

MEDICATION GUIDE

**OPDUALAG™ (op-DEW-uh-lag)
(nivolumab and relatlimab-rmbw)
injection**

What is the most important information I should know about OPDUALAG?

OPDUALAG is a medicine that may treat a type of skin cancer called melanoma by working with your immune system. OPDUALAG 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 severe or can lead to death. These problems may happen anytime during treatment or even after your treatment has ended. You may have more than one of these problems at the same time.

Call or see your healthcare provider right away if you develop any new or worse signs of symptoms, including:

Lung problems.

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

Intestinal problems.

- diarrhea (loose stools) or more frequent bowel movements than usual
- stool that are black, tarry, sticky, or have blood or mucus
- severe stomach-area (abdominal) pain or tenderness

Liver problems.

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

Hormone gland problems.

- headaches that will not go away or unusual headaches
- eye sensitivity to light
- eye problems
- rapid heartbeat
- increased sweating
- extreme tiredness
- weight gain or weight loss
- feeling more hungry or thirsty than usual
- urinating more often than usual
- hair loss
- feeling cold
- constipation
- your voice gets deeper
- dizziness or fainting
- changes in mood or behavior, such as decreased sex drive, irritability, or forgetfulness

Kidney problems.

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

Skin problems.

- rash
- itching
- skin blistering or peeling
- painful sore or ulcers in mouth or nose, throat, or genital area

Heart problems.

- new or worse chest pain
- irregular heartbeat or feel like your heart is racing
- shortness of breath
- tiredness
- swelling in your ankles

Problems can also happen in other organs and tissues. These are not all of the signs and symptoms of immune system problems that can happen with OPDUALAG. Call or see your healthcare provider right away for any new or worsening sign or symptoms, which may include:

- Confusion, sleepiness, memory problems, changes in mood or behavior, stiff neck, balance problems, tingling or numbness of the arms or legs
- Double vision, blurry vision, sensitivity to light, eye pain, changes in eyesight
- Persistent or severe muscle pain or weakness, muscle cramps
- Low red blood cells, bruising

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 OPDUALAG. 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 OPDUALAG, if you have severe side effects.

What is OPDUALAG?

OPDUALAG is a prescription medicine used to treat:

- adults and children 12 years of age or older with a type of skin cancer called melanoma that has spread or cannot be removed by surgery.

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

- in children 12 years of age or older who weigh less than 88 pounds (40 kg), or
- in children younger than 12 years of age.

Before you receive OPDUALAG, tell your healthcare provider if you:

- have immune system problems such as Crohn's disease, ulcerative colitis, or lupus
- have received an organ transplant
- have received or plan to receive a stem cell transplant that uses donor stem cells (allogeneic)
- have a condition that affects your nervous system, such as myasthenia gravis or Guillain-Barré syndrome
- are pregnant or plan to become pregnant. OPDUALAG can harm your unborn baby.

Females who are able to become pregnant:

- Your healthcare provider should do a pregnancy test before you start receiving OPDUALAG.
- You should use an effective method of birth control during and for at least 5 months after the last dose of OPDUALAG. 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 OPDUALAG.
- are breastfeeding or plan to breastfeed. It is not known if OPDUALAG passes into your breast milk. Do not breastfeed during treatment with OPDUALAG and for 5 months after the last dose of OPDUALAG.

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

How will I receive OPDUALAG?

- Your healthcare provider will give you OPDUALAG into your vein through an intravenous (IV) line over 30 minutes.
- OPDUALAG is usually given every 4 weeks.
- 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 OPDUALAG?

OPDUALAG can cause serious side effects, including:

- **See "What is the most important information I should know about OPDUALAG?"**
- **Severe infusion reactions.** Tell your healthcare provider or nurse right away if you get these symptoms during an infusion of OPDUALAG:
 - chills or shaking
 - itching or rash
 - flushing
 - shortness of breath
 - dizziness
 - feel like passing out
 - fever
 - back or neck pain
- **Complications of stem cell transplant that uses donor stem cells (allogeneic).** These complications can be severe and can lead to death. These complications may happen if you underwent transplantation either before or after being treated with OPDUALAG. Your healthcare provider will monitor you for signs of complications if you have an allogeneic stem cell transplant.

The most common side effects of OPDUALAG include:

- muscle and bone pain
- tiredness
- decreased red blood cell and white blood cell counts
- increased liver function test results
- rash
- itching
- diarrhea
- decreased salt (sodium) in your blood

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<p>These are not all the possible side effects of OPDUALAG. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.</p>
<p>General information about the safe and effective use of OPDUALAG. Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. You can ask your pharmacist or healthcare provider for information about OPDUALAG that is written for health professionals.</p>
<p>What are the ingredients in OPDUALAG? Active ingredients: nivolumab and relatlimab Inactive ingredients: histidine, L-histidine hydrochloride monohydrate, pentetic acid, polysorbate 80, sucrose, and Water for Injection.</p> <p>OPDUALAG™ is trademark of Bristol-Myers Squibb Company. Other brands listed are the trademarks of their respective owners. Manufactured by: Bristol-Myers Squibb Company Princeton, NJ 08543 USA U.S. License No. 1713 For more information, call 1-855-673-4861 or go to www.OPDUALAG.com.</p>

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

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