



# Patient Medication Guide

## Introduction

- This guide provides you with information about treatment with nivolumab or nivolumab in combination with 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 do not worsen and you are treated as quickly and effectively as possible.
- Nivolumab or nivolumab in combination with ipilimumab 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.

**Please note:** Contact your Cancer Specialist (doctor) if you need advice, information or support.

My Cancer Specialist's (Doctor's) Contact Information (who prescribed nivolumab or nivolumab in combination with ipilimumab)

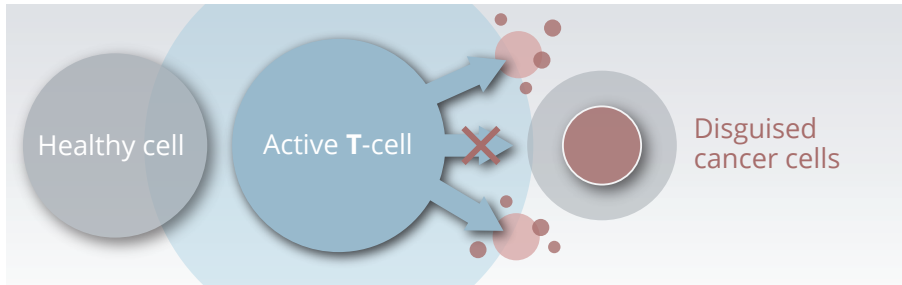
Name of Doctor:

Office Phone:After-hours Phone:

# What is Nivolumab?

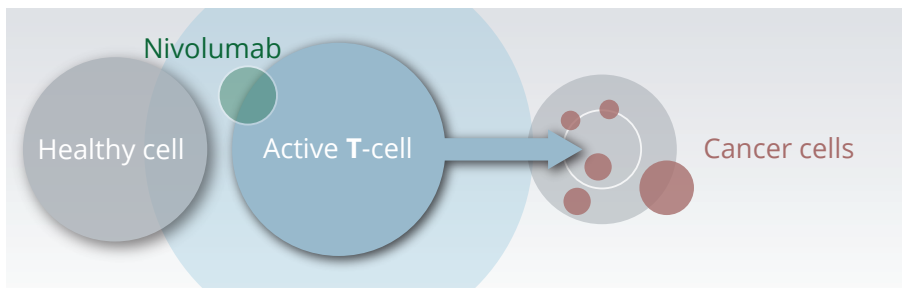
Nivolumab is a protein that helps your immune system to attack and destroy cancer cells.

## 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.

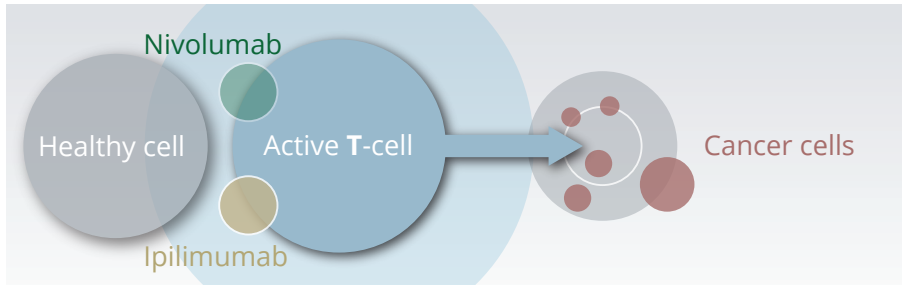
## How does Nivolumab work on cancer cells?



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

With nivolumab, 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 nivolumab treatment has ended.

## How does Nivolumab in combination with Ipilimumab work on cancer cells?



Ipilimumab is a different medicine, which acts on T-cells in another way, so it can produce a combined effect when taken together with nivolumab.

Ipilimumab 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 Nivolumab treatment involve?

Nivolumab (or nivolumab in combination with ipilimumab) is a doctor-prescribed medicine that is infused directly into the bloodstream. You will receive the medicine(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.

Nivolumab (or nivolumab and ipilimumab) will be slowly injected over time (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.

If receiving nivolumab monotherapy, nivolumab will be given to you over a period of 30 to 60 minutes.

If receiving nivolumab in combination with ipilimumab, nivolumab will be given to you first over a period of 30 to 60 minutes and ipilimumab second over a period of 30 to 90 minutes.



### It is important that you:

- Tell your doctor before receiving nivolumab or nivolumab in combination with ipilimumab 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)
  - are on a low-sodium (low-salt) diet
  - are allergic to nivolumab, ipilimumab or any of the other ingredients present in these medicines
- Talk to your healthcare team **immediately** about any new or worsening signs and symptoms you experience.
- Do NOT breastfeed as it is not known if nivolumab or ipilimumab can pass into your breast milk.
- Tell your doctor **immediately** if you become pregnant during your treatment with nivolumab or nivolumab in combination with ipilimumab.
- Use an effective method of birth control, during and for at least 5 months after the last dose of nivolumab or nivolumab combined with ipilimumab if you are a woman who can become pregnant. Discuss birth control methods that you can use during this time with your doctor.
- Re-schedule any missed appointments right away.

## Signs and Symptoms of Your Treatment

Although they may not be experienced by every patient, nivolumab or nivolumab in combination with ipilimumab can cause serious or even life-threatening immune-related side effects which may affect different parts of the body. 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 nivolumab or nivolumab in combination with ipilimumab. For more information, ask your Cancer Specialist (doctor).

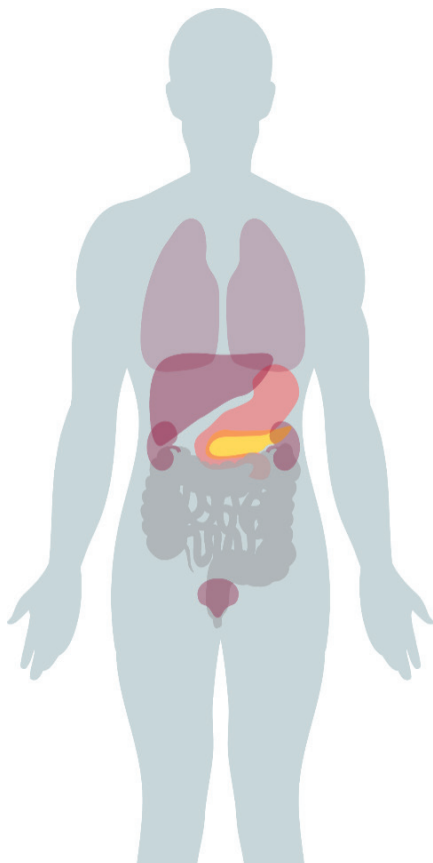
**Please note:** Some signs and/or symptoms that are shown occurring in one part of your body may be related to a side effect in another part of your body (for example, yellow skin may represent a liver problem).

## Signs and symptoms to look out for include:



### General

- Changes in mood or behavior, such as decreased sex drive, irritability, forgetfulness, or depression
- Hallucinations
- 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 mucus 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 color than normal (tea-colored)

## Other important side effects:

### Severe infusion reactions

- Reactions to infusing nivolumab or nivolumab in combination with ipilimumab 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 nivolumab or nivolumab in combination with ipilimumab: 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 nivolumab

- 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 nivolumab, in order for your doctor 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 nivolumab.
- **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.**

Contact your Cancer Specialist (doctor) immediately if you experience any of the symptoms previously described, if they get worse, or if you experience anything unusual while on nivolumab or nivolumab in combination with ipilimumab.

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 (doctor). 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 nivolumab or nivolumab in combination with ipilimumab will need to be temporarily or permanently stopped.

**REMEMBER: If you have any concerns or would like more information, please talk to your Cancer Specialist (doctor).**

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