

**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 your melanoma or lung cancer by working with your immune system. OPDIVO can cause your immune system to attack normal organs and tissues in many areas 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

**Hormone gland problems (especially the thyroid, pituitary, and adrenal glands).**

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

**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

**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:

- rash
- changes in eyesight
- severe or persistent muscle or joint pains
- severe muscle weakness

**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:

- **a type of skin cancer called melanoma.**

**OPDIVO may be used alone when your melanoma:**

- has spread or cannot be removed by surgery (advanced melanoma), **and**,
- after you have tried a medicine called ipilimumab and it did not work or is no longer working **and**,
- if your tumor has an abnormal "BRAF" gene, and you have also tried a different medicine called a BRAF inhibitor, and it did not work or is no longer working.

**OPDIVO may be used in combination with the medicine ipilimumab when your melanoma:**

- has spread or cannot be removed by surgery (advanced melanoma), **and**
- has a normal BRAF gene (wild-type)

- **a type of advanced stage lung cancer (called non-small cell lung cancer)**

**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.

It is not known if OPDIVO is safe and effective in children less than 18 years of age.

### **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 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 60 minutes.
- OPDIVO is usually given every 2 weeks.
- When used in combination with ipilimumab, OPDIVO is usually given every 3 weeks, for a total of 4 doses. After that, OPDIVO will be given alone every 2 weeks. Ipilimumab will be given through an IV line over 90 minutes.
- 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
  - feeling like passing out
  - difficulty breathing

#### **The most common side effect of OPDIVO when used alone in people with melanoma is rash.**

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

- rash
- headache
- itching
- vomiting
- inflammation of the intestines (colitis). **See "What is the most important information I should know about OPDIVO?"**

**The most common side effects of OPDIVO in people with non-small cell lung cancer include:**

- feeling tired
- pain in muscles, bones, and joints
- decreased appetite
- cough
- constipation

Tell your healthcare provider if you have any side effect that bothers you or that does not go away.

These are not all the possible side effects of OPDIVO. For more information, ask your healthcare provider or pharmacist. 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. For more information, call 1-855-673-4861 or go to [www.OPDIVO.com](http://www.OPDIVO.com).

**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

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

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