

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. You can report side effects to your doctor, or directly at www.tga.gov.au/reporting-problems.

KEYTRUDA®

powder for injection and concentrated injection

pembrolizumab (rch)

Consumer Medicine Information

This medicine has provisional approval in Australia for unresectable or metastatic, microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) cancer and endometrial carcinoma. The decision to provisionally register these new uses of the medicine has been made on the basis of promising results from preliminary studies. More evidence is required to be submitted when available to fully confirm the benefit of the medicine for these uses.

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 called melanoma in adults.
- a kind of lung cancer called non-small cell lung cancer in adults.
- a kind of head and neck cancer called head and neck squamous cell carcinoma in adults.
- a kind of cancer called classical Hodgkin Lymphoma in adults.
- a kind of cancer called primary mediastinal B-cell lymphoma in adults and children.
- a kind of cancer called urothelial carcinoma, including bladder cancer in adults.
- a kind of cancer in adults and children that can occur in any part of the body and is shown by laboratory tests to be microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR).
- 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 uterine cancer called endometrial carcinoma
- a kind of kidney cancer called renal cell carcinoma in adults.

It is not known if KEYTRUDA is safe and effective in children with MSI-H or dMMR cancers of the brain or spinal cord (central nervous system cancers).

KEYTRUDA contains the active substance pembrolizumab.

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

Adults get KEYTRUDA after they had surgery to remove melanoma to help prevent their cancer from coming back.

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 specific medicines, please ask your doctor.

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

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.

Before you are given KEYTRUDA

KEYTRUDA can be used in children with primary mediastinal B-cell lymphoma.

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 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 breastfeeding, tell your doctor.
- Do not breastfeed 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 heart beat
 - 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)
 - 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)
 - inflammation of the heart muscle, which may present as shortness of breath, irregular heartbeat, feeling tired, or chest pain (pericarditis)
 - inflammation of the covering of the heart and accumulation of fluid around the heart (pericardial effusion)
 - inflammation of the nerves that may cause pain, weakness, and paralysis in the arms and legs (peripheral neuropathy)
 - 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)
- **Signs and symptoms of infusion (IV) reactions**
 - shortness of breath
 - itching or rash
 - dizziness
 - fever
- **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.
 - **Complications, including graft-versus-host-disease (GVHD), in people with bone marrow (stem cell) transplant that uses donor stem cells (allogeneic).** These complications can be severe and can lead to death. They may occur if you had this kind of transplant in the past or if you get it in the future. Your doctor will monitor you for the following signs and symptoms: skin rash, liver inflammation, abdominal pain, and diarrhoea.

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
- fever
- infections of the upper respiratory tract
- a decreased number of white blood cells (which are important in fighting infection) in patients with primary mediastinal B-cell lymphoma

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
- decrease in white blood cell count
- joint pain
- rash
- swelling of the lining of the digestive system (for example mouth, intestines)
- mouth sores
- decrease in red blood cell count
- nausea
- constipation
- vomiting

Common side effects when KEYTRUDA is given in combination with lenvatinib include:

- feeling tired
- high blood pressure
- joint and muscle pain
- diarrhoea
- decreased appetite
- low levels of thyroid hormone
- nausea
- mouth sores
- vomiting
- weight loss
- stomach-area (abdominal) pain
- headache
- constipation
- urinary tract infection
- hoarseness
- bleeding
- low magnesium level
- blisters or rash on the palms of your hands and soles of your feet
- shortness of breath
- cough
- rash

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

- diarrhoea
- fatigue
- high blood pressure
- liver problems
- low levels of thyroid hormone
- decreased appetite
- blisters or rash on the palms of your hands and soles of your feet
- nausea
- mouth sores or swelling of the lining of the mouth, nose, eyes, throat, intestines, or vagina
- hoarseness
- rash

- cough
- constipation

The most common side effects when KEYTRUDA is given to children are:

- fever
- vomiting
- fatigue
- constipation
- stomach pain
- nausea

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 powder for injection comes as a white to off-white powder in a glass vial. KEYTRUDA concentrated injection comes as a clear to slightly opalescent, colourless to slightly yellow solution in a glass vial.

Ingredients

Active ingredient:

- pembrolizumab

Inactive ingredients:

- Histidine
- Histidine hydrochloride monohydrate
- Sucrose
- Polysorbate 80
- Water for Injections

Supplier

KEYTRUDA is supplied in Australia by:

Merck Sharp & Dohme (Australia) Pty Limited
Level 1, Building A, 26 Talavera
Road, Macquarie Park NSW 2113,
AUSTRALIA

This leaflet was prepared 22 February 2021.

Australian Register Numbers:

AUST R 226597 - KEYTRUDA 50mg Powder
for injection

AUST R 263932 - KEYTRUDA 100mg/4mL
concentrated injection

RCN000013027