

OPDIVO[®]

(nivolumab)

Patient Information Guide



Introduction

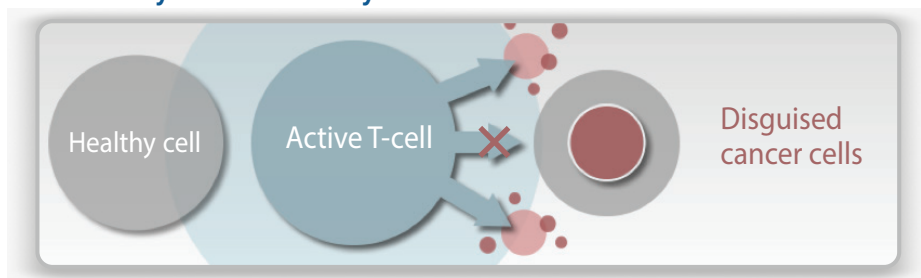
- This guide provides you with information about treatment with OPDIVO® or OPDIVO® in combination with YERVOY® (ipilimumab) and describes potential signs and symptoms that you might experience.
- It also provides important advice on what you should do if you experience signs and symptoms, to help make 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.
- **This guide includes a Patient Alert Card.** Remember to always carry your OPDIVO® Patient Alert Card with you and to inform healthcare professionals 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 Doctor's Contact Information' section of the Patient Alert Card.

Please note: Contact your doctor if you need advice, information and support.

What is OPDIVO®?

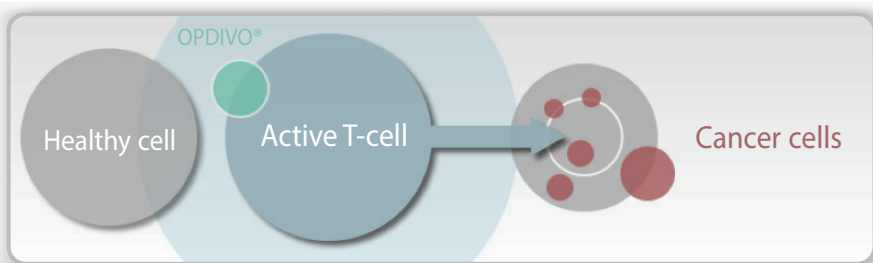
OPDIVO® contains the active substance nivolumab, which is a protein that helps your immune system to attack and destroy cancer cells.

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 defense 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 defense (for example, by blocking T-cell activity). This allows the cancer to spread and grow.

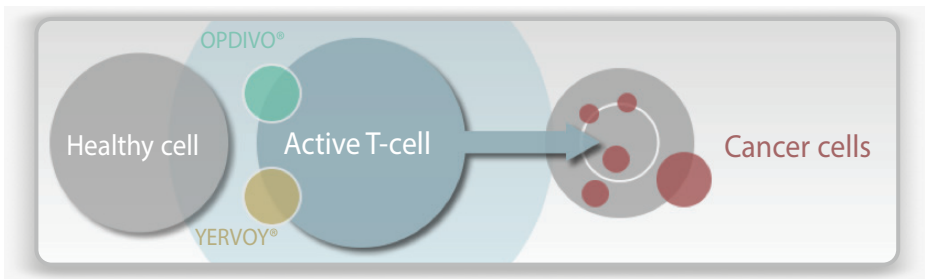
How does OPDIVO® work on cancer cells?



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?



YERVOY® is a different medicine which acts on T-cells in another way, so it can produce a combined effect when taken 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.

Receiving Treatment

What does OPDIVO® treatment involve?

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

OPDIVO® or OPDIVO® and YERVOY® will be slowly infused through this needle, and the actual time you will spend in the treatment center may vary. Your doctor will discuss with you what treatments you will receive.



It is important that you:

- Tell your doctor 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 doctor **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 any time during treatment or even months after your treatment has ended.



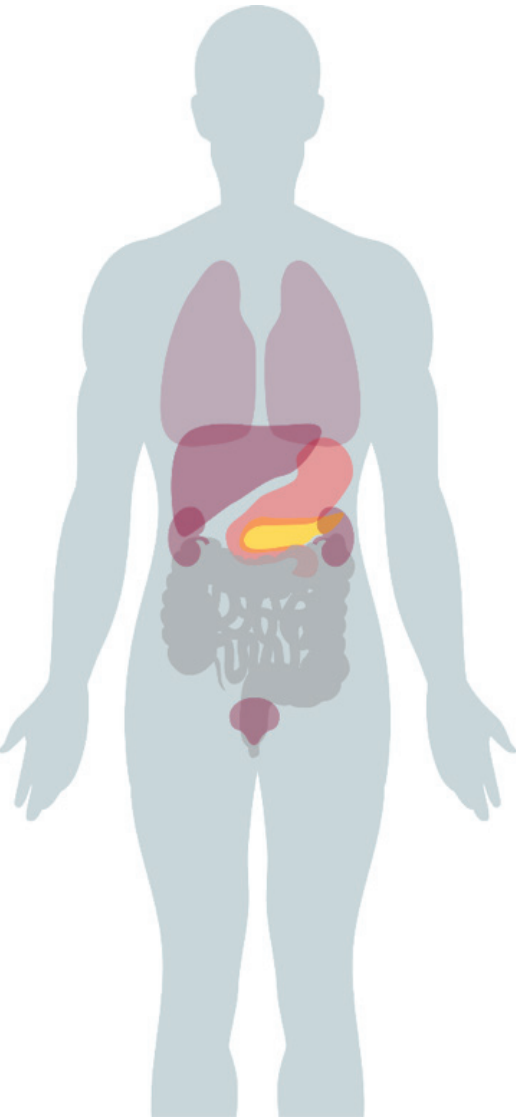
What to do if you suspect a side effect:

- Call your doctor **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.
- **DO NOT** treat any signs and symptoms yourself.
- **DO NOT** feel embarrassed or worry that you are bothering your doctor.

The following are 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 doctor or nurse and/or read the OPDIVO® [local patient label] (and also, if relevant, the YERVOY® [local patient label]).

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:



General

Changes in mood or behavior, 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



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



Kidneys, bladder and urine

Decreased amount of urine
Increased amount of urine
Urine darker color than normal (tea-colored)



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
Diarrhea (watery, loose or soft stools)
Heartburn or indigestion
Pain or tenderness in your stomach or abdominal area

Other important side effects:

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 doctor 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; and 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 doctor if you underwent an allogeneic stem cell transplant either before or after being treated with OPDIVO®, in order for your doctor to monitor you for signs of complications (e.g. skin rash, liver inflammation, abdominal pain, and diarrhea).**

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 doctor before treatment if you have had organ transplantation.**

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 Alert Card with you.

Contact your cancer specialist doctor (oncologist) immediately if you experience any of the 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 Oncology Care Team. 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 Alert Card

- A Patient Alert 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.
- You should always keep the Patient Alert Card with you since it contains important information about your cancer treatment.
- Show the Patient Alert Card to any healthcare professional involved in your medical treatment, not just to your oncologist.
- 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 doctor who is treating you completes the My Doctor’s Contact Information on the Patient Alert Card and below.

My Doctor’s Contact Information (who prescribed OPDIVO® or OPDIVO® in combination with YERVOY®)	
Name of Doctor:	
Office Phone:	
After-Hours Phone:	

ANNEX

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.



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 healthcare team about any concerns you may have.
- You may consider reaching out to or joining a patient support group.
- It is important that caregivers also remember to access support when needed.
- Your doctor is your primary source of contact, advice, information and support.

For more information, consult the OPDIVO® local Patient leaflet which can be found in the product pack.

For reporting any suspected adverse reactions via the national reporting system :

Bristol Myers Squibb, Saudi Arabia:

At: medinfo.saudiarabia@bms.com or call: 800 844 7710

The national Pharmacovigilance and Drug safety Center:

At: <https://ade.sfda.gov.sa/index.aspx/>

Email: npc.drug@sfda.gov.sa

Toll free number: 8002490000



Opdivo® Opdivo® and Yervoy® and the related logos are trademarks of Bristol Myers Squibb Company.
©2020 Bristol Myers Squibb Company. All rights reserved.