

New Zealand Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about KEYTRUDA. It does not contain all the available information.

It does not take the place of talking to your doctor.

All medicines have risks and benefits. Your doctor has weighed the risks of you using KEYTRUDA against the benefits they expect it will have for you.

If you have any concerns about being given this medicine, ask your doctor.

Keep this leaflet.

You may need to read it again.

What KEYTRUDA is used for

KEYTRUDA is used to treat:

- a kind of skin cancer in adults and children called melanoma.
- a kind of lung cancer called non-small cell lung cancer.
- a kind of cancer called malignant pleural mesothelioma that affects the lining of the lungs and chest wall in adults and children.
- a kind of cancer in adults and children called classical Hodgkin lymphoma.
- a kind of cancer called urothelial carcinoma, including bladder cancer.

- a kind of head and neck cancer called head and neck squamous cell carcinoma.
- a kind of cancer in adults and children 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).

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).

- a kind of cancer called colon or rectal cancer in adults that is shown by a laboratory test to be MSI-H or dMMR.
- a kind of bile duct or gallbladder cancer called biliary tract carcinoma in adults.
- a kind of skin cancer called Merkel cell carcinoma (MCC) in adults and children.
- a kind of cancer called renal cell carcinoma in adults.
- a kind of uterine cancer called endometrial carcinoma in adult women.
- a kind of stomach cancer called gastric or gastroesophageal junction adenocarcinoma in adults.
- a kind of cancer called oesophageal carcinoma in adults.
- a kind of skin cancer called cutaneous squamous cell carcinoma.

- a kind of cancer called cervical cancer in adult women.
- a kind of cancer called triple-negative breast cancer in adults.

KEYTRUDA contains the active substance pembrolizumab.

Adults get KEYTRUDA when their cancer has spread or cannot be taken out by surgery.

People get KEYTRUDA after they had surgery to remove melanoma, non-small cell lung cancer, or renal cell carcinoma to help prevent their cancer from coming back.

Adults get KEYTRUDA before surgery to treat non-small cell lung cancer or triple-negative breast cancer and then continue getting KEYTRUDA after surgery to help prevent their cancer from coming back.

KEYTRUDA may be given in combination with other anti-cancer medicines with or without radiation therapy. 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.

KEYTRUDA works by helping your immune system fight your cancer.

Ask your doctor if you have any questions about why KEYTRUDA has been prescribed for you.

This medicine is available only with a doctor's prescription.

Before you are given KEYTRUDA

KEYTRUDA can be used in children below 18 years of age with melanoma, malignant pleural mesothelioma, classical Hodgkin lymphoma or previously treated MSI-H or dMMR 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 this leaflet.

Before you are given KEYTRUDA

Tell your doctor if you:

- have a disease of your immune system like Crohn's, ulcerative colitis or lupus
- had an organ transplant (like a kidney transplant) or had a bone marrow (stem cell) transplant that used donor stem cells (allogeneic)
- have pneumonia or swelling of your lungs (called pneumonitis)
- have liver damage

Pregnancy

- 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.

Breast-feeding

- If you are breast-feeding, tell your doctor.
- Do not breast-feed while taking KEYTRUDA.

Taking other medicines

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
- take other medicines that make your immune system weak. Examples of these may include steroids, such as prednisone.

How KEYTRUDA is given

- Your doctor will give you KEYTRUDA through an IV for about 30 minutes.
- Most people get KEYTRUDA every 3 weeks or every 6 weeks, depending on the dose you are given.
- Your doctor will decide how many treatments you need.

If you miss a dose

- Call your doctor right away to reschedule your appointment.
- It is very important that you do not miss a dose of this medicine.

While you are being treated with KEYTRUDA

Things you must do

Tell any other doctors, dentists, and pharmacists who are treating you that you are being given KEYTRUDA.

If you are about to be started on any new medicine, tell your doctor, dentist or pharmacist that you are being given KEYTRUDA.

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.

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.

If you have any of the following symptoms, call or see your doctor right away.

- **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 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 kidney problems**

- changes in the amount or colour of your urine
- **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 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 problems in other organs**
 - muscle pain or weakness
 - changes in eyesight
 - stomach area pain with nausea and vomiting (pancreatitis)
 - shortness of breath, irregular heartbeat, feeling tired, or chest pain (myocarditis, pericarditis)
 - confusion, fever, memory problems, or seizures (encephalitis)
 - swollen lymph nodes, rash or tender lumps on skin, cough, or eye pain (sarcoidosis)

- pain, numbness, tingling, or weakness in the arms or 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, feeling tired 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, feeling tired, 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.

- **Signs and symptoms of infusion (IV) reactions**
 - shortness of breath
 - itching or rash
 - dizziness
 - fever

The following side effects have been reported in clinical trials:

Very common (may affect more than 1 in 10 people)

- diarrhoea, nausea
- itching, rash
- joint pain
- back pain
- feeling tired
- cough
- patches of skin which have lost colour
- stomach pain
- decreased sodium levels in the blood
- low levels of thyroid hormone

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

The following side effects have been reported in more than 1 in 5 people when KEYTRUDA was given in combination with chemotherapy or chemotherapy with radiation therapy:

- 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
- low levels of thyroid hormone

The most common side effects when KEYTRUDA is given in combination with axitinib are:

- diarrhoea
- high blood pressure
- feeling tired
- 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

Less common side effects can happen.

Also, your doctor may do blood tests to check for side effects.

KEYTRUDA may cause other side effects that are not listed. For more information, ask your doctor.

If you have any side effect that bothers you or that does not go away, tell your doctor.

Ask your doctor to answer any questions you may have.

Storage

It is unlikely that you will be asked to store KEYTRUDA yourself. It will usually be stored in the pharmacy or on the ward.

Product Description

What it looks like

KEYTRUDA concentrate for solution for infusion comes as a clear to slightly opalescent, colourless to slightly yellow solution in a glass vial.

Ingredients

Active ingredient:

- pembrolizumab

Inactive ingredients:

- Histidine
- Histidine monohydrochloride monohydrate
- Sucrose
- Polysorbate-80
- Water for injection

Supplier

KEYTRUDA is supplied in New Zealand by:

Merck Sharp & Dohme (New Zealand) Limited
PO Box 99-851
Newmarket
Auckland 1149
New Zealand

Telephone: 0800 500 673

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