-1' (PD-1), which switches off the activity of certain cells of the immune system (the body's natural defences) called T cells. When it attaches to PD-1, nivolumab blocks the receptor and prevents it from switching off these immune cells. This increases the ability of the immune system to kill cancer cells.

What benefits of Nivolumab BMS have been shown in studies?

Nivolumab BMS have been shown to improve patients' survival in one main study involving 272 patients with previously treated squamous NSCLC that was advanced or had spread throughout the body. Treatment with Nivolumab BMS was compared with another cancer medicine, docetaxel, and the main measure of effectiveness was overall survival (how long patients lived). The average survival among 135 patients given Nivolumab BMS was around 9 months, whereas among the 137 patients given docetaxel it was 6 months. Supportive information was also provided from another study indicating that Nivolumab BMS could produce a response in patients whose disease had progressed despite several previous treatments.

What are the risks associated with Nivolumab BMS?

The most common side effects with Nivolumab BMS (which may affect more than 1 in 10 people) are tiredness, decreased appetite, and nausea (feeling sick), which are mostly mild or moderate in severity.

Nivolumab BMS is also commonly associated with side effects related to the activity of the immune system on body organs. Most will resolve following appropriate treatment or on stopping Nivolumab BMS.

For the full list of all side effects and restrictions with Nivolumab BMS, see the package leaflet.

Why is Nivolumab BMS approved?

The Agency's Committee for Medicinal Products for Human Use (CHMP) decided that Nivolumab BMS's benefits are greater than its risks and recommended that it be approved for use in the EU. The medicine was associated with improved survival over docetaxel in patients with advanced, previously treated squamous NSCLC, a patient group who have few treatment options. Patients whose cancer clearly expressed PD-1 seem to show most benefit, but as other patients also responded, further study to clarify patient groups most likely to benefit from the medicine is needed. Side effects were considered manageable with appropriate measures and were outweighed by the benefits.

What measures are being taken to ensure the safe and effective use of Nivolumab BMS?

A risk management plan has been developed to ensure that Nivolumab BMS is used as safely as possible. Based on this plan, safety information has been included in the summary of product characteristics and the package leaflet for Nivolumab BMS, including the appropriate precautions to be followed by healthcare professionals and patients.

In addition, the company that markets Nivolumab BMS will provide educational packs for doctors who are expected to prescribe the medicine, containing information on how it should be used and how to manage side effects, particularly side effects related to the activity of the immune system. The company will also provide an alert card for patients with information on the risks of the medicine, as well as instructions on when to contact their doctor if they experience symptoms of side effects. It will also conduct further studies on the long-term benefits of Nivolumab BMS, and try to identify which patients are most likely to benefit from treatment with the medicine.

Further information can be found in the summary of the risk management plan.

Other information about Nivolumab BMS

The European Commission granted a marketing authorisation valid throughout the European Union for Nivolumab BMS on 20. July 2015.

The full EPAR and risk management plan summary for Nivolumab BMS can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/European public assessment reports. For more information about treatment with Nivolumab BMS, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 07-2015.