OPDIVO® (nivolumab)

Patient Information Guide

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Bristol Myers Squibb®

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Introduction

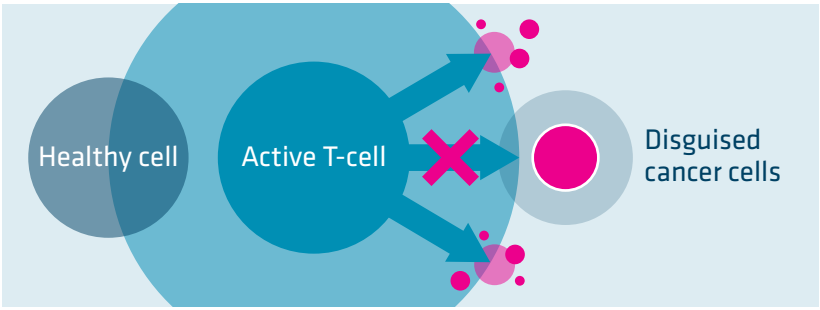
- This guide provides you with information about treatment with OPDIVO® (nivolumab) or OPDIVO in combination with YERVOY® (ipilimumab) and describes potential signs and symptoms (side effects) that you might experience.
- It also provides important advice on what you should do if you experience signs and symptoms to help make sure that they don't worsen and you are treated as quickly and effectively as possible.
- OPDIVO or OPDIVO in combination with YERVOY can cause serious side effects in various parts of the body that need to be addressed immediately, regardless of their severity, to avoid their worsening.
- **A Patient Card is available from BMS Medical Information, you can contact them on 0800 167 567 or medinfo.australia@bms.com. It is recommended that you print out a copy of the Patient Card and carry it with you at all times. Please also inform any healthcare professionals caring for you that you are receiving treatment with OPDIVO or OPDIVO in combination with YERVOY.**
- The healthcare professional treating you with OPDIVO or OPDIVO in combination with YERVOY should complete the 'My Cancer Specialist's Contact Information' section of this Patient Card.

Please note: Your cancer specialist is your primary source of contact for advice, information and support in relation to your condition or treatment with OPDIVO or OPDIVO in combination with YERVOY. Ask your doctor if OPDIVO or OPDIVO in combination with YERVOY is right for you.

What is OPDIVO?

OPDIVO contains the active substance nivolumab, which is a protein that helps your immune system to attack and destroy cancer cells.[1]

Cancer and your immune system



Your immune system consists of a variety of cells (including white blood cells called T-cells) that act as the body's natural defence system. T-cells detect and destroy things that the body considers to be 'foreign', such as bacteria, viruses and cancer cells. Sometimes, cancer can find ways to escape the immune system's defence (for example, by blocking T-cell activity). This allows the cancer to spread and grow.

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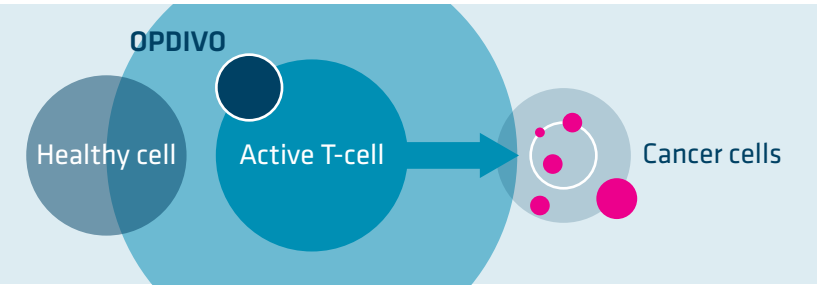
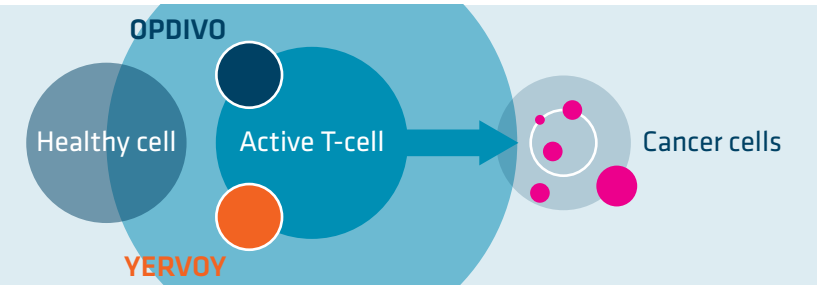
How does OPDIVO work on cancer cells?[1,2]



OPDIVO is a medicine that helps reactivate your immune system's T-cells so they regain the ability to fight cancer cells.

With OPDIVO, there is a risk that your activated immune system can harm healthy cells in your body, which may cause potentially serious or even life-threatening side effects. These problems may happen any time during treatment or even after OPDIVO treatment has ended.

How does OPDIVO in combination with YERVOY work on cancer cells?[3]



YERVOY is a different medicine that acts on T-cells in another way, so it can produce a combined effect when used together with OPDIVO.

YERVOY can also cause your T-cells to attack healthy cells in many parts of your body, which may sometimes lead to serious or even life-threatening side effects.

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Receiving treatment

What does OPDIVO treatment involve?[1]

OPDIVO (or OPDIVO in combination with YERVOY) is a doctor-prescribed medicine that is infused directly into the bloodstream. You will receive the medicine(s) at a treatment centre, where you will have a needle placed in a vein, usually in your arm or the back of your hand.

OPDIVO (or OPDIVO in combination with YERVOY) will be slowly injected over time (infused) through this needle, and the actual time you will spend in the treatment centre may vary. Your cancer specialist will discuss with you what treatments you will receive.

It is important that you:

- Tell your cancer specialist before receiving OPDIVO or OPDIVO in combination with YERVOY if you:
  - have any medical conditions, including an auto-immune disease (a condition where the body attacks its own cells) or any history of inflammation of the lungs
  - are pregnant, planning to become pregnant, or breastfeeding
  - take corticosteroids or any other treatment that affects the immune system
  - take or have taken any other medicines (including prescribed and over-the-counter products, and herbal and vitamin supplements)
  - have received a stem cell transplant that uses donor stem cells (allogeneic)
  - have received an organ transplant (e.g. kidney, liver, heart, cornea or skin).
- Talk to your healthcare team **immediately** about any new or worsening signs and symptoms you experience.
- **DO NOT** breastfeed, and tell your cancer specialist **immediately** if you become pregnant during your treatment with OPDIVO or OPDIVO in combination with YERVOY.
- Re-schedule any missed appointments right away.

Signs and symptoms of your treatment

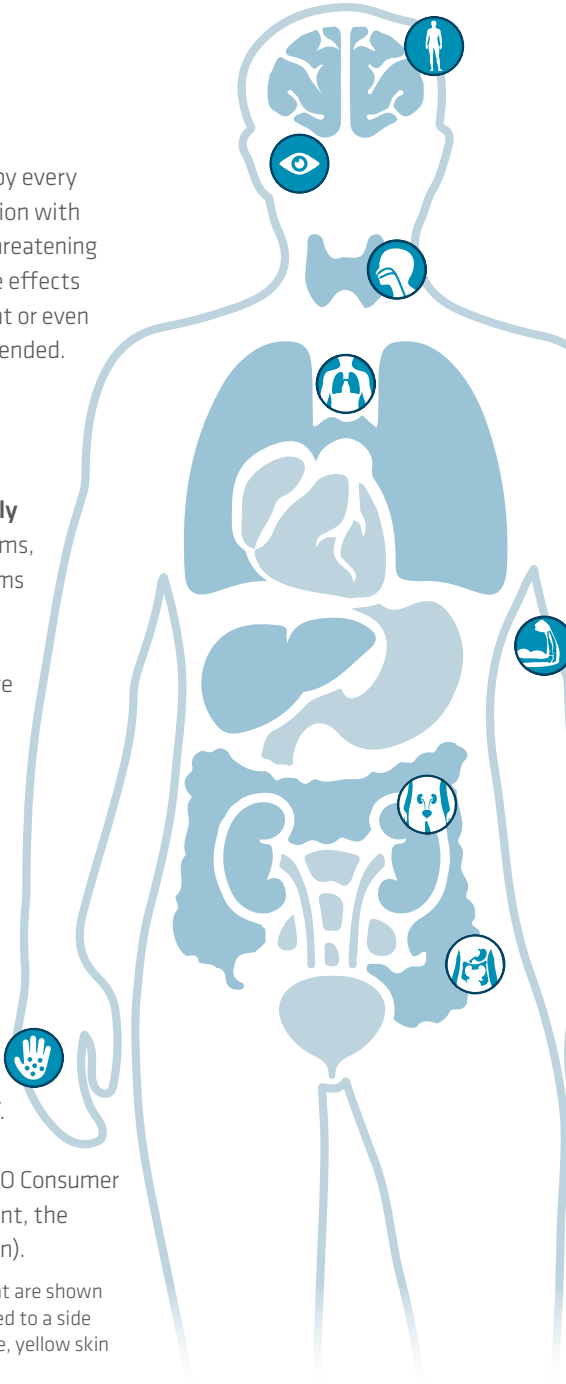
Although they may not be experienced by every patient, OPDIVO or OPDIVO in combination with YERVOY can cause serious or even life-threatening side effects. Signs and symptoms of side effects may happen at any time during treatment or even many months after your treatment has ended.

What to do if you suspect a side effect:[1]

- Call your cancer specialist **immediately** if you experience any signs or symptoms, or if they get worse. Signs and symptoms that may appear mild can quickly worsen if left untreated.
  - If you speak with another healthcare professional, ensure you present them with your Patient Card.
- **DO NOT** treat any signs and symptoms yourself.
- **DO NOT** feel embarrassed or worry that you are bothering your cancer specialist.

The following are some, but NOT all of the possible signs and symptoms of side effects from treatment with OPDIVO or OPDIVO in combination with YERVOY. For more information, ask your cancer specialist or nurse and/or read the OPDIVO Consumer Medicine Information (and also, if relevant, the YERVOY Consumer Medicine Information).

Please note: Some signs and/or symptoms that are shown occurring in one part of your body may be related to a side effect in another part of your body (for example, yellow skin may represent a liver problem).



Signs and symptoms to look out for include:[1,2]

General

- Changes in mood or behaviour, such as decreased sex drive, irritability, forgetfulness or depression
- Confusion
- Feeling unwell
- Fever
- Headaches
- Increased appetite or loss of appetite
- Nausea or vomiting
- Seizures (fits)
- Swollen lymph nodes
- Thirst (excessive thirst)
- Tiredness (extreme tiredness)
- Weight gain or weight loss
- Sleepiness or drowsiness

Eyes

- Changes in eyesight (blurry vision or other vision problems)
- Eye pain
- Eye redness
- Yellowing of the whites of your eyes

Skin

- Dry skin
- Itching
- Raised skin lumps/bumps (skin nodules)
- Rash
- Severe skin reactions
- Skin blistering/peeling
- Skin yellowing (jaundice)
- Tingling and/or numbness (e.g. in your fingers or toes)

Muscles and bones

- Difficulty walking
- Numbness in arms and/or legs
- Muscle or joint pains
- Muscle weakness
- Stiffness
- Stiff neck

Mouth, nose and throat

- Ulcers in the mouth or other mucous membranes (e.g. nose, eyelids)

Chest

- Breathing difficulties
- Chest pain
- Cough (new or worsening)
- Irregular heartbeat, palpitations (being more aware of heartbeat than normal)

Stomach and bowel (gut)

- Dark, tarry, sticky stools
- Blood or mucous in your stools
- Diarrhoea (watery, loose or soft stools)
- Heartburn or indigestion
- Pain or tenderness in your stomach or abdominal area

Kidneys and bladder

- Decreased amount of urine
- Increased amount of urine
- Urine darker colour than normal (tea-coloured)

Other important side effects:[2,4]

Severe infusion reactions

- Reactions to infusing OPDIVO or OPDIVO in combination with YERVOY into the bloodstream might occur, usually during or within 24 hours of receiving a dose.
- **Tell your cancer specialist or nurse right away if you get these symptoms during an infusion of OPDIVO or OPDIVO in combination with YERVOY: chills or shaking; itching or rash; flushing; difficulty breathing; dizziness; fever or feeling like passing out.**

Complications of stem cell transplant that uses donor stem cells (allogeneic) after treatment with OPDIVO

- Donated stem cells contain T-cells that can attack your own body cells if they see them as foreign. These complications can be severe and can lead to death.
- **Inform your cancer specialist if you underwent an allogeneic stem cell transplant either before or after being treated with OPDIVO or OPDIVO in combination with YERVOY, in order for your cancer specialist to monitor you for signs of complications (e.g. skin rash, liver inflammation, abdominal pain and diarrhoea).**

Rejection of a transplanted organ

- People who have had an organ transplant may have an increased risk of organ transplant rejection if they are treated with OPDIVO.
- **Please tell your cancer specialist before treatment if you have had an organ transplantation.**

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Monitoring signs and symptoms

Signs and symptoms that may appear mild can quickly worsen if left untreated. Do not try to treat any signs and symptoms yourself. Always carry your Patient Card with you.

Contact your cancer specialist immediately if you experience any of the signs and symptoms previously described, if they get worse, or if you experience anything unusual while on OPDIVO or OPDIVO in combination with YERVOY.

These are not all of the possible side effects of treatment, so you should report any discomfort or changes in the way you are feeling to your cancer specialist or a member of your broader medical oncology care team (e.g. cancer nurse). Some side effects may occur many months after treatment.

Getting medical treatment right away may keep the problem from becoming more serious. This also reduces the likelihood that treatment with OPDIVO or OPDIVO in combination with YERVOY will need to be temporarily or permanently stopped.

Patient Card

- A Patient Card is available to help remind you about side effects that could occur during or after treatment with OPDIVO or OPDIVO in combination with YERVOY, and what to do if you suspect you have a problem.
- Ask your doctor for a copy of the Patient Card or contact BMS Medical Information on 0800 167 567 or medinfo.australia@bms.com.
- It is recommended that you print out a copy or request a Patient Card from your doctor and carry it with you at all times, since it contains important information about your cancer treatment.
- Show the Patient Card to any healthcare professional involved in your medical treatment, not just to your cancer specialist.
- You must keep this card with you for at least 5 months after completing your treatment because there may be active drug remaining in your body.

Please ensure that the cancer specialist who is treating you completes the 'My Cancer Specialist's Contact Information' on the Patient Card and below.

My cancer specialist: .....

Specialist contact number: .....

After-hours contact number: .....

Specialist nurse: .....

Infusion centre: .....

Infusion centre contact number: .....

Contact your cancer specialist immediately if you experience any signs or symptoms (side effects).

Getting medical treatment right away may keep the problem from becoming more serious. This also reduces the likelihood that treatment with OPDIVO or OPDIVO in combination with YERVOY will need to be temporarily or permanently stopped.

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Support

Accessing support during your illness

Being diagnosed with cancer is a difficult, traumatic experience. When you first hear about your diagnosis, you may feel anxious, scared or overwhelmed.

You may face many treatment decisions and you will likely have many questions. That is why it is important to communicate with your healthcare team about any concerns you may have about important areas of your health including nutrition, exercise, your mood and managing stress.

Patient support groups

Patient support groups are one way to help people with cancer and those they are close to. They offer patients and their families and friends an opportunity to expand support networks and to reach out to others with similar experiences. Please ask your healthcare team if there is a suitable support group for you.

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Information for caregivers

When someone you are close to, such as a relative or friend, is diagnosed with cancer you may be called upon to help take care of them, becoming what is often referred to as a caregiver.

As a caregiver, the person you are caring for may need you to work with the healthcare team, and/or help with daily activities. You may also be providing emotional and/or spiritual support.

Remember, as a caregiver, you are trying to strike a balance each day by caring for your loved one while also keeping up with the demands of your family and work, and your own needs. It is important to remember to reach out for support when you need it, for example, from your family doctor or patient and caregiver support groups.

Remember:

- Communicate with your cancer specialist or a member of your broader medical oncology care team (e.g. cancer nurse) about any concerns you may have.
- Patient support groups are a source of information and support.
- It is important that caregivers also remember to access support when needed.
- Your cancer specialist is your primary source of contact for advice, information and support.

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Please note: Your cancer specialist is your primary source of contact for advice, information and support in relation to your condition or treatment with OPDIVO®, YERVOY® or OPDIVO in combination with YERVOY. Ask your doctor if OPDIVO, YERVOY or OPDIVO in combination with YERVOY is right for you.

OPDIVO, YERVOY or OPDIVO in combination with YERVOY are funded for certain indications. A prescription charge and normal Doctor's fees may apply. OPDIVO and YERVOY are not funded by Pharmac for the treatment of other cancers listed above. Ask your health professional about the cost of the medicine and any other medical fees that may apply**.**

OPDIVO (nivolumab 10mg/mL) is a prescription medicine that can be used on its own (monotherapy) in the treatment of advanced melanoma, a type of kidney cancer (renal cell carcinoma), certain types of lung cancer, a type of head and neck cancer (squamous cell carcinoma of the head and neck), a type of bladder cancer (urothelial carcinoma), a type of blood cancer (classical Hodgkin lymphoma), a type of liver cancer (hepatocellular carcinoma) and a type of food pipe cancer (oesophageal squamous cell carcinoma). OPDIVO monotherapy can be used as adjuvant treatment after surgical removal of cancer in certain types of melanoma, food pipe cancer (oesophageal), cancer of the connection between the stomach and the food pipe (gastro-oesophageal junction), and bladder cancer (urothelial carcinoma). OPDIVO (nivolumab 10 mg/mL) and YERVOY (ipilimumab 5 mg/mL) are prescription medicines that can be used together to treat certain types of advanced melanoma, advanced renal cell carcinoma, malignant pleural mesothelioma (a type of lung cancer that affects the lining of the lung), unresectable or metastatic hepatocellular carcinoma (liver cancer) and colorectal (bowel) cancer that is shown by a laboratory test to have certain biological markers (microsatellite instability (MSI-H) or mismatch repair deficient (dMMR)). OPDIVO in combination with YERVOY and chemotherapy is used to treat a certain type of lung cancer. OPDIVO in combination with chemotherapy is used to treat cancer of the stomach (gastric adenocarcinoma), cancer of the connection between the stomach and food pipe (gastro-oesophageal junction adenocarcinoma) and the food pipe (oesophageal adenocarcinoma or oesophageal squamous cell carcinoma). OPDIVO, in combination with chemotherapy, is used to treat a type of lung cancer (non-small cell lung cancer) before you have surgery. OPDIVO, in combination with chemotherapy, is used to treat a type of bladder cancer (urothelial carcinoma). OPDIVO in combination with cabozantinib can be used to treat advanced kidney cancer.

YERVOY (ipilimumab 5mg/ml) is a prescription medicine that can be used on its own (monotherapy) in the treatment of advanced melanoma; in combination with OPDIVO for a type of kidney cancer (renal cell carcinoma), advanced melanoma and malignant pleural mesothelioma (cancer that affects the lining of the lung),unresectable or metastatic hepatocellular carcinoma (liver cancer) and colorectal (bowel) cancer that is shown by a laboratory test to have certain biological markers (microsatellite instability (MSI-H) or mismatch repair deficient (dMMR)); and in combination with OPDIVO and chemotherapy for a type of lung cancer (non-small cell lung cancer).

Do not use OPDIVO or YERVOY if you are allergic (hypersensitive) to nivolumab or ipilimumab, or to any of the other ingredients of OPDIVO or YERVOY. If you are not sure talk to your doctor. OPDIVO, YERVOY and OPDIVO + YERVOY have risks and benefits, please discuss these with your doctor. Tell your doctor of any previous or current medical conditions, including if you have had a stem cell transplant that uses donor stem cells (allogeneic), if you have an auto-immune disease and if you are taking any other medicines.

OPDIVO, YERVOY or OPDIVO in combination with YERVOY can increase the risk of serious or even life-threatening side effects, which may affect different parts of the body. Signs and symptoms of side effects may happen at any time during treatment or even many months after your treatment has ended. If you experience any side effects, inform your doctor immediately. Early assessment and management of side effects by your doctor reduces the likelihood that treatment with OPDIVO, YERVOY or OPDIVO in combination with YERVOY will need to be temporarily or permanently stopped. Signs and symptoms that may appear mild can quickly worsen if left untreated. Do not try to treat these symptoms yourself. Possible signs and symptoms to look out for include the following (although these are not the only ones) – chest (heart and lungs): breathing difficulties, cough, wheeze, chest pain, irregular heartbeat, palpitations (increased awareness of your heartbeat); gut (stomach and bowels): diarrhoea (watery, loose or soft stools), blood or mucous in stools, dark-coloured stools, pain or tenderness in your stomach or abdominal area; liver: eye or skin yellowing (jaundice), pain on the right side of your stomach area; kidneys: change in amount and/or frequency of urine; hormone producing glands (including diabetes): headaches, blurry or double vision, fatigue (tiredness), weight changes, behavioural changes (e.g. lower sex drive, irritability or forgetfulness), excessive thirst, increased appetite with weight loss, weakness, drowsiness, depression, feeling unwell, change in amount and/or frequency of urine; skin: rash, itching, blisters and/or peeling of the skin (possibly fatal), ulcers, dry skin, skin nodules; other: weakness, fatigue (tiredness), decreased appetite, nausea, vomiting, tingling or numbness in arms and legs, difficulty walking, fever, swollen lymph nodes, headache, seizures, stiff neck, confusion, drowsiness, muscle pain, stiffness, dark urine, eye pain or redness, blurry vision, or other vision problems.

For more information about OPDIVO or YERVOY and a list of side effects, please see the OPDIVO Consumer Medicine Information at https://www.medsafe.govt.nz/Consumers/CMI/o/opdivo.pdf and/or the YERVOY Consumer Medicine Information at https://www.medsafe.govt.nz/consumers/cmi/y/yervoy.pdf or call BMS Medical Information on 0800 167 567 (toll free) or email medinfo.australia@bms.com to request a copy.

Please inform any healthcare professional caring for you that you are receiving treatment with OPDIVO or YERVOY, or OPDIVO in combination with YERVOY. Use OPDIVO, YERVOY or OPDIVO + YERVOY strictly as directed.

References: 1. OPDIVO® (nivolumab) Consumer Medicine Information (www.medsafe.govt.nz/Consumers/CMI/o/opdivo.pdf). **2.** OPDIVO® (nivolumab) Data Sheet. **3.** YERVOY® (ipilimumab) Consumer Medicine Information (www.medsafe.govt.nz/consumers/cmi/y/yervoy.pdf). **4.** YERVOY® (ipilimumab) Data Sheet.

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