

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

▼ This medicine is new or being used differently. Please report side effects. See the [full CMI](#) for further details.

1. Why am I using KEYTRUDA?

KEYTRUDA contains the active ingredient pembrolizumab. KEYTRUDA is used to treat multiple kinds of cancer.

For more information, see Section [1. Why am I using KEYTRUDA?](#) in the full CMI.

2. What should I know before I use KEYTRUDA?

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use KEYTRUDA?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with KEYTRUDA and affect how it works.

For more information, see Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use KEYTRUDA?

- 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.

More instructions can be found in Section [4. How do I use KEYTRUDA?](#) in the full CMI.

5. What should I know while using KEYTRUDA?

| | |
|----------------------------------|--|
| Things you should do | <ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using KEYTRUDA.• If you miss a dose of KEYTRUDA, call your doctor right away to reschedule your appointment |
| Driving or using machines | <p>Be careful before you drive or use any machines or tools until you know how KEYTRUDA affects you.</p> <ul style="list-style-type: none">• Fatigue has been reported following administration of KEYTRUDA. |

For more information, see Section [5. What should I know while using KEYTRUDA?](#) in the full CMI.

6. Are there 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.

When you get KEYTRUDA, you can have some serious side effects.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

▼ This medicine is subject to additional monitoring due to **provisional approval** of an extension of indication. 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®

Active ingredient: pembrolizumab (rch)

Concentrated injection

This medicine has **provisional registration** in Australia for the treatment of patients with high-risk, non-muscle invasive bladder cancer that has not responded to treatment with Bacillus Calmette-Guerin (BCG), and the treatment of adult and paediatric patients with unresectable or metastatic tumour mutational burden-high (TMB-H) solid tumours. 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 substantiate the benefit of the medicine for these uses.

Consumer Medicine Information (CMI)

This leaflet provides important information about using KEYTRUDA. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using KEYTRUDA.**

Where to find information in this leaflet:

1. [Why am I using KEYTRUDA?](#)
2. [What should I know before I use KEYTRUDA?](#)
3. [What if I am taking other medicines?](#)
4. [How do I use KEYTRUDA?](#)
5. [What should I know while using KEYTRUDA?](#)
6. [Are there any side effects?](#)
7. [Product details](#)

1. Why am I using KEYTRUDA?

KEYTRUDA contains the active ingredient pembrolizumab. KEYTRUDA works by helping your immune system fight your cancer. Adults may get KEYTRUDA if their cancer has spread or cannot be taken out by surgery.

Adults and adolescents (12 years and older) get KEYTRUDA after they had surgery to remove melanoma to help prevent their cancer from coming back.

Adults get KEYTRUDA after they had surgery to remove 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, head and neck 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 specific medicines, please ask your doctor.

KEYTRUDA is used to treat:

- a kind of skin cancer called melanoma in adults and adolescents (12 years and older).
- a kind of lung cancer called non-small cell lung cancer in adults.

- a kind of cancer called malignant pleural mesothelioma that affects the lining of the lungs and chest wall 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 and children.
- 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 bile duct or gallbladder cancer called biliary tract carcinoma in adults.
- a kind of uterine cancer called endometrial carcinoma.
- a kind of cancer called cervical cancer in adult women.
- a kind of skin cancer called Merkel cell carcinoma (MCC) in adults and adolescents (12 years and older).
- a kind of kidney cancer called renal cell carcinoma in adults.
- 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 in adults that is locally advanced or recurrent or metastatic and not curable by surgery or radiation.
- a kind of cancer called triple-negative breast cancer in adults.

KEYTRUDA also has provisional approval to treat:

- a kind of bladder cancer called high-risk non-muscle invasive bladder cancer that has not responded to treatment with Bacillus Calmette-Guerin (BCG).
- a kind of cancer that is shown by a test to be tumour mutational burden high (TMB-H). KEYTRUDA may be used in adults and children to treat:

- o cancer that has spread or cannot be removed by surgery (advanced cancer), and
- o you have received anti-cancer treatment, and it did not work or is no longer working.

It is not known if KEYTRUDA is safe and effective in children with other cancers.

2. What should I know before I use KEYTRUDA?

Warnings

Check with your doctor if you:

- have an autoimmune disease (a condition where the body attack its own cells) 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

KEYTRUDA acts on your immune system and may cause inflammation in parts of your body. If you already have an autoimmune disease, your risk of these side effects may be higher. You may also experience flares of your autoimmune disease, which in the majority of cases are mild.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

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

Talk to your doctor if you are breastfeeding or intend to breastfeed.

Do not breastfeed while taking KEYTRUDA.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

It is especially important to tell your doctor or pharmacist if you take other medicines that make your immune system weak. Examples of these may include steroids, such as prednisone.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect KEYTRUDA.

4. How do I use KEYTRUDA?

How much to take

- Your doctor will give you KEYTRUDA through an IV for about 30 minutes.

When to take KEYTRUDA

- 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

- If you miss a dose of KEYTRUDA, call your doctor right away to reschedule your appointment
- It is very important that you do not miss a dose of this medicine

5. What should I know while using KEYTRUDA?

Things you should 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.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how KEYTRUDA affects you.

Fatigue has been reported following administration of KEYTRUDA.

Looking after your medicine

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

6. Are there 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.

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.

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

Serious side effects

| Serious side effects | What to do |
|--|---|
| <p>Signs and symptoms of lung problems:</p> <ul style="list-style-type: none"> • shortness of breath • chest pain • coughing <p>Signs and symptoms of problems with your intestines:</p> <ul style="list-style-type: none"> • diarrhoea or more bowel movements than usual • your stools are black, tarry, sticky or have blood or mucus • severe stomach pain or tenderness <p>Signs and symptoms of liver problems:</p> <ul style="list-style-type: none"> • 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 <p>Signs and symptoms of kidney problems:</p> <ul style="list-style-type: none"> • changes in the amount or colour of your urine <p>Signs and symptoms of hormone gland problems (especially the thyroid, pituitary, and adrenal glands):</p> <ul style="list-style-type: none"> • 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 | <p>Call or see your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p> |

| Serious side effects | What to do |
|--|------------|
| <p>Signs and symptoms of blood sugar problems:</p> <ul style="list-style-type: none"> • feeling more hungry or thirsty • needing to urinate more often • weight loss <p>Signs and symptoms of skin problems:</p> <ul style="list-style-type: none"> • rash • itching • skin blistering, peeling or sores • ulcers in mouth or in lining of nose, throat, or genital area <p>Signs and symptoms of problems in other organs:</p> <ul style="list-style-type: none"> • 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) • inflammation of the blood vessels (vasculitis) • decreased function of the parathyroid gland, which may include muscle cramps or | |

| Serious side effects | What to do |
|--|------------|
| <p>spasms, fatigue and weakness (hypoparathyroidism)</p> <ul style="list-style-type: none"> ● 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 the whites of the 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) ● a condition in which some or all of the following happen together: muscle pain or weakness, changes in eyesight, feeling tired, shortness of breath, chest pain, or irregular heartbeat (myocarditis-myositis-myasthenia gravis overlap syndrome) ● decreased production of blood cells, which may result in weakness, shortness of breath, dizziness, fast or irregular heartbeat, frequent infections, unexplained or easy bruising, or bleeding from gums or other tissues (aplastic anaemia) <p>Signs and symptoms of infusion (IV) reactions:</p> <ul style="list-style-type: none"> ● shortness of breath ● itching or rash ● dizziness ● fever <p>There are possible side effects of treatment with KEYTRUDA in people who have received a transplant:</p> <ul style="list-style-type: none"> ● Rejection of a transplanted organ. | |

| Serious side effects | What to do |
|---|------------|
| <ul style="list-style-type: none"> ● 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. <p>Complications, including graft-versus-host-disease (GVHD), in people with bone marrow (stem cell) transplant that uses donor stem cells (allogeneic).</p> <ul style="list-style-type: none"> ● 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) | What to do |
|--|--|
| <ul style="list-style-type: none"> ● 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 ● low levels of thyroid hormone ● a decreased number of white blood cells (which are important in fighting infection) in patients with primary mediastinal B-cell lymphoma | <p>Speak to your doctor if you have any of these side effects and they worry you.</p> |
| <p>The following side effects have been reported in more than 1 in 5 people when KEYTRUDA was given in combination with chemotherapy or</p> | |

| Very common (may affect more than 1 in 10 people) | What to do |
|--|------------|
| <p>chemotherapy with radiation therapy:</p> <ul style="list-style-type: none"> • 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 red blood cell count • nausea • constipation • weight loss • decrease in number of platelets in the blood • elevated liver enzymes • low levels of thyroid hormone • urinary tract infection • radiation skin injury • difficulty swallowing • dry mouth • pain and stiffness in muscle <p>Common side effects when KEYTRUDA is given in combination with lenvatinib include:</p> <ul style="list-style-type: none"> • low levels of thyroid hormone • high blood pressure • feeling tired • diarrhoea • joint and muscle pain • nausea • decreased appetite • vomiting • mouth sores • weight loss • stomach-area (abdominal) pain • urinary tract infection • protein in your urine • constipation • headache • bleeding • blisters or rash on the palms of your hands and soles of your feet • hoarseness • rash | |

| Very common (may affect more than 1 in 10 people) | What to do |
|---|------------|
| <p>The most common side effects when KEYTRUDA is given in combination with axitinib are:</p> <ul style="list-style-type: none"> • 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 <p>Rash is more common when KEYTRUDA is given in combination with enfortumab vedotin than when KEYTRUDA is given alone.</p> <p>The most common side effects when KEYTRUDA is given alone to children are:</p> <ul style="list-style-type: none"> • fever • vomiting • headache • stomach area (abdominal) pain • decrease in number of red blood cells • cough <p>Less common side effects can happen.</p> | |

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

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

What KEYTRUDA contains

| | |
|---|---|
| Active ingredient (main ingredient) | pembrolizumab |
| Other ingredients (inactive ingredients) | Histidine Histidine hydrochloride monohydrate Sucrose Polysorbate 80 Water for Injections |

What KEYTRUDA looks like

KEYTRUDA concentrated injection comes as a clear to slightly opalescent, colourless to slightly yellow solution in a glass vial.

Australian Register Number:

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

Who distributes KEYTRUDA

KEYTRUDA is supplied in Australia by:

Merck Sharp & Dohme (Australia) Pty Limited

Level 1, Building A, 26 Talavera Road, Macquarie Park NSW 2113, AUSTRALIA

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