

PATIENT BOOKLET



Models are for illustrative purposes only



KEYTRUDA® (pembrolizumab) is available as a 100 mg/4 mL concentrate for solution for infusion.

The KEYTRUDA Consumer Medicine Information (CMI) is available at www.medsafe.govt.nz.

KEYTRUDA is a **Prescription Medicine** and may be used in **adults**:

- After surgery to remove melanoma, non-small cell lung cancer or renal cell carcinoma to help prevent the cancer from coming back
- Before surgery to treat triple-negative breast cancer and then continued after surgery to help prevent the cancer from coming back
- To treat bladder cancer which has not spread to nearby tissues but is at high-risk of spreading and where bladder removal is not preferred
- To treat certain patients with the following types of advanced cancers:
 - Melanoma
 - Non-small cell lung cancer
 - Malignant pleural mesothelioma (MPM)
 - Classical Hodgkin Lymphoma (cHL)
 - Urothelial carcinoma
 - Head and neck squamous cell carcinoma
 - Renal cell carcinoma
 - Gastric or gastroesophageal junction adenocarcinoma
 - Oesophageal carcinoma
 - Cutaneous squamous cell carcinoma
 - Cervical cancer
 - Endometrial carcinoma
 - Triple-negative breast cancer
 - A kind of cancer that can occur in any part of the body and is shown by a laboratory test to be microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR)
 - Colon or rectal cancer that is shown by a laboratory test to be MSI-H or dMMR
 - Merkel cell carcinoma (MCC)
 - Biliary tract carcinoma

KEYTRUDA may be used in **children** with MPM, cHL, MCC, MSI-H or dMMR cancer, or after surgery to remove melanoma. It is not known if KEYTRUDA is safe and effective in children with MSI-H or dMMR cancer of the brain or spinal cord (central nervous system cancers).

You should not be given KEYTRUDA if you are allergic to pembrolizumab or to any of the other ingredients listed at the end of the CMI.

KEYTRUDA has risks and benefits. Talk to your doctor to see if KEYTRUDA is right for you. If symptoms continue or you have side effects, tell your doctor. (v54)

KEYTRUDA is funded to treat certain patients with the following types of advanced cancers: melanoma, non-small cell lung cancer, MSI-H or dMMR colorectal cancer, triple-negative breast cancer, head and neck squamous cell carcinoma, urothelial carcinoma, and classical Hodgkin lymphoma – further restrictions apply. KEYTRUDA is not funded for the treatment of all other cancers listed above.

Ask your health professional about the cost of the medicine and any other medical fees that may apply.

For more information visit our website www.fightcancer.co.nz

Merck Sharp & Dohme (New Zealand) Limited.
Level 3, 123 Carlton Gore Road, Newmarket, Auckland.

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About this booklet

This booklet describes how KEYTRUDA may help you, how it works and what you can expect while being treated with KEYTRUDA.

For more information, speak to your Oncologist, Oncology Nurse or refer to the Consumer Medicine Information for KEYTRUDA.

What is KEYTRUDA?

KEYTRUDA is a prescription medicine and contains the active substance pembrolizumab. KEYTRUDA is available as a 100 mg/4 mL concentrate for solution for infusion.

KEYTRUDA is known as an immunotherapy because it works with the body's immune system to help find and fight cancer cells. KEYTRUDA helps the immune system do what it is designed to do - help your own body treat cancer.

KEYTRUDA is not chemotherapy.

KEYTRUDA has risks and benefits. Talk to your doctor to see if KEYTRUDA is right for you. If symptoms continue or you have side effects, tell your doctor.

What is KEYTRUDA used for?

KEYTRUDA may be used in **adults**:

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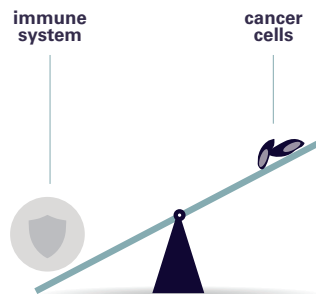
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How KEYTRUDA works with your immune system

The immune system is the body's natural defence against disease. It sends types of cells called T cells through the body to find and fight infections and diseases - including cancer.

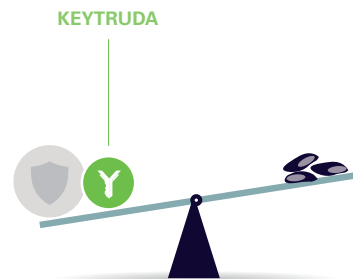
Some cancer cells grow by hiding from the immune system. Immunotherapies like KEYTRUDA work with the immune system to help find and fight certain cancer cells.



The immune system finds and fights cancer cells as they grow, before they form tumours.



The immune system destroys some cancer cells, but other cancer cells may hide from the immune system. These hiding cancer cells can then grow into tumours.



KEYTRUDA helps the immune system find and fight cancer.



START

**KEYTRUDA HAS BEEN
PRESCRIBED FOR YOU TO
HELP TREAT YOUR CANCER.**

How KEYTRUDA is given

KEYTRUDA is given by an injection via a vein in your arm (intravenous infusion) over 30 minutes. KEYTRUDA is usually given once every 3 weeks, or every 6 weeks, depending on the dose you are given, often referred to as 'cycles'.

KEYTRUDA may be given in combination with other anti-cancer medicines. It is important that you also read the Consumer Medicine Information for these other medicines. If you have any questions about these medicines, please ask your doctor.

Your treatment will usually be given by your Oncologist/Specialist or Nurse in a hospital clinic. Your Oncologist/Specialist will decide how many treatments/cycles you need.



Intravenous
infusion



Over
30 minutes



Once every 3 weeks
or every 6 weeks,
depending on the
dose you are given

Considerations before treatment

You should not be given KEYTRUDA if you are allergic to pembrolizumab or to any of the other ingredients listed at the end of the KEYTRUDA Consumer Medicine Information.

Before you receive KEYTRUDA, tell your doctor if you have an immune system disease such as Crohn's disease, ulcerative colitis, or lupus; have had an organ transplant or a bone marrow (stem cell) transplant that used donor stem cells (allogeneic); have pneumonia or swelling of your lungs (called pneumonitis); have liver damage; or have any other medical disease.

If you are pregnant, think you may be pregnant or are planning to have a baby, tell your doctor. KEYTRUDA can cause harm or death to your unborn baby. You must use effective contraception while you are being treated with KEYTRUDA and for at least 4 months after the last dose of KEYTRUDA if you are a woman who could become pregnant. If you are breastfeeding, tell your doctor. Do not breast feed during treatment with KEYTRUDA.

Tell your doctor if you are taking any other medicines, including medicines that you buy without a prescription from your pharmacy, supermarket or health food shop, or other medicines that make your immune system weak. Examples of these may include steroids, such as prednisone.

Working during treatment

It may be possible for you to continue working during treatment with KEYTRUDA, but you may not be able to maintain your usual work commitments because of your cancer or side effects associated with therapy.

Talk with your Nurse, Healthcare Professional or the Cancer Society (contact details at the end of brochure) for advice on talking to your employer about your cancer and ability to work.



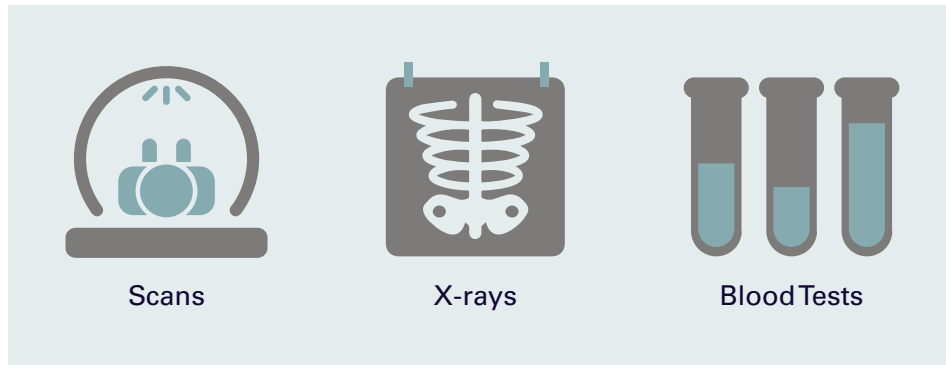
MONITOR & MANAGE

**DURING YOUR TREATMENT
WITH KEYTRUDA, THERE WILL
BE REGULAR APPOINTMENTS
TO MONITOR YOUR HEALTH
AND ANY SIDE EFFECTS.**

KEYTRUDA treatment experience

Before starting KEYTRUDA, your Oncologist/Specialist and Nurse would have asked you about your general health and any other medical problems.

Medical tests that you may need during your treatment with KEYTRUDA may include:



These tests will help your Oncologist/Specialist keep track of how you are responding to treatment.

Side effects may occur while taking KEYTRUDA

During your treatment with KEYTRUDA, there will be regular appointments to monitor your health and any side effects.

Like all medicines, KEYTRUDA can cause side effects, although not everybody gets them. Your doctor will discuss these with you and will explain the risks and benefits of your treatment.

KEYTRUDA can cause your immune system to affect healthy cells in other parts of your body. These side effects can sometimes become serious and in some cases, fatal.

It is important side effects are treated as early as possible

Tell your Oncologist/Specialist if you notice any side effects or symptoms. Early treatment of side effects may stop them becoming more serious.

You may be able to continue KEYTRUDA treatment if side effects are treated early

However, you may need to stop KEYTRUDA treatment if side effects become more serious. Do not try and manage any side effects by yourself.



Common side effects

The following side effects have been reported in clinical trials.

Very common side effects (may affect more than 1 in 10 people) with KEYTRUDA are:

- Patches of skin which have lost colour
- Stomach pain
- Decreased sodium levels in the blood
- Low levels of thyroid hormone
- Diarrhoea, nausea
- Joint pain
- Back pain
- Itching, rash
- Feeling tired
- Cough

The following side effects have been reported in more than 1 in 5 people when KEYTRUDA was given in combination with chemotherapy: hair loss, feeling tired, diarrhoea, vomiting, rash, fever, decrease in white blood cell count, decreased appetite, joint pain, swelling of the lining of the digestive system (for example mouth, intestines), mouth sores, decrease in number of red blood cells, decrease in number of platelets in the blood.

The most common side effects when KEYTRUDA is given in combination with axitinib are: diarrhoea, high blood pressure, fatigue, low levels of thyroid hormone, decreased appetite, blisters or rash on the palms of your hands and soles of your feet, nausea, increase in liver enzyme levels, hoarseness, cough, constipation.

The most common side effects when KEYTRUDA is given in combination with lenvatinib are: high blood pressure, diarrhoea, feeling tired, decreased appetite, low levels of thyroid hormone, nausea, vomiting, weight loss, joint pain, headache, constipation, hoarseness, urinary tract infection, stomach-area (abdominal) pain, blisters or rash on the palms of your hands and soles of your feet, rash, protein in your urine, increase in liver enzyme levels, feeling weak.

The most common side effects when KEYTRUDA is given alone to children are: fever, vomiting, headache, stomach pain, decrease in number of red blood cells, cough, constipation.

Less common side effects can happen. KEYTRUDA may cause side effects that are not listed. For more information, ask your doctor.

If you have any side effects that bother you or that do not go away, tell your doctor.

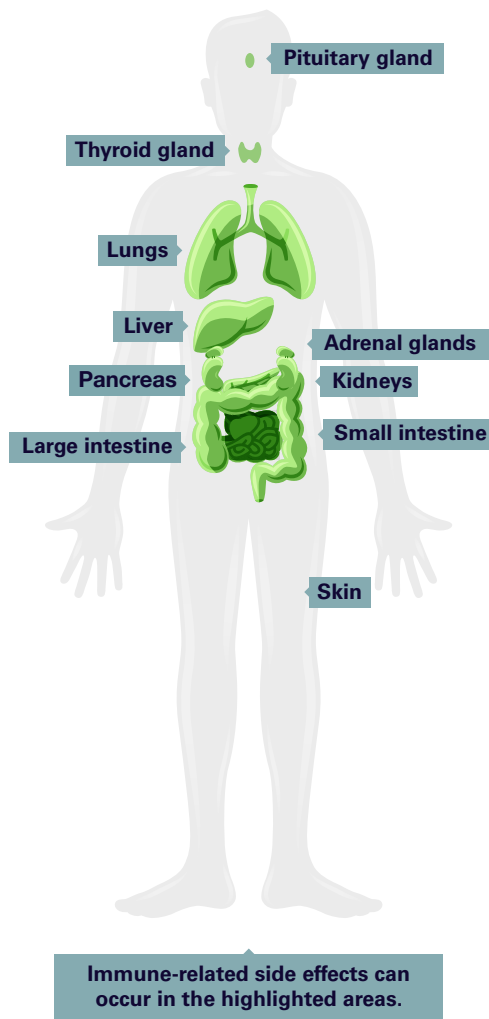
Immune-related side effects

As KEYTRUDA works with the immune system, there are specific side effects that may result from its action on the immune system.

It is important to watch for these immune side effects so they can be treated quickly. This may allow you to continue with KEYTRUDA treatment.

You may not have to stop KEYTRUDA treatment if your side effects are manageable.

The following pages guide you through possible immune-related side effects. Your Oncologist/Specialist or Nurse will decide how to manage these side effects. KEYTRUDA treatment may be delayed or stopped if these side effects are severe.



Side effects that require prompt action

Call or see your Oncologist/ Specialist or Nurse right away if you develop any of the following signs and symptoms.

They will advise you on the best way to manage any side effects.

When you get KEYTRUDA, you can have some serious side effects. These side effects can sometimes become life-threatening and can lead to death. These side effects may happen anytime during treatment or even after your treatment has ended. You may experience more than one side effect at the same time.

Signs and symptoms of lung problems

- shortness of breath
- chest pain
- coughing

Signs and symptoms of problems with your intestines

- diarrhoea or more bowel movements than usual

- your stools are black, tarry, sticky or have blood or mucus
- severe stomach pain or tenderness

Signs and symptoms of hormone gland problems (especially the thyroid, pituitary, and adrenal glands)

- rapid heartbeat
- weight loss
- increased sweating
- weight gain
- hair loss
- feeling cold
- constipation
- your voice gets deeper
- muscle aches
- dizziness or fainting
- headaches that will not go away or unusual headache

Signs and symptoms of blood sugar problems

- feeling more hungry or thirsty
- needing to urinate more often
- weight loss

Signs and symptoms of kidney problems

- changes in the amount or colour of your urine

Signs and symptoms of skin problems

- rash
- itching
- skin blistering, peeling or sores
- ulcers in mouth or in lining of nose, throat, or genital area

Signs and symptoms of liver problems

- nausea or vomiting
- feeling less hungry
- pain on the right side of your stomach
- your skin looks yellow
- the whites of your eyes look yellow
- dark urine
- you bleed or bruise more easily than normal

Signs and symptoms of infusion (IV) reactions

- shortness of breath
- itching or rash
- dizziness
- fever

Signs and symptoms of problems in other organs

- muscle pain or weakness
- changes in eyesight
- stomach area pain with nausea and vomiting (pancreatitis)
- confusion, fever, memory problems, or seizures (encephalitis)
- swollen lymph nodes, rash or tender lumps on skin, cough or eye pain (sarcoidosis)
- shortness of breath, irregular heartbeat, feeling tired, or chest pain (myocarditis, pericarditis)
- pain, numbness, tingling, or weakness in the arms and legs; bladder or bowel problems including needing to urinate more frequently, urinary incontinence, difficulty urinating and constipation (myelitis)
- inflammation of the blood vessels (vasculitis)
- decreased function of the parathyroid gland, which may include muscle cramps or spasms, fatigue and weakness (hypoparathyroidism)

- inflammation of the stomach lining, which may include severe stomach pain or tenderness, nausea or vomiting (gastritis)
- destruction of red blood cells, which may include dark urine, pale or yellow skin/eyes, lightheadedness, feeling tired, rapid heartbeat, or shortness of breath (haemolytic anaemia)
- pain in the upper right part of the stomach, swelling of the liver or spleen, fatigue, itching or yellowing of the skin or whites of eyes (sclerosing cholangitis)
- decreased ability of the pancreas to make digestive enzymes, which may include diarrhoea with loose and oily stools, weight loss, metabolic bone disease, and vitamin or mineral deficiencies (exocrine pancreatic insufficiency)

There are possible side effects of treatment with KEYTRUDA in people who have received a transplant.

Rejection of a transplanted organ. People who have had an organ transplant may have an increased risk of organ transplant rejection. Your doctor should tell you what signs and symptoms you should report and monitor you, depending on the type of organ transplant that you have had.

Graft-versus-host-disease (GVHD) in people with bone marrow (stem cell) transplant that uses donor stem cells (allogeneic). GVHD may occur if you had this transplant in the past. Your doctor will monitor you for the following signs and symptoms: skin rash, liver inflammation, abdominal pain, and diarrhoea.

Be involved with your KEYTRUDA treatment

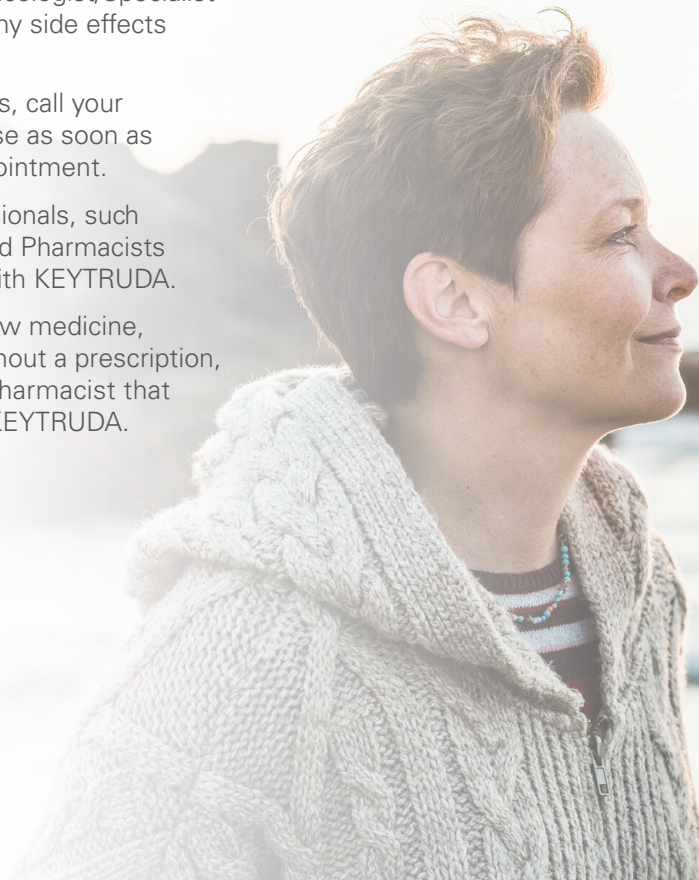
Your regular appointments with your treatment team (eg. Oncologist/Specialist, Nurse, Pharmacist, Dietician, Physiotherapist) will allow you to get to know them.

It is important to tell your Oncologist/Specialist or Nurse if you experience any side effects during treatment.

If you miss any appointments, call your Oncologist/Specialist or Nurse as soon as possible to make a new appointment.

Tell other Healthcare Professionals, such as your Doctors, Dentists and Pharmacists that you are being treated with KEYTRUDA.

If you plan to start on any new medicine, including those available without a prescription, tell your Doctor, Dentist or Pharmacist that you are being treated with KEYTRUDA.



More information and support

If you have any questions about KEYTRUDA, other parts of your treatment or your cancer, please talk to your Oncologist/Specialist or Nurse.

Additional product information can be found by referring to the KEYTRUDA Consumer Medicine Information obtained by phoning MSD on 0800 500 673, or from www.medsafe.govt.nz.

If you require support, it may be helpful to reach out to a patient organisation. Here is a list of some of them you may want to contact:

Cancer Society

www.cancernz.org.nz

Tel: 0800 CANCER / 0800 226 237

Lung Foundation New Zealand

www.lungfoundation.org.nz

Tel: (+64) 21 959 450

Melanoma New Zealand

www.melanoma.org.nz

Tel: 0800 463 526

Head and Neck Cancer Foundation Aotearoa

www.headandneckcancer.org.nz

Email: office@headandneckcancer.org.nz

Head and Neck Cancer Support Network

www.headandneck.org.nz

Tel: (+64) 21 213 0178

Head and Neck Cancer Support Aotearoa

www.hnlsa.org.nz

Tel: (+64) 22 083 5199 or (+64) 21 0449 378

Gut Cancer Foundation

www.gutcancer.org.nz

Tel: 0800 112 775

Bowel Cancer New Zealand

www.bowelcancernz.org.nz

Tel: 0800 226 901

Talk Peach Gynaecological Cancer Foundation

www.talkpeach.org.nz

Email: info@talkpeach.org.nz

Breast Cancer Foundation New Zealand

www.breastcancerfoundation.org.nz

Tel: 0800 BC NURSE / 0800 226 8773

Breast Cancer Aotearoa Coalition (BCAC)

www.breastcancer.org.nz

Email: bcac@breastcancer.org.nz

Leukaemia & Blood Cancer New Zealand

www.leukaemia.org.nz

Tel: 0800 151 015

Lynch Syndrome New Zealand

Facebook Page

www.facebook.com/LynchSyndromeNZ/

Lynch Syndrome New Zealand Forum

[www.facebook.com/groups/](http://www.facebook.com/groups/1742442089110371)

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Notes for my next appointment



DATE

My notes:

Questions to ask my Oncologist/Specialist:

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Your Oncologist/Specialist

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Phone _____

Phone (after hours) _____

Your Specialist Nurse

Name _____

Phone _____

Phone (after hours) _____

Your Treatment Centre

Name _____

Phone _____

Phone (after hours) _____

References

- KEYTRUDA Consumer Medicine Information • KEYTRUDA Data Sheet • Cancer Council Australia. 2021. Understanding Immunotherapy. A guide for people affected by cancer. Available at: <https://www.cancer.org.au/assets/pdf/understanding-immunotherapy-fact-sheet>. Accessed on: 02/06/2022.