OPDIVO®

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.

1. Why am I given OPDIVO?

OPDIVO contains the active ingredient nivolumab. OPDIVO is used to treat various kinds of cancer.

For more information, see Section 1. Why am I given OPDIVO? in the full CMI.

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

Do not use if you have ever had an allergic reaction to OPDIVO 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 am given OPDIVO? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with OPDIVO and affect how it works.

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 OPDIVO?

- OPDIVO will be given to you in hospital or clinic under the supervision of an experienced doctor and/or nurse
- It will be given to you as an infusion (a drip) into a vein (intravenously)
- Your doctor will decide how many treatments you should be given

More instructions can be found in Section 4. How am I given OPDIVO? in the full CMI.

5. What should I know while receiving OPDIVO?

Things you should do	• Tell any other doctors, dentists, nurses, and pharmacists who are treating you that you are being given OPDIVO • Ensure you tell your doctor if you have autoimmune disease, any history of inflammation of the lungs, melanoma of the eye, if you have cancer that has spread to the brain, if you were previously given ipilimumab, another medicine for the treatment of advanced melanoma, and experienced side effects because of this medicine or if you are taking any medicines that suppress your immune system, such as corticosteroids • OPDIVO 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 OPDIVO • Tell your doctor immediately if you have any signs or symptoms of possible side effects or if they get worse despite medical care or management
Things you should not do	• Do not try to treat your symptoms with other medicines on your own without telling your doctor. Your doctor may give you other medicines to prevent complications or reduce your symptoms, your doctor may withhold the next dose of OPDIVO, or stop your treatment with OPDIVO altogether
Driving or using machines	• OPDIVO is unlikely to affect your ability to drive or use machines; however, use caution when performing these activities and notify your doctor if you notice any changes to your ability

For more information, see Section 5. What should I know while receiving OPDIVO? in the full CMI.

6. Are there any side effects?

Like all medicines, OPDIVO can cause side effects. Your doctor will discuss potential side effects with you and will explain the risks and benefits of your treatment. Some side effects can be 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 (changes to your normal self), particularly if they are getting worse or do not go away. 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.

Both OPDIVO and ipilimumab act on your immune system and may cause inflammation in parts of your body. Inflammation may cause serious damage to your body and some inflammatory conditions may be life-threatening.

These side effects are most likely to begin during treatment, however, side effects can show up months after your last infusion.

IT IS IMPORTANT TO TELL YOUR DOCTOR IMMEDIATELY IF YOU HAVE, OR DEVELOP, ANY OF THE SYMPTOMS LISTED UNDER POSSIBLE SIDE EFFECTS.

OPDIVO® (op-DEE-voh)

Active ingredient: *nivolumab* (nee-vol-u-mab)

Consumer Medicine Information (CMI)

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

Where to find information in this leaflet:

1. Why am I given OPDIVO?
2. What should I know before I am given OPDIVO?
3. What if I am taking other medicines?
4. How am I given OPDIVO?
5. What should I know while receiving OPDIVO?
6. Are there any side effects?
7. Product details

1. Why am I given OPDIVO?

OPDIVO contains the active ingredient nivolumab. OPDIVO is a protein which helps your immune system to attack and destroy cancer cells.

OPDIVO is used to treat:

- Advanced skin cancer (unresectable or metastatic melanoma)
- A type of lung cancer (advanced squamous and non-squamous non-small cell lung cancer)
- A type of kidney cancer (clear cell renal cell carcinoma)
- A type of head and neck cancer (squamous cell cancer of the head and neck)
- A type of blood cancer called classical Hodgkin lymphoma that has come back after or has not responded to previous therapies, including an autologous stem-cell transplant (a transplant of your own blood-producing cells) in adults
- A type of bladder cancer (urothelial carcinoma)
- A type of liver cancer (hepatocellular carcinoma)
- A type of food pipe cancer (oesophageal squamous cell cancer), if your cancer has not responded, or if it has stopped responding, to earlier treatment
- Cancer of the oesophagus (food pipe) or gastro-oesophageal junction (area which connects your food pipe and stomach) after chemoradiotherapy followed by surgical removal of the cancer
- Bladder cancer (urothelial carcinoma) after surgical removal of the cancer. Treatment after surgery is also called adjuvant therapy.
- Skin cancer (melanoma) after surgical removal of the cancer in adults and adolescents (12 years and older)

OPDIVO in combination with ipilimumab is used to treat:

- Advanced melanoma (unresectable or metastatic melanoma)
- A type of advanced kidney cancer (renal cell carcinoma)
- A type of cancer that affects the lining of the lung (Malignant pleural mesothelioma)
- A type of liver cancer (unresectable or metastatic hepatocellular carcinoma)
- A type of cancer of the food pipe (oesophageal squamous cell cancer).
- A type of cancer of the colon or rectum, together referred to as colorectal cancer or bowel cancer, that is shown by a laboratory test to have certain biological markers (microsatellite instability-high [MSI-H] or mismatch repair deficient [dMMR])

OPDIVO in combination with ipilimumab and chemotherapy is used to treat:

- A type of lung cancer (non-small cell lung cancer without certain biological markers)

OPDIVO in combination with cabozantinib is used to treat:

- A type of kidney cancer (renal cell carcinoma)

OPDIVO in combination with chemotherapy is used to treat:

- A type of cancer of the stomach (gastric adenocarcinoma), the connection between the stomach and food pipe (gastro-oesophageal junction adenocarcinoma) or the food pipe (oesophageal adenocarcinoma or oesophageal squamous cell cancer)
- A type of lung cancer (non-small cell lung cancer) before you have surgery
- A type of lung cancer (non-small cell lung cancer) before surgery and following surgery (treatment before surgery is called neoadjuvant therapy; treatment after surgery is called adjuvant therapy)
- A type of bladder cancer (unresectable or metastatic urothelial carcinoma)
- Advanced classical Hodgkin lymphoma that has not been treated in adults and adolescents 12 years of age and older.

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

Warnings

You should not be given OPDIVO if:

- you are allergic to nivolumab, or any of the ingredients listed in Section 7. Product details

Always check the ingredients or talk to your doctor to make sure you can use this medicine.

Check with your doctor if you:

- have an autoimmune disease (a condition where the body attacks its own cells) like Crohn's, ulcerative colitis or lupus
- have any history of inflammation of the lungs
- have been told your cancer has spread to your brain
- have melanoma of the eye
- were previously given ipilimumab, another medicine for the treatment of advanced melanoma, and experienced side effects because of this medicine.
- are taking any medicines that suppress your immune system, such as corticosteroids, since these medicines may interfere with the effect of OPDIVO. However, once you are treated with OPDIVO, 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.

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

Check with your doctor if you are pregnant, intend to become pregnant, or if you are breast-feeding.

You must not use OPDIVO if you are pregnant unless your doctor specifically recommends it.

The effects of OPDIVO in pregnant women are not known, but it is possible that the active substance, nivolumab, could harm an unborn baby.

- You must use effective contraception while you are being treated with OPDIVO, and for at least 5 months following the last dose of OPDIVO, if you are a woman who could become pregnant
- If you become pregnant while using OPDIVO, tell your doctor

You should stop breast-feeding if you are being treated with OPDIVO.

It is not known whether nivolumab gets into breast milk. A risk to the breast-fed infant cannot be excluded.

Use in children or adolescents

- For treatment of adjuvant melanoma or untreated,classical Hodgkin lymphoma, it is recommended to use this medicine in adolescents (12 years and older).
- For all other indications, it is not recommended to use this medicine in children or an adolescent (below 18 years) until further information becomes available.

Important information about some of the ingredients of OPDIVO

- Tell your doctor if you are on a low-sodium (low-salt) diet before you are given OPDIVO. This medicine contains 2.5 mg sodium per mL of concentrate.

3. What if I am taking other medicines?

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

Ask your doctor for advice before taking any medicine or dietary supplement/vitamin during your treatment.

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

4. How am I given OPDIVO?

How is OPDIVO given

- OPDIVO will be given to you in hospital or clinic under the supervision of an experienced doctor
- It will be given to you as an infusion (a drip) into a vein (intravenously)
- Your doctor will decide how many treatments you should be given

Dosage and frequency of administration of OPDIVO

- The recommended dose (amount) and frequency (timing) of OPDIVO can be different depending on the type of cancer it is being used to treat
- Some types of cancer are treated with OPDIVO in combination with other prescription anti-cancer medicines
- Your doctor will advise you which treatments you will be given and will tell you about the dose and frequency of these treatments
- Please refer to the Consumer Medicine Information of the other prescription anti-cancer medicines in order to understand the use of these other prescription anti-cancer medicines. If you have questions about these medicines, please ask your doctor

If you miss a dose of OPDIVO

It is very important for you to keep all appointments to receive OPDIVO. If you miss an appointment, ask your doctor when to schedule your next dose.

If you are given too much OPDIVO

As OPDIVO is given to you under the supervision of your doctor, it is unlikely that you will be given too much.

However, if you experience any side effects after being given OPDIVO, tell your doctor immediately.

5. What should I know while receiving OPDIVO?

Things you should do

Tell any other doctors, dentists, nurses and pharmacists who are treating you that you are being given OPDIVO.

If you are about to be started on any new medicine, tell your doctor, dentist or pharmacist that you are being given OPDIVO.

Call your doctor straight away if you:

- Have any signs or symptoms of possible side effects or if they get worse. See Section 6. Are there any side effects?
- Develop symptoms of an allergic reaction. These symptoms may include 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.

Things you should not do

Do not try to treat your symptoms with other medicines on your own without telling your doctor.

- Your doctor may:
- Give you other medicines in order to prevent complications and reduce your symptoms
- Withhold the next dose of OPDIVO
- Or stop your treatment with OPDIVO altogether

Please note that these signs and symptoms are sometimes delayed, and may develop weeks or months after your last dose. Before treatment, your doctor will check your general health. You will also have blood tests during treatment.

Take special care with OPDIVO

- OPDIVO is a medicine that influences your immune system and may cause inflammation in 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 OPDIVO
- Tell your doctor immediately if you have any of the symptoms of inflammation listed in Section 6. Are there any side effects?

Driving or using machines

No studies on the effects of OPDIVO on the ability to drive and use machines have been performed.

OPDIVO is unlikely to affect your ability to drive or use machines; however, use caution when performing these activities until you are sure that OPDIVO does not adversely affect you and notify your doctor if you notice any changes to your ability.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

OPDIVO alone or in combination may cause changes in the results of tests carried out by your doctor.

Serious side effects

Serious side effects	What to do
Lung problems: • Problems with your lungs such as breathing difficulties, shortness of breath, or cough. These may be signs of inflammation of the lungs (pneumonitis or interstitial lung disease) **Stomach and Intestinal problems:** • Inflammation of the intestines (colitis, enterocolitis, coeliac disease, pancreatic exocrine insufficiency), stomach (gastritis) and duodenum (duodenitis) which can worsen to bleeding or bowel perforation • Symptoms may include diarrhoea (watery, loose or soft stools), an increased number of bowel movements (an increase by two or more per day), constipation, vomiting, nausea, mucus and blood in your stools, or darker-coloured stools, stomach pain or tenderness in your stomach area **Liver problems:** • Inflammation of the liver (hepatitis) and Inflammation of the bile duct system (cholangitis). • Symptoms may include yellowing of the eyes or skin (jaundice), pain on the right side of your stomach area, tiredness, nausea or vomiting, fever or chills **Kidney problems:** • Inflammation in the kidney (nephritis) • Signs and symptoms may include abnormal kidney function tests, decreased volume of urine and	**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.**

Serious side effects	What to do
kidney failure (including abrupt loss of kidney function) **Hormone gland problems:** • Underactive thyroid gland, which can cause tiredness or weight gain • Overactive thyroid gland, which can cause rapid heart rate, sweating and weight loss • Decreased secretion of hormones produced by adrenal glands (glands situated above the kidneys), underactive function (hypopituitarism) or inflammation (hypophysitis) of the pituitary gland situated at the base of the brain, swelling of the thyroid gland • Decrease in parathyroid hormone • Acid in the blood produced by diabetes (diabetic ketoacidosis) • 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 (diabetes) **Skin problems:** • Inflammation of the skin that can lead to rash and itching • Severe and possibly fatal peeling of the skin (toxic epidermal necrolysis, Steven-Johnson syndrome) • Severe condition of the skin that causes red, often itchy spots, similar to rash of measles, which starts on the limbs and sometimes on the face and the rest of the body (erythema multiforme), skin disease with thickened patches of red skin, often silvery scales (psoriasis), hives (itchy, bumpy rash) **Brain and nervous system problems:** • Damage to nerves causing numbness and weakness, including in the extremities like hands or feet (polyneuropathy, peripheral neuropathy) • Inflammation of the brain (encephalitis) • A condition in which the muscles become weak and tire easily (myasthenic syndrome)	

Serious side effects	What to do
• Inflammation of the nerves causing numbness, weakness, tingling or burning pain of the arms and legs, headaches, dizziness (autoimmune neuropathy) • Loss of the covering around the nerves (demyelination) pain • A temporary inflammation of the nerves that causes pain, weakness and paralysis in the extremities (Guillain-Barré syndrome) • Sensations like numbness and tingling (paraesthesia), dizziness • Inflammation of the spinal cord (myelitis) causing back and neck pain, weakness in the arms or legs, loss of bladder or bowel control • Inflammation of the tissue around the brain and spinal cord (aseptic meningitis) causing headache, neck stiffness (with or without fever), light sensitivity, muscle pain and altered levels of consciousness **Complications of allogeneic Haematopoietic Stem Cell Transplant (HSCT):** • Complications of stem cell transplant that uses donor cells (allogeneic) may occur after treatment with OPDIVO. • 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. **Problems in other organs:** • Inflammation of the heart (myocarditis). Symptoms may include shortness of breath, fatigue, palpitations or chest pain • Changes in the rhythm or rate of the heart, abnormal heart rhythm • Inflammation of muscles (myositis). Symptoms may include muscle pain, stiffness, weakness, chest pain or severe fatigue • Muscle breakdown/injury (rhabdomyolysis). Symptoms may include muscle pain, weakness, nausea or vomiting.	

Serious side effects	What to do
• Inflammation of the eye, which causes pain and redness, blurred vision • Solid organ transplant rejection • A condition where the immune system mistakenly destroys red blood cells (oxygen carrying cells) and results in decreased number of red blood cells (autoimmune haemolytic anaemia) • A condition where the bone marrow fails to produce enough new blood cells (aplastic anaemia) which can result in anaemia (decreased red blood cells), and susceptibility to infection or bruising • A condition where the immune system makes too many infection-fighting cells called histiocytes and lymphocytes that may cause various symptoms (called haemophagocytic lymphohistiocytosis). Symptoms may include enlarged liver and/or spleen, skin rash, lymph node enlargement, breathing problems, easy bruising, kidney abnormalities, and heart problems. • Inflammation throughout the body (systemic inflammatory response syndrome) leading to redness and swelling (oedema) in the affected parts, intense pain, fatigue, fast heart rate, abnormal breathing, fever or chills • A group of metabolic complications occurring after cancer treatment characterised by high blood levels of potassium and phosphate, and low blood levels of calcium (tumour lysis syndrome). • A condition where a combination of the heart, muscles, and nerves can become inflamed and weak – can cause chest pain, irregular heartbeats, severe muscle weakness or pain, and vision/swallowing difficulties. **Infusion reactions:** • Allergic reaction, reaction related to the infusion of the medicine • Life threatening allergic reaction	

Serious side effects	What to do
• Hypovolaemic shock, causing rapid heart rate, shallow breathing, cool, clammy skin, confusion or dizziness	

Other side effects

Other side effects	What to do
The following side effects have been reported in clinical trials when OPDIVO has been given alone: • **Very Common side effects** • Diarrhoea (watery, loose or soft stools), nausea • Skin rash sometimes with blisters, itching • Feeling tired or weak • **Common side effects** • Infections of the upper respiratory tract • Decreased appetite • Coughing, shortness of breath (dyspnoea) • Stomach pain, constipation • Mouth ulcers and cold sores (stomatitis), vomiting, dry mouth • Skin colour changes in patches (vitiligo), dry skin, redness of the skin, hair loss or thinning • Pain in the muscles, bones and joints • Fever, oedema (swelling) • High blood pressure (hypertension) • Dry eye	**Speak to your doctor if you have any of these side effects and they worry you.**
The following side effects have been reported in clinical trials when OPDIVO has been given in combination with ipilimumab: • **Very Common side effects** • Decreased appetite • Headache • Shortness of breath (dyspnoea) • Skin rash sometimes with blisters, itching • Pain in the joints, muscles and bones • Feeling tired or weak • Fever **Common side effects** • Serious lung infection (pneumonia), infections of the upper respiratory tract	**Speak to your doctor if you have any of these side effects and they worry you.**

Other side effects	What to do
• Dehydration • Inflammation of the eye, which causes pain and redness, blurred vision • Fast heart rate • High blood pressure (hypertension) • Mouth ulcers and cold sores (stomatitis), inflammation of the pancreas (pancreatitis), constipation, dry mouth • Skin colour change in patches (vitiligo), dry skin, redness of the skin, unusual hair loss or thinning, hives (itchy rash) • Pain in the muscles and bones • Inflammation of the joints (arthritis) • Oedema (swelling), pain	
The following side effects have been reported in clinical trials when OPDIVO has been given in combination with ipilimumab and chemotherapy • **Very Common side effects** • Decreased appetite • Diarrhoea (watery, loose or soft stools), vomiting, nausea • Skin rash sometimes with blisters, itching • Feeling tired or weak • **Common side effects** • Conjunctivitis • Serious lung infection (pneumonia), infections of the upper respiratory tract • Dry eyes • headache • Shortness of breath (dyspnoea) • Mouth ulcers and cold sores (stomatitis), inflammation of the pancreas (pancreatitis), constipation, dry mouth • Dry skin, redness of the skin, unusual hair loss or thinning • Pain in the joints, muscles and bones, inflammation of the joints • Fever • Oedema (swelling)	**Speak to your doctor if you have any of these side effects and they worry you.**
The following side effects have been reported in clinical trials when OPDIVO has been given in combination with cabozantinib	**Speak to your doctor if you have any of these side effects and they worry you.**
• **Very Common side effects** • Decreased appetite, altered sense of taste • High blood pressure (hypertension) • Hoarseness • Diarrhoea, nausea, mouth ulcers and cold sores (stomatitism), vomiting, abdominal pain, indigestion • Blisters, pain of the hands or soles of the feet, rash or redness of the skin, rash, itching • Feeling tired or weak • **Common side effects** • Infections of the upper respiratory tract • Dehydration • Headache, dizziness, inflammation of the nerves causing numbness or burning pain of the arms and legs • Dry eye • Blood clots • Dry mouth, constipation, inflammation of the stomach (gastritis), oral pain • Dry skin, unusual hair loss or thinning, redness of the skin, hair colour change • Pain in the joints, muscle spasm, pain in the muscles or bones, pains, inflammation in the joints • Oedema (swelling), fever, pain	**effects and they worry you.**
The following side effects have been reported in clinical trials when OPDIVO has been given in combination with chemotherapy • **Very Common side effects** • Decreased appetite • Constipation • Diarrhoea (watery, loose or soft stools), vomiting, nausea • Mouth ulcers and cold sores (stomatitis) • Feeling tired or weak • Skin rash sometimes with blisters, itching, tingling and tenderness developing to symmetrical redness, swelling and pain primarily on the palm of the hand and sole of the foot (palmar-plantar erythrodysaesthaesia syndrome)	**Speak to your doctor if you have any of these side effects and they worry you.**

Other side effects	What to do
• Pain in the joints, muscles and bones • Low white blood cell count • Increased liver enzymes • **Common side effects** • Serious lung infection (pneumonia), infections of the upper respiratory tract • Headache • Dry eyes • Blurred vision • Shortness of breath (dyspnoea) • Blood clots, low blood pressure (hypotension) • Dry mouth • Abdominal pain • Dry skin, redness of the skin, unusual hair loss or thinning, skin colour change in patches, hives (itchy rash) • Inflammation of the joints, muscle weakness • Fever • Oedema (swelling) • Inflammation of the blood vessels (vasculitis) • High blood pressure (hypertension)	

Tell your doctor, nurse 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

This medicine is only available with a doctor's prescription.

What OPDIVO contains

Active ingredient (main ingredient)	nivolumab
Other ingredients (inactive ingredients)	• sodium citrate dihydrate • sodium chloride • mannitol (E421) • pentetic acid • polysorbate 80 • sodium hydroxide • hydrochloric acid • water for injections

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

What OPDIVO looks like

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

OPDIVO is available in the following presentations:

- OPDIVO (nivolumab) concentrate solution for infusion 40 mg in 4 mL (10 mg/mL) AUST R 231867
- OPDIVO (nivolumab) concentrate solution for infusion 100 mg in 10 mL (10 mg/mL) AUST R 231868
- OPDIVO (nivolumab) concentrate solution for infusion 240 mg in 24 mL (10 mg/mL) AUST R 318057 (not marketed)

Who distributes OPDIVO

Bristol-Myers Squibb Australia Pty Ltd

Level 2, 4 Nexus Court

Mulgrave VIC 3170 Australia

Toll free number: 1800 067 567

Email: MedInfo.Australia@bms.com

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