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Nivolumab: Patient drug information

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(For additional information see "Nivolumab: Drug information")

Brand Names: US Opdivo

Brand Names: Canada Opdivo

What is this drug used for?

- It is used to treat a type of skin cancer (melanoma).
- It is used to treat lung cancer.
- · It is used to treat kidney cancer.
- It is used to treat a type of lymphoma.
- It is used to treat cancer of the head and neck.
- · It is used to treat bladder cancer.
- It may be given to you for other reasons. Talk with the doctor.

What do I need to tell my doctor BEFORE I take this drug?

- If you have an allergy to this drug or any part of this drug.
- If you are allergic to any drugs like this one, any other drugs, foods, or other substances. Tell your doctor about the allergy and what signs you had, like rash; hives; itching; shortness of breath; wheezing; cough; swelling of face, lips, tongue, or throat; or any other signs.
- If you are breast-feeding. Do not breast-feed while you take this drug.

This drug may interact with other drugs or health problems.

Tell your doctor and pharmacist about all of your drugs (prescription or OTC, natural products, vitamins) and health problems. You must check to make sure that it is safe for you to take this drug with all of your drugs and health problems. Do not start, stop, or change the dose of any drug without checking with your doctor.

What are some things I need to know or do while I take this drug?

Have blood work checked as you have been told by the doctor. Talk with the doctor.

- If you have high blood sugar (diabetes), talk with your doctor. This drug may raise blood sugar.
- Check your blood sugar as you have been told by your doctor.
- Tell your doctor if you have signs of high blood sugar like confusion, feeling sleepy, more thirst, more hungry, passing urine more often, flushing, fast breathing, or breath that smells like fruit.
- Very bad health problems like some organ problems can happen with this drug. This includes lung, liver, thyroid gland, pituitary gland, adrenal gland, and kidney problems. A very bad rash may also happen. Sometimes, these problems can be life-threatening. These problems may happen anytime during treatment or after treatment has stopped. Talk with your doctor.
- A certain brain problem has happened with this drug. Rarely, this has been deadly. Call your doctor right away if you have a change in thinking clearly or with logic, feeling sleepy, feeling very tired or weak, fever, hallucinations, memory problems, seizures, stiff neck, or very bad headache.
- Some patients have had side effects during the infusion. Tell your doctor if you have any of these side effects during the infusion: back or neck pain, chills or shaking, dizziness, feeling like passing out, fever, flushing, itching, rash, shortness of breath, swelling of the face, or wheezing.
- It is common to have loose stools (diarrhea) with this drug. However, a very bad bowel problem (colitis) with diarrhea has happened with this drug. This may lead to tears or holes in the bowels and may be life-threatening. Call your doctor right away if you have bloody stools; dark, tarry, or sticky stools; diarrhea; or very bad stomach pain.
- A very bad skin reaction (Stevens-Johnson syndrome/toxic epidermal necrolysis) may happen. It can cause very bad health problems that may not go away, and sometimes death. Get medical help right away if you have signs like red, swollen, blistered, or peeling skin (with or without fever); red or irritated eyes; or sores in your mouth, throat, nose, or eyes.
- If you are having a stem cell transplant, talk with your doctor. Some problems with stem cell
 transplants using stem cells from someone else (allogeneic) have happened after treatment with this
 drug. These problems can be very bad and can lead to death.
- This drug may cause harm to the unborn baby if you take it while you are pregnant.
- Use birth control you can trust to prevent pregnancy while you are taking this drug and for 5 months after you stop taking it.
- If you get pregnant while taking this drug or within 5 months after your last dose, call your doctor right away.

What are some side effects that I need to call my doctor about right away?

WARNING/CAUTION: Even though it may be rare, some people may have very bad and sometimes deadly side effects when taking a drug. Tell your doctor or get medical help right away if you have any of the following signs or symptoms that may be related to a very bad side effect:

For all uses of this drug:

- Signs of an allergic reaction, like rash; hives; itching; red, swollen, blistered, or peeling skin with or without fever; wheezing; tightness in the chest or throat; trouble breathing or talking; unusual hoarseness; or swelling of the mouth, face, lips, tongue, or throat.
- Signs of thyroid, pituitary, or adrenal gland problems. Some signs may be change in mood or the way you act, change in weight, constipation, deeper voice, dizziness, fainting, feeling cold, feeling very tired, hair loss, headache that lasts or is very bad, or lowered interest in sex.
- Signs of kidney problems like unable to pass urine, change in how much urine is passed, blood in the urine, or a big weight gain.
- · Signs of liver problems like dark urine, feeling tired, not hungry, upset stomach or stomach pain, light-

colored stools, throwing up, or yellow skin or eyes.

- Signs of electrolyte problems like mood changes, confusion, muscle pain or weakness, a heartbeat that does not feel normal, seizures, not hungry, or very bad upset stomach or throwing up.
- Signs of lung or breathing problems like shortness of breath or other trouble breathing, cough, or fever.
- · Any unexplained bruising or bleeding.
- · Very bad muscle pain or weakness.
- · Very bad joint pain.
- · Swelling in the arms or legs.
- · Change in eyesight.
- · Chest pain.
- · Feeling very tired or weak.
- · A heartbeat that does not feel normal.

Bladder cancer treatment:

• Signs of a urinary tract infection (UTI) like blood in the urine, burning or pain when passing urine, feeling the need to pass urine often or right away, fever, lower stomach pain, or pelvic pain.

What are some other side effects of this drug?

All drugs may cause side effects. However, many people have no side effects or only have minor side effects. Call your doctor or get medical help if any of these side effects or any other side effects bother you or do not go away:

- · Headache.
- · Bone, joint, or muscle pain.
- Hard stools (constipation).
- · Not hungry.
- Upset stomach or throwing up.
- · Belly pain.
- · Feeling tired or weak.

These are not all of the side effects that may occur. If you have questions about side effects, call your doctor. Call your doctor for medical advice about side effects.

You may report side effects to your national health agency.

How is this drug best taken?

Use this drug as ordered by your doctor. Read all information given to you. Follow all instructions closely.

- It is given as an infusion into a vein over a period of time.
- Tell all of your health care providers that you take this drug. This includes your doctors, nurses, pharmacists, and dentists.
- This drug may be used with another drug called ipilimumab. Some side effects that can happen may
 happen more often if this drug is used with ipilimumab. If you are also using ipilimumab, talk with your
 doctor about the risks and side effects that may happen.

What do I do if I miss a dose?

• Call your doctor to find out what to do.

How do I store and/or throw out this drug?

• If you need to store this drug at home, talk with your doctor, nurse, or pharmacist about how to store it.

General drug facts

- If your symptoms or health problems do not get better or if they become worse, call your doctor.
- Do not share your drugs with others and do not take anyone else's drugs.
- Keep a list of all your drugs (prescription, natural products, vitamins, OTC) with you. Give this list to your doctor.
- Talk with the doctor before starting any new drug, including prescription or OTC, natural products, or vitamins.
- Keep all drugs in a safe place. Keep all drugs out of the reach of children and pets.
- Check with your pharmacist about how to throw out unused drugs.
- Some drugs may have another patient information leaflet. If you have any questions about this drug, please talk with your doctor, nurse, pharmacist, or other health care provider.
- If you think there has been an overdose, call your poison control center or get medical care right away. Be ready to tell or show what was taken, how much, and when it happened.

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Topic 99274 Version 40.0