

**MEDICATION GUIDE**  
**OPDIVO® (op-DEE-voh)**  
**(nivolumab)**  
**Injection**

Read this Medication Guide before you start receiving OPDIVO and before each infusion. There may be new information. If your healthcare provider prescribes OPDIVO in combination with ipilimumab (YERVOY®), also read the Medication Guide that comes with ipilimumab. This Medication Guide does not take the place of talking with your healthcare provider about your medical condition or your treatment.

**What is the most important information I should know about OPDIVO?**

OPDIVO is a medicine that may treat certain cancers by working with your immune system. OPDIVO can cause your immune system to attack normal organs and tissues in any area of your body and can affect the way they work. These problems can sometimes become serious or life-threatening and can lead to death. These problems may happen anytime during treatment or even after your treatment has ended. Some of these problems may happen more often when OPDIVO is used in combination with ipilimumab.

**Call or see your healthcare provider right away if you develop any symptoms of the following problems or these symptoms get worse:**

**Lung problems (pneumonitis).** Symptoms of pneumonitis may include:

- new or worsening cough
- chest pain
- shortness of breath

**Intestinal problems (colitis) that can lead to tears or holes in your intestine.** Signs and symptoms of colitis may include:

- diarrhea (loose stools) or more bowel movements than usual
- blood in your stools or dark, tarry, sticky stools
- severe stomach-area (abdomen) pain or tenderness

**Liver problems (hepatitis).** Signs and symptoms of hepatitis may include:

- yellowing of your skin or the whites of your eyes
- severe nausea or vomiting
- pain on the right side of your stomach area (abdomen)
- drowsiness
- dark urine (tea colored)
- bleeding or bruising more easily than normal
- feeling less hungry than usual
- decreased energy

**Hormone gland problems (especially the thyroid, pituitary, adrenal glands, and pancreas).** Signs and symptoms that your hormone glands are not working properly may include:

- headaches that will not go away or unusual headaches
- extreme tiredness
- weight gain or weight loss
- dizziness or fainting
- changes in mood or behavior, such as decreased sex drive, irritability, or forgetfulness
- hair loss
- feeling cold
- constipation
- voice gets deeper
- excessive thirst or lots of urine

**Kidney problems, including nephritis and kidney failure.** Signs of kidney problems may include:

- decrease in the amount of urine
- blood in your urine
- swelling in your ankles
- loss of appetite

**Skin Problems.** Signs of these problems may include:

- rash
- itching
- skin blistering
- ulcers in mouth or other mucous membranes

**Inflammation of the brain (encephalitis).** Signs and symptoms of encephalitis may include:

- headache
- fever
- tiredness or weakness
- confusion
- memory problems
- sleepiness
- seeing or hearing things that are not really there (hallucinations)
- seizures
- stiff neck

**Problems in other organs.** Signs of these problems may include:

- changes in eyesight
- severe or persistent muscle or joint pains
- severe muscle weakness
- chest pain

**Getting medical treatment right away may keep these problems from becoming more serious.**

Your healthcare provider will check you for these problems during treatment with OPDIVO. Your healthcare provider may treat you with corticosteroid or hormone replacement medicines. Your healthcare provider may also need to delay or completely stop treatment with OPDIVO, if you have severe side effects.

**What is OPDIVO?**

OPDIVO is a prescription medicine used to treat:

- **people with a type of skin cancer called melanoma:**
  - OPDIVO may be used alone or in combination with ipilimumab to treat melanoma that has spread or cannot be removed by surgery (advanced melanoma), **or**
  - OPDIVO may be used alone to help prevent melanoma from coming back after it and lymph nodes that contain cancer have been removed by surgery.
- **people with a type of advanced stage lung cancer called non-small cell lung cancer (NSCLC).**
  - OPDIVO may be used in combination with ipilimumab as your first treatment for NSCLC:
    - when your lung cancer has spread to other parts of your body (metastatic), and
    - your tumors are positive for PD-L1, but do not have an abnormal EGFR or ALK gene.
  - OPDIVO may be used in combination with ipilimumab and 2 cycles of chemotherapy that contains platinum and another chemotherapy medicine, as the first treatment of your NSCLC when your lung cancer:
    - has spread or grown, or comes back, **and**
    - your tumor does not have an abnormal EGFR or ALK gene.
  - OPDIVO may be used when your lung cancer:
    - has spread or grown, **and**
    - you have tried chemotherapy that contains platinum, and it did not work or is no longer working.

If your tumor has an abnormal EGFR or ALK gene, you should have also tried an FDA-approved therapy for tumors with these abnormal genes, **and** it did not work or is no longer working.
- **people with a type of lung cancer called small cell lung cancer.**
  - OPDIVO may be used when your lung cancer:
    - has spread or grown, **and**
    - you have tried at least two different types of chemotherapy, including one that contains platinum, and it did not work or is no longer working.
- **people with kidney cancer (renal cell carcinoma).**
  - OPDIVO may be used alone when your cancer has spread or grown after treatment with other cancer medicines.
  - OPDIVO may be used in combination with ipilimumab in certain people when their cancer has spread.
- **adults with a type of blood cancer called classical Hodgkin lymphoma.**
  - **OPDIVO may be used if:**
    - your cancer has come back or spread after a type of stem cell transplant that uses your own stem cells (autologous), **and**
    - you used the drug brentuximab vedotin before or after your stem cell transplant, **or**
    - you received at least 3 kinds of treatment including a stem cell transplant that uses your own stem cells (autologous).
- **people with head and neck cancer (squamous cell carcinoma).**
  - **OPDIVO may be used when your head and neck cancer:**
    - has come back or spread, **and**
    - you have tried chemotherapy that contains platinum and it did not work or is no longer working.
- **people with bladder cancer (urothelial carcinoma).**
  - **OPDIVO may be used when your bladder cancer:**
    - has spread or grown, **and**
    - you have tried chemotherapy that contains platinum, and it did not work or is no longer working.
- **adults and children 12 years of age and older, with a type of colon or rectal cancer (colorectal cancer).**
  - OPDIVO may be used alone or in combination with ipilimumab when your colon or rectal cancer:
    - has spread to other parts of the body (metastatic),

- is microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR), **and**
- you have tried treatment with a fluoropyrimidine, oxaliplatin, and irinotecan, and it did not work or is no longer working.

- **people with liver cancer (hepatocellular carcinoma).**

- OPDIVO may be used alone or in combination with ipilimumab if you have previously received treatment with sorafenib.

- **people with cancer of the tube that connects your throat to your stomach (esophageal cancer).**

- **OPDIVO may be used when your esophageal cancer:**

- is a type called squamous cell carcinoma, **and**
- cannot be removed with surgery, **and**
- has come back or spread to other parts of the body after you have received chemotherapy that contains fluoropyrimidine and platinum.

It is not known if OPDIVO is safe and effective when used:

- in children younger than 12 years of age with MSI-H or dMMR metastatic colorectal cancer, or
- in children younger than 18 years of age for the treatment of any other cancers.

## **What should I tell my healthcare provider before receiving OPDIVO?**

### **Before you receive OPDIVO, tell your healthcare provider if you:**

- have immune system problems such as Crohn's disease, ulcerative colitis, or lupus
- have had an organ transplant
- have lung or breathing problems
- have liver problems
- have any other medical conditions
- are pregnant or plan to become pregnant. OPDIVO can harm your unborn baby.

### **Females who are able to become pregnant:**

Your healthcare provider should do a pregnancy test before you start receiving OPDIVO.

- You should use an effective method of birth control during and for at least 5 months after the last dose of OPDIVO. Talk to your healthcare provider about birth control methods that you can use during this time.
- Tell your healthcare provider right away if you become pregnant during treatment with OPDIVO.
- are breastfeeding or plan to breastfeed. It is not known if OPDIVO passes into your breast milk. Do not breastfeed during treatment with OPDIVO.

### **Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.**

Know the medicines you take. Keep a list of them to show your healthcare providers and pharmacist when you get a new medicine.

## **How will I receive OPDIVO?**

- Your healthcare provider will give you OPDIVO into your vein through an intravenous (IV) line over 30 minutes.
- When OPDIVO is used alone, it is usually given every 2 weeks or 4 weeks depending on the dose you are receiving.
- When OPDIVO is used in combination with ipilimumab (except for treating NSCLC), OPDIVO is usually given every 3 weeks, for a total of 4 doses. Ipilimumab will be given on the same day. After that, OPDIVO will be given alone every 2 weeks or 4 weeks depending on the dose you are receiving.
- For NSCLC that has spread to other parts of your body, when OPDIVO is used in combination with ipilimumab, OPDIVO is given either every 2 weeks or every 3 weeks, and ipilimumab is given every 6 weeks for up to 2 years. Your healthcare provider will determine if you will also need to receive chemotherapy every 3 weeks for 2 cycles.
- Your healthcare provider will decide how many treatments you need.
- Your healthcare provider will do blood tests to check you for side effects.
- If you miss any appointments, call your healthcare provider as soon as possible to reschedule your appointment.

## **What are the possible side effects of OPDIVO?**

### **OPDIVO can cause serious side effects, including:**

- **See “What is the most important information I should know about OPDIVO?”**
- **Severe infusion reactions.** Tell your doctor or nurse right away if you get these symptoms during an infusion of OPDIVO:
  - chills or shaking
  - dizziness
  - itching or rash
  - fever

- flushing
- difficulty breathing
- feeling like passing out

- **Complications of stem cell transplant that uses donor stem cells (allogeneic).** These complications can be severe and can lead to death. Your healthcare provider will monitor you for signs of complications if you have an allogeneic stem cell transplant.

**The most common side effects of OPDIVO when used alone include:**

- feeling tired
- rash
- pain in muscles, bones, and joints
- itchy skin
- diarrhea
- nausea
- weakness
- cough
- vomiting
- shortness of breath
- constipation
- decreased appetite
- back pain
- upper respiratory tract infection
- fever
- headache
- stomach-area (abdominal) pain

**The most common side effects of OPDIVO when used in combination with ipilimumab include:**

- feeling tired
- diarrhea
- rash
- itching
- nausea
- pain in muscles, bones, and joints
- fever
- cough
- decreased appetite
- vomiting
- stomach-area (abdominal) pain
- shortness of breath
- upper respiratory tract infection
- headache
- low thyroid hormone levels (hypothyroidism)
- decreased weight
- dizziness

**The most common side effects of OPDIVO when used in combination with ipilimumab and chemotherapy include:**

- feeling tired
- pain in muscles, bones, and joints
- nausea
- diarrhea
- rash
- decreased appetite
- constipation
- itching

These are not all the possible side effects of OPDIVO.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

**General information about the safe and effective use of OPDIVO.**

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. If you would like more information about OPDIVO, talk with your healthcare provider. You can ask your healthcare provider for information about OPDIVO that is written for health professionals.

**What are the ingredients in OPDIVO?**

**Active ingredient:** nivolumab

**Inactive ingredients:** mannitol, pentetic acid, polysorbate 80, sodium chloride, sodium citrate dihydrate, and Water for Injection. May contain hydrochloric acid and/or sodium hydroxide.

Manufactured by: Bristol-Myers Squibb Company, Princeton, NJ 08543 USA U.S. License No. 1713

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For more information, call 1-855-673-4861 or go to [www.OPDIVO.com](http://www.OPDIVO.com).

This Medication Guide has been approved by the U.S. Food and Drug Administration.

Revised: June 2020