

OPDUALAG™

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

- ▼ This medicine is new or being used differently. Please report side effects. See the [full CMI](#) for further details.

1. Why am I given OPDUALAG?

OPDUALAG is a medicine that contains two active ingredients, nivolumab and relatlimab, in a single vial. OPDUALAG is used to treat advanced melanoma (a type of skin cancer) in adults and in adolescents (12 years of age and older weighing at least 40 kg). For more information, see Section [1. Why am I using OPDUALAG?](#) in the full CMI.

2. What should I know before I am given OPDUALAG?

Do not take this medicine if you are allergic to the active ingredient in OPDUALAG (nivolumab and relatlimab) or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding. For more information, see Section [2. What should I know before I use OPDUALAG?](#) in the full CMI.

3. What if I am taking other medicines?

Tell your doctor if you are taking or have recently taken any other medicines. Do not take any other medicines during your treatment without talking to your doctor first. A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How am I given OPDUALAG?

You will receive treatment with OPDUALAG in a hospital or clinic, under the supervision of an experienced healthcare professional. OPDUALAG will be given to you as an infusion (a drip) into a vein (intravenously). Your doctor will continue giving you OPDUALAG for as long as you keep benefitting from it or until you no longer tolerate the treatment. More information can be found in Section [4. How you will be given OPDUALAG?](#) in the full CMI.

5. What should I know while using OPDUALAG?

Things you should do

- Remind any doctor, dentist or pharmacist you visit that you are using OPDUALAG.
- Before you are given OPDUALAG, tell your doctor if you have autoimmune disease, melanoma of the eye, if you have cancer that has spread to the brain, you have a history of inflammation of the lungs or if you are taking any medicines that suppress your immune system, such as corticosteroids.
- Tell your doctor if you are pregnant, think you may be pregnant or are planning to become pregnant.
- Be aware of important symptoms of inflammation described in the CMI. Tell your doctor, pharmacist

	<p>or nurse straight away if you get any of these symptoms during treatment with OPDUALAG. OPDUALAG acts on your immune system and may cause inflammation in parts of your body which may be life threatening and need treatment or withdrawal of OPDUALAG.</p>
<p>Things you should not do</p>	<ul style="list-style-type: none"> • Do not use OPDUALAG if you are allergic to relatlimab, nivolumab or any of the other ingredients of this medicine. Talk to your doctor if you are not sure. Do not use this medicine during pregnancy as it may be harmful to your baby. Do not breast feed whilst taking OPDUALAG.
<p>Driving or using machines</p>	<ul style="list-style-type: none"> • OPDUALAG may have a minor influence on the ability to drive and use machines; however, use caution when performing these

	activities until you are sure that OPDUALAG does not adversely affect you.
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For more information, see Section [5. What should I know while receiving OPDUALAG?](#) in the full CMI.

6. Are there any side effects?

Like all medicines, this medicine can cause side effects, although not everybody gets them. Your doctor will discuss these with you and will explain the risks and benefits of your treatment. Sometimes they are serious and you may require medical attention. Contact your doctor immediately or go to the Emergency Department at your nearest hospital if you have any signs or symptoms of inflammation or if they get worse. For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

- ▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. You can report side effects to your doctor, or directly at www.tga.gov.au/reporting-problems.

OPDUALAG™

Active ingredient(s): nivolumab and relatlimab

Consumer Medicine Information (CMI)

This leaflet provides important information about using OPDUALAG. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using OPDUALAG.**

Where to find information in this leaflet:

- [1. Why am I given OPDUALAG?](#)
- [2. What should I know before I am given OPDUALAG?](#)
- [3. What if I am taking other medicines?](#)
- [4. How am I given OPDUALAG?](#)
- [5. What should I know while receiving OPDUALAG?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I given OPDUALAG?

OPDUALAG is a medicine that contains two active substances: nivolumab and relatlimab, which are monoclonal antibodies. They are designed to recognise and attach to a specific target substance in the body.

Nivolumab attaches to a target protein called programmed death 1 receptor (PD 1). Relatlimab attaches to a target protein called lymphocyte activation gene 3 (LAG 3). Those proteins can switch off the activity of T cells (a type of white blood cell that forms part of the immune system, the body's natural defence). By attaching to LAG 3 and PD 1, nivolumab and relatlimab block their action and prevent them from switching off your T cells. This helps increase their activity against the melanoma cancer cells.

OPDUALAG is used to treat:

advanced (unresectable or metastatic melanoma) in adults and in adolescents (12 years and older weighing at least 40 kg).

2. What should I know before I am given OPDUALAG?

Warnings

Do not use OPDUALAG if:

- you are allergic to nivolumab and relatlimab or any of the other ingredients of this medicine. Always check the ingredients and speak to your doctor to make sure you can use this medicine.
- Do not use OPDUALAG if you are pregnant unless your doctor specifically tells you to.

Talk to your doctor before using OPDUALAG as it may cause:

Problems with your lungs such as breathing difficulties or cough. These may be signs of inflammation of the lungs (pneumonitis or interstitial lung disease).

Diarrhoea (watery, loose or soft stools) or any symptoms of **inflammation of the intestines** (colitis), such as stomach pain and mucus or blood in stool.

Inflammation of the liver (hepatitis). Signs and symptoms of hepatitis may include abnormal liver function tests, eye or skin yellowing (jaundice), pain on the right side of your stomach area, or tiredness.

Inflammation or problems with your kidneys. Signs and symptoms may include abnormal kidney function tests, or decreased volume of urine.

Problems with your hormone producing glands (including the pituitary, the thyroid, the parathyroid and adrenal glands) that may affect how these glands work. Signs and symptoms that these glands are not working properly may include fatigue (extreme tiredness), weight change or headache, decreased blood levels of calcium and visual disturbances.

Diabetes (symptoms include excessive thirst, the passing of a greatly increased amount of urine, increase in appetite with a loss of weight, feeling tired, drowsy, weak, depressed, irritable and generally unwell) or **diabetic ketoacidosis** (acid in the blood produced from diabetes).

Inflammation of the skin that can lead to severe skin reaction (known as toxic epidermal necrolysis and Stevens Johnson syndrome). Signs and symptoms of severe skin reaction may include rash, itching, and peeling of the skin (possibly fatal).

Inflammation of the heart muscle (myocarditis). Signs and symptoms may include chest pain, irregular and/or rapid heartbeat, fatigue, swelling in the ankles or shortness of breath.

Solid organ transplant rejection.

Haemophagocytic lymphohistiocytosis. A rare disease in which your immune system makes too many of otherwise normal infection fighting cells called histiocytes and lymphocytes. Symptoms may include

enlarged liver and/or spleen, skin rash, lymph node enlargement, breathing problems, easy bruising, kidney abnormalities, and heart problems.

Graft versus host disease. This may happen if you received a stem cell transplant that used donor stem cells (allogeneic) before treatment with OPDUALAG.

Tell your doctor immediately if you have any of these signs or symptoms or if they get worse. These signs and symptoms are **sometimes delayed**, and may develop weeks or months after your last dose.

Check with your doctor if you:

- have any history of **inflammation of the lungs**
- have been taken **medicines to suppress your immune system**
- were previously given immunotherapy and experienced serious side effects because of that medicine; have an **autoimmune disease** (a condition where the body attacks its own organs) like 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
- have been told that your **cancer has spread to your brain**
- have **melanoma of the eye**
- are **pregnant** or think you might be or **plan to become pregnant**. OPDUALAG can harm your

unborn baby. Your healthcare provider should do a pregnancy test before you start receiving OPDUALAG.

- are **breastfeeding** or intend to breastfeed

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Do not use OPDUALAG if you are pregnant unless your doctor specifically tells you to. The effects of OPDUALAG in pregnant women are not known, but it is possible that the active substances, relatlimab and nivolumab, could harm an unborn baby.

Ask your doctor if you can breast-feed during or after treatment with OPDUALAG. It is not known if this medicine passes into human milk. A risk to the breast-fed infant cannot be excluded.

If you are pregnant, breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.

You must use effective contraception while you are being treated with OPDUALAG and for at least 5 months following the last dose of OPDUALAG, if you are a woman who could become pregnant. Talk to your doctor about contraceptive methods that may be right for you while you are taking OPDUALAG.

Tell your doctor straight away if you become pregnant during treatment.

Use in children or adolescents

- This medicine is not recommended for use in children and adolescents under 12 years of age.

OPDUALAG contains sugar (as sucrose)

- OPDUALAG contains sugar. If you have been told by your doctor that you have intolerance to some sugars, contact your doctor before taking this medicine.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect OPDUALAG.

Tell your doctor if you are taking any medicines that suppress your immune system, such as corticosteroids, since these medicines may interfere with the effect of OPDUALAG. However, once you are treated with OPDUALAG, your doctor may give you corticosteroids to reduce any possible side effects that you may have during your treatment and this will not impact the effect of the medicine.

Do not take any other medicines during your treatment without talking to your doctor first.

4. How am I given OPDUALAG?

How is OPDUALAG given

You will receive treatment with OPDUALAG in a hospital or clinic, under the supervision of an experienced healthcare professional.

OPDUALAG will be given to you as an infusion (a drip) into a vein (intravenously).

How much you will be given

The recommended dose in **adult patients** is:

OPDUALAG (480 mg nivolumab and 160 mg relatlimab) every 4 weeks administered as an intravenous infusion over 30 minutes

The recommended dose in **adolescent patients (12 years and older) weighing at least 40 kg** is:

OPDUALAG (480 mg nivolumab and 160 mg relatlimab) every 4 weeks administered as an intravenous infusion over 30 minutes

Depending on your dose, the appropriate amount of OPDUALAG will be diluted with sodium chloride 9 mg/mL (0.9%) solution for injection or glucose 50 mg/mL (5%) solution for injection before use. More than one vial of OPDUALAG may be necessary to obtain the required dose.

How often will you receive OPDUALAG

OPDUALAG is given every 4 weeks.

Your doctor will continue giving you OPDUALAG for as long as you keep benefitting from it or until you no longer tolerate the treatment.

Your healthcare provider will do blood tests regularly to check you for side effects.

If you miss any appointments, call your doctor as soon as possible to reschedule your appointment

If you have any further questions on the use of this medicine, ask your doctor.

5. What should I know while receiving OPDUALAG?

Things you should do

- Keep all of your doctor's appointments so that your progress can be checked.
- Tell any other doctors, dentists, and pharmacists who are treating you that you are being treated with OPDUALAG.
- Be aware of important symptoms of inflammation. OPDUALAG acts on your immune system and may cause inflammation in any parts of your body. Inflammation may cause serious damage to your body and some inflammatory conditions may be life

threatening and need treatment or withdrawal of OPDUALAG.

- Tell your doctor immediately if you experience any signs or symptoms of inflammation.
- Tell your doctor immediately if you become pregnant while being treated with OPDUALAG
- Use an effective method of contraception during treatment and for 5 months after stopping treatment.

Call your doctor straight away, or go to the Emergency Department at your nearest hospital if you:

- experience shortness of breath; wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash; itching; or hives on the skin. These could be symptoms of a serious allergic reaction.
- Experience signs and symptoms of a serious immune related problem or side effect (see Section 6, Are there any side effects in this CMI).

Things you should not do

- Do not use this medicine during pregnancy without speaking to your doctor.
- Do not breast feed if you are taking OPDUALAG without speaking to your doctor.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how OPDUALAG affects you.

OPDUALAG may have a minor influence on the ability to drive and use machines; however, use caution when performing these activities until you are sure that OPDUALAG does not adversely affect you.

Looking after your medicine

It is unlikely that you will be asked to store OPDUALAG yourself. It will be stored in the hospital or clinic where it is given to you.

6. Are there any side effects?

Like all medicines, this medicine can cause side effects, although not everybody gets them. Your doctor will discuss these with you and will explain the risks and benefits of your treatment.

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.

Do not try to treat your symptoms with other medicines on your own. Your doctor may

- give you other medicines in order to prevent complications and reduce your symptoms,
- withhold the next dose of OPDUALAG,
- or stop your treatment with OPDUALAG altogether.

Serious side effects

Serious side effects	What to do
<p>Lung problems:</p> <ul style="list-style-type: none"> • inflammation of the lung (pneumonitis) characterised by new or worsening cough • shortness of breath • breathing difficulties or chest pain <p>Intestinal problems:</p> <ul style="list-style-type: none"> • diarrhoea (watery, loose or soft 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 • Inflammation of the intestines (colitis) 	<p>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects or they get worse.</p>

Serious side effects	What to do
<p>Liver problems:</p> <ul style="list-style-type: none"> ● inflammation of the liver (hepatitis) and Inflammation of the bile duct system (cholangitis). ● yellowing of your skin or the whites of your eyes (jaundice) ● severe nausea or vomiting ● pain on the right side of your stomach area (abdomen) ● dark urine (tea colored) ● tiredness ● bleeding or bruising more easily than normal, fever or chills <p>Hormone gland problems:</p> <ul style="list-style-type: none"> ● headaches that will not go away or unusual headaches ● eye sensitivity to light ● eye problems ● rapid heartbeat 	

Serious side effects	What to do
<ul style="list-style-type: none"> ● 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 ● drowsiness, weakness, feeling generally unwell ● changes in mood or behavior, such as decreased sex drive, irritability, or forgetfulness <p>Kidney problems:</p> <ul style="list-style-type: none"> ● inflammation of the kidney ● kidney failure; high levels of proteins in the urine 	

Serious side effects	What to do
<ul style="list-style-type: none"> ● decrease in your amount of urine ● blood in your urine ● swelling in your ankles ● loss of appetite <p>Skin problems:</p> <ul style="list-style-type: none"> ● rash ● itching ● skin blistering or peeling (pemphigoid) ● painful sore or ulcers in mouth or nose, throat, or genital area <p>Heart problems:</p> <ul style="list-style-type: none"> ● chest pain ● irregular and/or rapid heartbeat ● swelling in your ankles ● fatigue ● shortness of breath ● fluid around the heart ● inflammation of the heart muscle <p>These are not all of the signs and symptoms of immune</p>	

Serious side effects	What to do
<p>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:</p> <ul style="list-style-type: none"> ● inflammation of the brain (encephalitis), ● confusion, sleepiness, memory problems, fever, changes in mood or behavior, stiff neck, balance problems, seizures, tingling or numbness of the arms or legs ● dizziness; inflammation of the nerves (causing numbness, weakness, tingling or burning pain of the arms and legs); impairment of the sense of taste ● double vision, blurry vision, sensitivity to light, eye pain, changes in eyesight 	

Serious side effects	What to do
<ul style="list-style-type: none"> ● persistent or severe muscle pain or weakness, muscle cramps ● low red blood cells, bruising ● a temporary inflammation of the nerves that causes pain, weakness, and paralysis in the extremities (Guillain-Barré syndrome); inflammation of the optic nerve that may cause a complete or partial loss of vision ● increased secretion of tears; increase blood congestion in the eye; an inflammatory disorder, most likely of autoimmune origin, affecting the eyes, skin and the membranes of the ears, brain and spinal cord (Vogt-Koyanagi-Harada syndrome) 	

Serious side effects	What to do
<ul style="list-style-type: none"> ● condition in which the immune system attacks its own tissues, causing widespread inflammation and tissue damage in the affected organs, such as joints, skin, brain, lungs, kidneys, and blood vessels (systemic lupus erythematosus) ● condition in which the immune system attacks the glands that make moisture for the body, such as tears and saliva (Sjogren’s syndrome) ● inflammation of the pancreas 	

Other side effects

Very Common side effects	What to do
<ul style="list-style-type: none"> ● decreased appetite ● nausea; stomach pain; constipation 	<p>Speak to your doctor or seek medical attention if you have any of these side effects.</p>

Very Common side effects	What to do
<ul style="list-style-type: none"> ● itching; skin colour change in patches (vitiligo) ● pain in the muscles, bones and joints ● feeling tired or weak, fever <p>Changes in the results of tests carried out by your doctor may show:</p> <ul style="list-style-type: none"> ● abnormal liver function (increased amounts of the liver enzymes alkaline phosphatase, aspartate aminotransferase, alanine aminotransferase in your blood) ● abnormal kidney function (increased amounts of creatinine in your blood), changes in blood levels of different salts (sodium, potassium, magnesium, calcium) 	

Very Common side effects	What to do
Common side effects	
<ul style="list-style-type: none"> ● infections of the upper respiratory tract ● decreased number of platelets (cells which help the blood to clot); increase in some white blood cells ● overactive thyroid gland; decreased secretion of hormones produced by adrenal glands (glands situated above the kidneys); inflammation of the thyroid gland; inflammation of the pituitary gland situated at the base of the brain ● weight loss; low sugar levels in the blood; high uric acid levels in the blood; decreased levels of albumin in the blood ● dizziness; inflammation of the nerves (causing numbness, weakness, tingling or burning pain of the arms and legs); 	

Very Common side effects	What to do
<p>impairment of the sense of taste</p> <ul style="list-style-type: none"> ● dry eyes, inflammation of the eye (which causes pain and redness, vision problems or blurry vision) ● inflammation of a vein, which can cause redness, tenderness and swelling ● nasal congestion ● vomiting; dry mouth; mouth ulcers and cold sores; difficulty in swallowing; inflammation of the stomach (gastritis) ● dry skin; unusual hair loss or thinning; thickened, sometimes scaly, skin growth; sensitivity to light ● painful joints; muscle spasms; muscle weakness ● oedema (swelling); flu-like symptoms; chills 	

Very Common side effects	What to do
<ul style="list-style-type: none"> ● reactions related to the administration of the medicine <p>Changes in the results of tests carried out by your doctor may show:</p> <ul style="list-style-type: none"> ● abnormal liver function (higher blood levels of the waste product bilirubin) ● increased levels of different enzymes in the blood 	
Uncommon side effects	
<ul style="list-style-type: none"> ● inflammation and infection in the hair follicles ● disorder in which red blood cells are destroyed faster than they can be made ● underactive function of the pituitary gland situated at the base of the brain; underactive 	

Very Common side effects	What to do
<p>function of the glands producing sex hormones</p> <ul style="list-style-type: none"> ● asthma ● inflammation of the food pipe ● inflammation of the bile duct ● skin disease with thickened patches of red skin, often with silvery scales (psoriasis); hives (itchy, bumpy rash); skin rashes; patches of white skin (vitiligo) ● inflammation of the bursa, fluid-filled sacs that act as a cushion between bones, tendons, joints, and muscles; inflammation of the muscles causing weakness, swelling, and pain or stiffness ● inflammation of muscles causing pain or stiffness; inflammation of the joints (painful joint disease) 	

Very Common side effects	What to do
<ul style="list-style-type: none"> ● absence of sperm in the semen <p>Changes in the results of tests carried out by your doctor may show:</p> <ul style="list-style-type: none"> ● abnormal c-reactive protein increased ● red blood cell sedimentation rate increased 	

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

OPDUALAG is only available with a doctor's prescription.

What OPDUALAG contains

Active ingredients	The active substances are nivolumab and relatlimab
Other ingredients (inactive ingredients)	The other ingredients are: <ul style="list-style-type: none">• histidine• histidine hydrochloride monohydrate• sucrose• pentetic acid• polysorbate 80 (E433)• water for injections

Do not take this medicine if you are allergic to any of these ingredients.

What OPDUALAG looks like

OPDUALAG concentrate for solution for infusion (sterile concentrate) is a clear to opalescent, colourless to slightly yellow liquid that may contain few light particles.

It is available in cartons containing one glass vial (AUST R 372783).

Who distributes OPDUALAG in Australia

Bristol-Myers Squibb Australia Pty Ltd

4 Nexus Court, Mulgrave,

Victoria 3170, Australia.

Toll free number: 1800 067 567

Email: MedInfo.Australia@bms.com

OPDUALAG™ is a trademark of Bristol-Myers Squibb Company.

This leaflet was prepared in October 2023.