

Patient Information Guide



Introduction

- This guide provides you with information about treatment with 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 these signs and symptoms do not worsen and you are treated as quickly and effectively as possible.
- 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.
- Call your Cancer Specialist (doctor) **immediately** if you experience any signs or symptoms as mentioned in this guide or any other signs or symptoms, or if they persist or get worse. Signs and symptoms that may appear mild can quickly worsen if left untreated.

My Cancer Specialist's (Doctor's) Contact Information (who prescribed ipilimumab)

Name of Doctor:

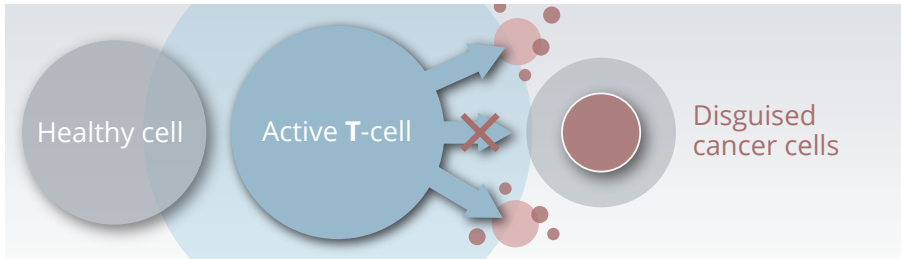
Office Phone:

After-hours Phone:

About Ipilimumab

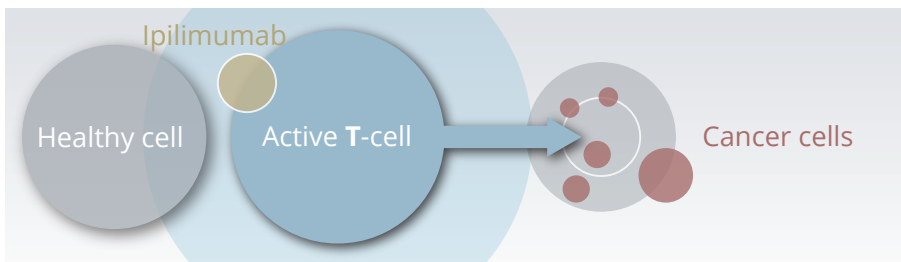
Ipilimumab is a protein that helps your immune system to attack and destroy cancer cells.

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 ipilimumab work on cancer cells?



Ipilimumab is a medicine that helps to activate your immune system so that T-cells can fight cancer cells.

With ipilimumab, 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.

What to check with your Cancer Specialist (doctor) before treatment



Before starting the treatment, you should inform your Cancer Specialist (doctor) of any previous treatment you received and any medical conditions you may have experienced or you are experiencing.

In addition, your Cancer Specialist (doctor) will check for the following before the treatment:

- if you take corticosteroids or other treatments that affect the immune system
- if you take any medicines that stop your blood from clotting (anticoagulants)
- if you have had a stem cell transplant that uses donor stem cells (allogeneic)
- liver function tests (LFTs)
- thyroid function tests
- if you have an autoimmune disease (a condition where the body attacks its own cells)
- if you have or have ever had a chronic viral infection of the liver, including:
 - hepatitis B (HBV)
 - hepatitis C (HCV)
- if you have human immunodeficiency virus (HIV) infection or acquired immune deficiency syndrome (AIDS)
- if you are pregnant, breast-feeding or planning to become pregnant
- your general physical condition to determine whether you are suitable for treatment.

The main side effects of your treatment

Although they may not be experienced by every patient, ipilimumab 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 Cancer Specialist (doctor) **immediately** if you experience any signs or symptoms, or if they persist or get worse. Signs and symptoms that may appear mild can quickly worsen if left untreated.
- **DO NOT** treat any signs and symptoms yourself.

Please note:

- The following signs and symptoms are **NOT** all of the possible signs and symptoms of side effects from treatment with ipilimumab.
- Some signs and/or symptoms 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).

Early treatment of side effects reduces the likelihood that ipilimumab treatment will need to be temporarily or permanently stopped, allowing you to get the maximum benefit from treatment.

Possible side effects



Bowel And Stomach

- diarrhoea (watery, loose or soft stools), bloody or dark-coloured stools
- more frequent bowel movements than usual
- pain or tenderness in your stomach or abdomen area, nausea, vomiting



Liver

- eye or skin yellowing (jaundice)
- pain on the right side of your stomach area
- dark urine



Skin

- skin rash with or without itching, dry skin
- blisters and/or peeling of the skin, mouth sores
- swelling of the face or lymph glands



Heart

- shortness of breath
- chest pain



Eye

- redness in the eye
- pain in the eye
- vision problems or blurry vision



Nerves

- muscle weakness
- numbness or tingling in legs, arms or face
- dizziness, loss of consciousness or difficulty waking up



General

- fever, headache, tiredness
- bleeding
- behavioral changes (e.g. less sex drive, being irritable or forgetful)
- dehydration, low blood pressure, shock

Other important side effects:

Complications of stem cell transplant that uses donor stem cells (allogeneic)

- 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 (doctor) if you have received or plan to receive an allogeneic stem cell transplant in order for your Cancer Specialist (doctor) to monitor you for signs of complications (e.g. skin rash, liver inflammation, abdominal pain, and diarrhea).**

Severe infusion reactions

- Reactions to infusing ipilimumab into the bloodstream might occur, usually during or within 24 hours of receiving a dose.
- **Tell your Cancer Specialist (doctor) or nurse right away if you get these symptoms during an infusion of ipilimumab: chills or shaking; itching or rash; flushing; difficulty breathing; dizziness; fever; and feeling like passing out.**

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