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Nivolumab Injection

pronounced as (nye vol' ue mab)

Why is this medication prescribed?

Nivolumab injection is used:

- alone or in combination with ipilimumab (Yervoy) to treat certain types of melanoma (a type of skin cancer) that has spread to other parts of the body or cannot be removed by surgery,
- to treat and prevent the return of a certain type of melanoma after surgery to remove it and any affected tissue and lymph nodes,
- in combination with ipilimumab (Yervoy) to treat a certain type of lung cancer (non-small cell lung cancer; NSCLC) that has spread to other parts of the body,
- in combination with ipilimumab (Yervoy) and platinum chemotherapy to treat a certain type of NSCLC that has returned or has spread to other parts of the body,
- alone to treat a certain type of NSCLC that has spread to other parts of the body and has worsened either during or after treatment with platinum chemotherapy medications,
- to treat advanced renal cell carcinoma (RCC, a type of cancer that begins in the cells of the kidneys) that worsened after treatment with other chemotherapy medications,
- in combination with ipilimumab (Yervoy) or with cabozantinib (Cabometyx, Cometriq) to treat advanced RCC in people who have not been treated with other chemotherapy medications,
- to treat Hodgkin's lymphoma (Hodgkin's disease) in adults who worsened or did not respond to autologous stem cell transplant (procedure in which certain blood cells are removed from the body and then returned to the body after chemotherapy and/or radiation treatment) and brentuximab vedotin (Adcetris) treatment or at least three other treatments including the stem cell transplant,
- to treat a certain type of head and neck cancer that keeps coming back or that has spread to other parts of the body or worsened during or after treatment with other chemotherapy medications,
- to treat urothelial cancer (cancer of the lining of the bladder and other parts of the urinary tract) that has spread to other parts of the body and has worsened during or after treatment with other chemotherapy medications, It is also used after surgery to remove urothelial cancer, to reduce the risk of the cancer coming back.
- alone or in combination with ipilimumab to treat a certain type of colorectal cancer (cancer that begins in the large intestine) in adults and children 12 years of age and older that has spread to other parts of the body and has worsened after treatment with other chemotherapy medications,

- in combination with ipilimumab to treat hepatocellular carcinoma (HCC; a type of liver cancer) in people who were previously treated with sorafenib (Nexafar),
- to treat a certain type of esophageal cancer (cancer of the tube that connects your throat to your stomach) that has spread to other parts of the body, has worsened after treatment with other chemotherapy medications, or cannot be treated with surgery. It can also be used in combination with fluorouracil and a platinum-containing chemotherapy medication (cisplatin, carboplatin) to treat another type of esophageal cancer that keeps coming back or has spread to other parts of the body,
- in combination with fluorouracil and a platinum-containing chemotherapy medication (cisplatin, carboplatin) to treat certain types of gastric cancer (cancer of the stomach) or gastroesophageal junction cancer (cancer located in the area where the stomach meets the esophagus) that has spread to other parts of the body,
- and in combination with ipilimumab to treat malignant pleural mesothelioma (a type of cancer that affects the inside lining of the lungs and chest cavity) in adults that cannot be removed by surgery.

Nivolumab is in a class of medications called monoclonal antibodies. It works by helping your immune system to slow or stop the growth of cancer cells.

How should this medicine be used?

Nivolumab comes as a liquid to be injected into a vein over 30 minutes by a doctor or nurse in a hospital or medical facility.

When nivolumab is given alone to treat melanoma, non-small cell lung cancer (NSCLC), Hodgkin lymphoma, head and neck cancer, urothelial cancer, advanced RCC, colorectal cancer, or esophageal cancer, it is usually given once every 2 or 4 weeks depending on your dosage for as long as your doctor recommends that you receive treatment.

When nivolumab is given in combination with ipilimumab to treat melanoma, hepatocellular carcinoma, colorectal cancer, or RCC, it is usually given once every 3 weeks for 4 doses with ipilimumab, and then alone once every 2 or 4 weeks depending on your dosage for as long as your doctor recommends that you receive treatment.

When nivolumab is given in combination with ipilimumab to treat NSCLC, it is usually given once every 2 weeks for as long as your doctor recommends that you receive treatment.

When nivolumab is given in combination with ipilimumab to treat malignant pleural mesothelioma, it is usually given once every 3 weeks for as long as your doctor recommends that you receive treatment.

When nivolumab is given in combination with ipilimumab and platinum chemotherapy to treat NSCLC, it is usually given once every 3 weeks for as long as your doctor recommends that you receive treatment.

When nivolumab is given in combination with cabozantinib to treat advanced RCC, it is usually given once every 2 or 4 weeks depending on your dosage for as long as your doctor recommends that you receive treatment.

When nivolumab is given in combination with fluorouracil and a platinum-containing chemotherapy medication to treat gastric cancer, gastroesophageal junction cancer, or esophageal cancer, it is usually

given once every 2 or 3 weeks depending on your dosage for as long as your doctor recommends that you receive treatment.

Nivolumab may cause serious or life-threatening reactions during an infusion. A doctor or nurse will watch you closely while you are receiving the infusion and shortly after the infusion to be sure you are not having a serious reaction to the medication. Tell your doctor or nurse immediately if you experience any of the following symptoms that may occur during the infusion: chills or shaking, itching, rash, flushing, difficulty breathing, dizziness, fever, and feeling faint.

Your doctor may slow down your infusion, delay it, or stop your treatment with nivolumab injection, or treat you with additional medications depending on your response to the medication and any side effects that you experience. Talk to your doctor about how you are feeling during your treatment.

Your doctor or pharmacist will give you the manufacturer's patient information sheet (Medication Guide) when you begin treatment with nivolumab injection. Read the information carefully and ask your doctor or pharmacist if you have any questions.

Other uses for this medicine

This medication may be prescribed for other uses; ask your doctor or pharmacist for more information.

What special precautions should I follow?

Before receiving nivolumab injection,

- tell your doctor and pharmacist if you are allergic to nivolumab, any other medications, or any of the ingredients in nivolumab injection. Ask your pharmacist or check the Medication Guide for a list of the ingredients.
- tell your doctor and pharmacist what other prescription and nonprescription medications, vitamins, nutritional supplements, and herbal products you are taking or plan to take. Your doctor may need to change the doses of your medications or monitor you carefully for side effects.
- tell your doctor if you have ever had an organ transplant. Also tell your doctor if you have or have ever had an autoimmune disease (condition in which the immune system attacks a healthy part of the body) such as Crohn's disease (condition in which the immune system attacks the lining of the digestive tract causing pain, diarrhea, weight loss, and fever), ulcerative colitis (condition that causes swelling and sores in the lining of the colon [large intestine] and rectum), or lupus (condition in which the immune system attacks many tissues and organs including the skin, joints, blood, and kidneys); any type of lung disease or breathing problems; or thyroid, kidney or liver disease.
- tell your doctor if you are pregnant or plan to become pregnant. You will need to take a pregnancy test before you receive nivolumab. You should not become pregnant while you are receiving nivolumab injection. You should use effective birth control to prevent pregnancy during your treatment with nivolumab injection and for at least 5 months after your final dose. Talk to your doctor about birth control methods that will work for you. If you become pregnant while receiving nivolumab injection, call your doctor immediately. Nivolumab injection may harm the fetus.
- tell your doctor if you are breastfeeding or plan to breastfeed. You should not breastfeed while receiving nivolumab injection and for 5 months after your final dose.

What special dietary instructions should I follow?

Unless your doctor tells you otherwise, continue your normal diet.

What should I do if I forget a dose?

If you miss an appointment to receive nivolumab injection, call your doctor as soon as possible.

What side effects can this medication cause?

Nivolumab injection may cause side effects. Tell your doctor if any of these symptoms are severe or do not go away:

- joint, back, jaw, or bone pain
- muscle pain or weakness
- dry, cracked, scaly skin
- redness, swelling, or pain on the palms of your hand or soles of your feet
- mouth sores
- dry eyes or mouth
- change in sense of taste

Some side effects can be serious. If you experience any of these symptoms or those listed in the HOW section, tell your doctor immediately or get emergency medical treatment:

- shortness of breath
- new or worsening cough
- coughing up blood
- chest pain
- diarrhea
- stomach area pain or tenderness
- stools that are black, tarry, sticky, or contain blood
- tiredness or weakness
- feeling cold
- deepening of voice or hoarseness
- rapid heartbeat
- increased sweating
- changes in weight (gain or loss)
- changes in mood or behavior (decreased sex drive, irritability, or forgetfulness)
- pain, burning, tingling, or numbness in the hands or feet
- headaches, including those that are unusual or will not go away

- confusion
- fever
- hair loss
- itching, rash, hives, or blisters on your skin
- constipation
- nausea
- vomiting
- drowsiness
- dizziness or fainting
- yellowing of skin or eyes, dark-colored urine, bleeding or bruising more easily than normal, loss of appetite, decreased energy, or pain on right side of stomach area
- increased thirst
- decreased or increased urination
- swelling of face, arms, legs, feet or ankles
- blood in urine
- changes in vision, including sensitivity to light
- breath that smells fruity
- painful sores in mouth, nose, throat, or genital area

Nivolumab injection may cause other side effects. Call your doctor if you have any unusual problems while receiving this medication.

If you experience a serious side effect, you or your doctor may send a report to the Food and Drug Administration's (FDA) MedWatch Adverse Event Reporting program online (<http://www.fda.gov/Safety/MedWatch> [<http://www.fda.gov/Safety/MedWatch>]) or by phone (1-800-332-1088).

What other information should I know?

Keep all appointments with your doctor and the laboratory. Your doctor will order certain lab tests to check your body's response to nivolumab injection. For some conditions, your doctor will order a lab test before you begin your treatment to see whether your cancer can be treated with nivolumab.

It is important for you to keep a written list of all of the prescription and nonprescription (over-the-counter) medicines you are taking, as well as any products such as vitamins, minerals, or other dietary supplements. You should bring this list with you each time you visit a doctor or if you are admitted to a hospital. It is also important information to carry with you in case of emergencies.

Brand names

- Opdivo[®]

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