

Nivolumab (Opdivo®)

About This Drug

Nivolumab is used to treat cancer. It is given in the vein (IV).

Possible Side Effects

- Nausea
- Pain in your abdomen
- Diarrhea (loose bowel movements)
- Constipation (not able to move bowels)
- Tiredness and weakness
- Fever
- Decreased appetite (decreased hunger)
- Joint, muscle and bone pain
- Back pain
- Headache
- Cough and trouble breathing
- Upper respiratory infection
- Rash and itching

Note: Each of the side effects above was reported in 20% or greater of patients treated with nivolumab. Not all possible side effects are included above. Your side effects may be different or more severe if you receive nivolumab in combination with other chemotherapy agents.

Warnings and Precautions

- This drug works with your immune system and can cause inflammation in any of your organs and tissues and can change how they work. This may put you at risk for developing serious medical problems which can be life-threatening. These side effects may require treatment with steroids at the discretion of your doctor.
- Colitis (swelling (inflammation) in the colon) - symptoms are loose bowel movements (diarrhea) stomach cramping, and sometimes blood in the bowel movements
- Changes in your liver function
- Changes in your kidney function

- Inflammation (swelling) of the lungs which can be life-threatening - you may have a dry cough or trouble breathing.
- This drug may affect some of your hormone glands (especially the thyroid, adrenals, pituitary and pancreas).
- Blood sugar levels may change and you may develop diabetes. If you already have diabetes, changes may need to be made to your diabetes medication.
- Severe allergic skin reaction which can very rarely be life-threatening. You may develop blisters on your skin that are filled with fluid or a severe red rash all over your body that may be painful.
- Changes in your central nervous system can happen. The central nervous system is made up of your brain and spinal cord. You could feel extreme tiredness, agitation, confusion, hallucinations (see or hear things that are not there), trouble understanding or speaking, loss of control of your bowels or bladder, eyesight changes, numbness or lack of strength to your arms, legs, face, or body, and coma. If you start to have any of these symptoms let your doctor know right away.
- While you are getting this drug in your vein (IV), you may have a reaction to the drug. Sometimes you may be given medication to stop or lessen these side effects. Your nurse will check you closely for these signs: fever or shaking chills, flushing, facial swelling, feeling dizzy, headache, trouble breathing, rash, itching, chest tightness, or chest pain. **These reactions may happen after your infusion. If this happens, call 911 for emergency care.**
- Increased risk of complications, which can be life-threatening in patients who will undergo a stem cell transplant after receiving nivolumab.

Important Information

- This drug may be present in the saliva, tears, sweat, urine, stool, vomit, semen, and vaginal secretions. Talk to your doctor and/or your nurse about the necessary precautions to take during this time.

Treating Side Effects

- Drink plenty of fluids (a minimum of eight glasses per day is recommended).
- If you throw up or have diarrhea, you should drink more fluids so that you do not become dehydrated (lack of water in the body from losing too much fluid).
- To help with nausea and vomiting, eat small, frequent meals instead of three large meals a day. Choose foods and drinks that are at room temperature. Ask your nurse or doctor about other helpful tips and medicine that is available to help stop or lessen these symptoms.
- If you have diarrhea, eat low-fiber foods that are high in protein and calories and avoid foods that can irritate your digestive tracts or lead to cramping.
- If you are not able to move your bowels, check with your doctor or nurse before you use any enemas, laxatives, or suppositories
- Ask your doctor or nurse about medicines that are available to help stop or lessen constipation, diarrhea and/or nausea.
- To help with decreased appetite, eat small, frequent meals. Eat foods high in calories and protein, such as meat, poultry, fish, dry beans, tofu, eggs, nuts, milk, yogurt, cheese, ice cream, pudding, and nutritional supplements.
- Consider using sauces and spices to increase taste. Daily exercise, with your doctor's approval, may increase your appetite.

- Manage tiredness by pacing your activities for the day. Be sure to include periods of rest between energy-draining activities
- Keeping your pain under control is important to your wellbeing. Please tell your doctor or nurse if you are experiencing pain.
- If you have diabetes, keep good control of your blood sugar level. Tell your nurse or your doctor if your glucose levels are higher or lower than normal
- If you get a rash do not put anything on it unless your doctor or nurse says you may. Keep the area around the rash clean and dry. Ask your doctor for medicine if your rash bothers you.
- Infusion reactions may occur after your infusion. **If this happens, call 911 for emergency care.**

Food and Drug Interactions

- There are no known interactions of nivolumab with food.
- This drug may interact with other medicines. Tell your doctor and pharmacist about all the prescription and over-the-counter medicines and dietary supplements (vitamins, minerals, herbs and others) that you are taking at this time. Also, check with your doctor or pharmacist before starting any new prescription or over-the-counter medicines, or dietary supplements to make sure that there are no interactions.

When to Call the Doctor

Call your doctor or nurse if you have any of these symptoms and/or any new or unusual symptoms:

- Fever of 100.4° F (38° C) or higher
- Chills
- Easy bleeding or bruising
- Wheezing or trouble breathing
- Dry cough, or cough with yellow, green or bloody mucus
- Headache that does not go away
- Confusion and/or agitation
- Hallucinations
- Trouble understanding or speaking
- Blurry vision or changes in your eyesight
- Numbness or lack of strength to your arms, legs, face, or body
- Feeling dizzy or lightheaded
- Diarrhea, 4 times in one a day or diarrhea with weakness or lightheadedness
- Nausea that stops you from eating or drinking, and/or that is not relieved by prescribed medicines
- Lasting loss of appetite or rapid weight loss of five pounds in a week
- No bowel movement for 3 days or you feel uncomfortable
- Bad abdominal pain, especially in upper right area
- Tiredness or extreme weakness that interferes with normal activities
- Decreased urine
- Unusual thirst or passing urine often

- Blood in your stool
- Abnormal blood sugar
- Unusual thirst, passing urine often, headache, sweating, shakiness, irritability
- Rash or itching that is not relieved by prescribed medicines
- Pain that does not go away, or is not relieved by prescribed medicines
- Flu-like symptoms: fever, headache, muscle and joint aches, and fatigue (low energy, feeling weak)
- Signs of liver problems: dark urine, pale bowel movements, bad stomach pain, feeling very tired and weak, unusual itching, or yellowing of the eyes or skin.
- Signs of infusion reaction: fever or shaking chills, flushing, facial swelling, feeling dizzy, headache, trouble breathing, rash, itching, chest tightness, or chest pain. **If this happens, call 911 for emergency care.**
- If you think you may be pregnant

Reproduction Warnings

- **Pregnancy warning:** This drug can have harmful effects on the unborn baby. Women of childbearing potential should use effective methods of birth control during your cancer treatment and for at least 5 months after treatment. Let your doctor know right away if you think you may be pregnant.
- **Breastfeeding warning:** It is not known if this drug passes into breast milk. For this reason, women should not breastfeed during treatment and for 5 months after the last treatment because this drug could enter the breast milk and cause harm to a breastfeeding baby.
- **Fertility warning:** Human fertility studies have not been done with this drug. Talk with your doctor or nurse if you plan to have children. Ask for information on sperm or egg banking.

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