

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 CMI is for the subcutaneous dosage form of OPDIVO. For information about the intravenous dosage form of OPDIVO, please refer to the intravenous OPDIVO CMI.

1. Why am I given OPDIVO SC?

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

For more information, see Section [1. Why am I given OPDIVO SC?](#) in the full CMI.

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

Do not use if you have ever had an allergic reaction to OPDIVO SC 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 SC?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with OPDIVO SC 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 SC?

- OPDIVO SC 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 injection under the skin (subcutaneously) of the abdomen or thigh over a period of 3 to 5 minutes by a doctor or nurse
- Your doctor will decide how many treatments you should be given

More instructions can be found in Section [4. How am I given OPDIVO SC?](#) in the full CMI.

5. What should I know while receiving OPDIVO SC?

Things you should do	<ul style="list-style-type: none">• Tell any other doctors, dentists, nurses, and pharmacists who are treating you that you are being given OPDIVO SC• 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 used to treat various kinds of cancer) and experienced side effects because of this medicine or if you are taking any medicines that suppress your immune system, such as corticosteroids• OPDIVO SC 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 SC• 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	<ul style="list-style-type: none">• 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 SC, or stop your treatment with OPDIVO SC altogether
Driving or using machines	<ul style="list-style-type: none">• OPDIVO SC 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 SC?](#) in the full CMI.

6. Are there any side effects?

Like all medicines, OPDIVO SC 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.

OPDIVO® SC (op-DEE-voh S-C)

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

Consumer Medicine Information (CMI)

This leaflet provides important information about using OPDIVO SC. **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 SC.**

Where to find information in this leaflet:

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

1. Why am I given OPDIVO SC?

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

OPDIVO SC alone 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 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

OPDIVO SC alone as continuing therapy (single-agent phase) following combination therapy of intravenous OPDIVO with ipilimumab (combination phase) is used to treat:

- Advanced melanoma (unresectable or metastatic melanoma)
- A type of advanced kidney cancer (renal cell carcinoma)

- A type of liver cancer (unresectable or metastatic hepatocellular carcinoma)
- 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 SC in combination with cabozantinib is used to treat:

- A type of kidney cancer (renal cell carcinoma)

OPDIVO SC 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)

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

Warnings

You should not be given OPDIVO SC 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 used to treat various kinds of cancer) 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 SC. However,

once you are treated with OPDIVO SC, 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 SC if you are pregnant unless your doctor specifically recommends it.

The effects of OPDIVO SC 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 SC, and for at least 5 months following the last dose of OPDIVO SC, if you are a woman who could become pregnant
- If you become pregnant while using OPDIVO SC, tell your doctor

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

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

- It is not recommended to use this medicine in children or an adolescent (below 18 years).

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 SC.

4. How am I given OPDIVO SC?

How is OPDIVO SC given

- OPDIVO SC will be given to you in hospital or clinic under the supervision of an experienced doctor
- It will be given to you as an injection under the skin (subcutaneously) of the abdomen or thigh over a period of 3 to 5 minutes by a doctor or nurse
- Your doctor will decide how many treatments you should be given

Dosage and frequency of administration of OPDIVO SC

- The recommended dose (amount) and frequency (timing) of OPDIVO SC can be different depending on the type of cancer it is being used to treat
- Some types of cancer are treated with OPDIVO SC 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 SC

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

If you are given too much OPDIVO SC

As OPDIVO SC 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 SC, tell your doctor immediately.

5. What should I know while receiving OPDIVO SC?

Things you should do

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

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

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 SC
- Or stop your treatment with OPDIVO SC 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 SC

- OPDIVO SC 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 SC
- 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 SC on the ability to drive and use machines have been performed.

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

Patient Card

You will also find key messages from this CMI in the Patient Card you have been given by your doctor. It is important that you keep this Patient Card with you and show it to your partner, caregivers and Healthcare Professionals.

Looking after your medicine

OPDIVO SC is administered in a hospital or clinic by a Healthcare Professional (e.g. nurse) under the supervision of an experienced doctor. There is no need to store this medicine at home.

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 SC 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: <ul style="list-style-type: none"> • Problems with your lungs such as breathing difficulties, shortness of breath, or cough. These may be signs of inflammation of the lungs 	Call your doctor straight away, or go straight to the Emergency Department at

Serious side effects	What to do
<p>(pneumonitis or interstitial lung disease)</p> <p>Stomach and Intestinal problems:</p> <ul style="list-style-type: none"> • 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 <p>Liver problems:</p> <ul style="list-style-type: none"> • 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 <p>Kidney problems:</p> <ul style="list-style-type: none"> • Inflammation in the kidney (nephritis) • Signs and symptoms may include abnormal kidney function tests, decreased volume of urine and kidney failure (including abrupt loss of kidney function) <p>Hormone gland problems:</p> <ul style="list-style-type: none"> • 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 	<p>your nearest hospital if you notice any of these serious side effects.</p>

Serious side effects	What to do
<ul style="list-style-type: none"> 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) <p>Skin problems:</p> <ul style="list-style-type: none"> 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) <p>Brain and nervous system problems:</p> <ul style="list-style-type: none"> 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) 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 	

Serious side effects	What to do
<p>legs, loss of bladder or bowel control</p> <ul style="list-style-type: none"> 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 <p>Complications of allogeneic Haematopoietic Stem Cell Transplant (HSCT):</p> <ul style="list-style-type: none"> Complications of stem cell transplant that uses donor cells (allogeneic) may occur after treatment with OPDIVO SC. 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. <p>Problems in other organs:</p> <ul style="list-style-type: none"> 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. 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 	

Serious side effects	What to do
<ul style="list-style-type: none"> 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 <p>Reactions to administration of medication:</p> <ul style="list-style-type: none"> Allergic reaction, reaction related to the administration of the medicine Life threatening allergic reaction Hypovolaemic shock, causing rapid heart rate, shallow breathing, cool, clammy skin, confusion or dizziness 	

Other side effects

Other side effects	What to do
<p>The following side effects have been reported in clinical trials when nivolumab has been given alone:</p> <p>Very Common side effects</p> <ul style="list-style-type: none"> Diarrhoea (watery, loose or soft stools), nausea Skin rash sometimes with blisters, itching Feeling tired or weak <p>Common side effects</p> <ul style="list-style-type: none"> 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 	<p>Speak to your doctor if you have any of these side effects and they worry you.</p>
<p>The following side effects have been reported in clinical trials when</p>	<p>Speak to your doctor if you have any of</p>

Other side effects	What to do
<p>nivolumab has been given in combination with ipilimumab:</p> <p>Very Common side effects</p> <ul style="list-style-type: none"> 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 <p>Common side effects</p> <ul style="list-style-type: none"> Serious lung infection (pneumonia), infections of the upper respiratory tract 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 	<p>these side effects and they worry you.</p>
<p>The following side effects have been reported in clinical trials when nivolumab has been given in combination with cabozantinib</p> <p>Very Common side effects</p> <ul style="list-style-type: none"> Decreased appetite, altered sense of taste High blood pressure (hypertension) Hoarseness Diarrhoea, nausea, mouth ulcers and cold sores (stomatitis), vomiting, abdominal pain, indigestion Blisters, pain of the hands or soles of the feet, rash or redness of the skin, rash, itching 	<p>Speak to your doctor if you have any of these side effects and they worry you.</p>

Other side effects	What to do
<ul style="list-style-type: none"> Feeling tired or weak <p>Common side effects</p> <ul style="list-style-type: none"> 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 	
<p>The following side effects have been reported in clinical trials when nivolumab has been given in combination with chemotherapy</p> <p>Very Common side effects</p> <ul style="list-style-type: none"> 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 erythrodysesthesia syndrome) <p>Common side effects</p> <ul style="list-style-type: none"> 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 	<p>Speak to your doctor if you have any of these side effects and they worry you.</p>

Other side effects	What to do
<ul style="list-style-type: none"> Abdominal pain Dry skin, redness of the skin, unusual hair loss or thinning, skin colour change in patches, hives (itchy rash) Pain in the joints, muscles and bones, inflammation of the joints, muscle weakness Fever Oedema (swelling) Inflammation of the blood vessels (vasculitis) High blood pressure (hypertension) 	
<p>The following side effects have been reported in a clinical trial with OPDIVO SC</p> <ul style="list-style-type: none"> Injection site reactions (redness, swelling, or itching) Pain in muscles, bones, and joints Feeling tired Rash Low thyroid hormone levels Diarrhoea (watery, loose or soft stools) Cough Stomach (abdominal) pain 	<p>Speak to your doctor if you have any of these side effects and they worry you.</p>

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 SC contains

Active ingredient (main ingredient)	nivolumab
Other ingredients (inactive ingredients)	<ul style="list-style-type: none"> Vorhyaluronidase alfa Histidine Histidine hydrochloride monohydrate

	<ul style="list-style-type: none"> • Sucrose • Pentetic acid • Polysorbate 80 • Methionine • Water for injections
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Do not take this medicine if you are allergic to any of these ingredients.

What OPDIVO SC looks like

OPDIVO SC solution for injection is a clear to opalescent, colourless to pale yellow liquid that may contain a few light particles.

OPDIVO SC is available in the following presentation:

- OPDIVO SC (nivolumab) solution for injection 600 mg in 5 mL (120 mg/mL) AUST R 462669

Who distributes OPDIVO SC

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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