Keytruda

Generic Name: pembrolizumab (PEM broe LIZ ue mab)
Brand Names: *Keytruda*

Medically reviewed by **Judith Stewart, BPharm**. Last updated on Nov 2, 2020.

What is Keytruda?

Keytruda (**pembrolizumab**) is a cancer medicine that interferes with the growth and spread of cancer cells in the body.

Keytruda is used alone or in combination with other medicines to treat certain types of cancer such as:

- **skin cancer** (**melanoma** or **Merkel cell carcinoma**);
- **lung cancer**;
- **head and neck cancer**;
- classical **Hodgkin lymphoma**;
- primary mediastinal large B-cell lymphoma;
- cancer of the kidney, bladder, and urinary tract;
- liver cancer;
- cancer of the cervix or uterus;
- advanced **stomach cancer** or **esophageal cancer**; or
- a type of cancer that laboratory testing proves to have certain specific DNA mutations, including colorectal cancer.

Keytruda is often given when the cancer has spread to other parts of the body, or cannot be treated with surgery or radiation, or when other cancer treatments did not work or have stopped working.

For some types of cancer, Keytruda is given only if your tumor tests positive for "PD-L1", or if the tumor has a specific genetic marker (an abnormal "EGFR," "ALK," or "HER2/neu" gene).

Important Information

Keytruda can change the way your immune system works, which may cause certain side effects that can lead to serious medical problems.

Keytruda can cause side effects in many different parts of your body. Some side effects may need to be treated with other medicine, and your cancer treatments may be delayed. **You will need frequent medical tests to help your doctor determine if it is safe for you to keep receiving Keytruda.**

Call your doctor at once if you have: skin problems, vision problems, fever, swollen glands, neck stiffness, chest pain, cough, shortness of breath, muscle or joint pain, pale skin, weakness, diarrhea, severe stomach pain, blood in your stools, bruising or bleeding, dark urine, yellowing of the skin or eyes, a hormonal disorder (frequent headaches, feeling light-headed, rapid heartbeats, a deeper voice, increased thirst or urination, feeling cold, weight gain or loss), or a change in the amount or color of your urine.

Before taking this medicine

Tell your doctor if you have ever had:

- lung disease or a breathing disorder;
- liver disease;
- diabetes, or a thyroid disorder;
- an adrenal gland disorder;
- an autoimmune disorder such as **lupus**, **Crohn's disease**, or **ulcerative colitis**; or
- an **organ transplant** or stem cell transplant.

You may need to have a negative pregnancy test before starting this treatment. **Do not use Keytruda if you are pregnant.** Pembrolizumab could harm the unborn baby. Use effective **birth control** to prevent pregnancy while you are using this medicine and for at least 4 months after your last dose. Tell your doctor right away if you become pregnant.

Do not breastfeed while using pembrolizumab, and for at least 4 months after your last dose.

How is Keytruda given?

Keytruda is given as an infusion into a vein, usually once every 3 weeks or every 6 weeks. A healthcare provider will give you this injection.

Your doctor will perform a blood test to make sure Keytruda is the right treatment for your condition.

This medicine must be given slowly, and the infusion can take at least 30 minutes to complete.

You will need frequent medical tests to help your doctor determine if it is safe for you to keep receiving Keytruda. Do not miss any follow-up visits.

Keytruda dosing information

Usual Adult Dose for Melanoma -- Metastatic:

Unresectable or metastatic melanoma:
200 mg IV over 30 minutes every 3 weeks until disease progression or unacceptable toxicity

Adjuvant treatment of melanoma:
200 mg IV over 30 minutes every 3 weeks until disease recurrence, unacceptable toxicity, or for up to 12 months in patients without disease recurrence

Uses:
-Treatment of patients with unresectable or metastatic melanoma
-Adjuvant treatment of patients with melanoma with involvement of lymph node(s) following complete resection

Usual Adult Dose for Non-Small Cell Lung Cancer:

200 mg IV over 30 minutes every 3 weeks until disease progression, unacceptable toxicity, or up to 24 months in patients without disease progression

Uses:

SINGLE AGENT:
-For the first-line treatment of patients with non-small cell lung cancer (NSCLC) expressing PD-L1 (Tumor Proportion Score [TPS] 1% or greater) as determined by an FDA-approved test with no EGFR or ALK genomic tumor aberrations, and is stage III where patients are not candidates for surgical resection or definitive chemoradiation OR metastatic
-For the treatment of patients with metastatic NSCLC whose tumors express PD-L1 (TPS 1% or greater) as determined by an FDA-approved test with disease progression on or after platinum-containing chemotherapy; patients with EGFR or ALK genomic tumor aberrations should have disease progression on FDA-approved therapy for these aberrations prior to receiving this drug
COMBINATION THERAPY:
-In combination with pemetrexed and platinum chemotherapy for first-line treatment of metastatic nonsquamous non-small cell lung cancer (NSCLC) with no EGFR or ALK genomic tumor aberrations
-In combination with carboplatin and either paclitaxel or paclitaxel protein-bound for first-line treatment of patients with metastatic squamous NSCLC

Usual Adult Dose for Small Cell Lung Cancer:

200 mg IV over 30 minutes every 3 weeks until disease progression, unacceptable toxicity, or up to 24 months in patients without disease progression

Use: For the treatment of metastatic small cell lung cancer (SCLC) with disease progression on or after platinum-based chemotherapy and at least one prior line of therapy

Usual Adult Dose for Head and Neck Cancer:

200 mg IV over 30 minutes every 3 weeks until disease progression, unacceptable toxicity, or up to 24 months in patients without disease progression

Comments:
-When administering this drug in combination with chemotherapy, administer this drug prior to chemotherapy when given on the same day.
-Refer to the Prescribing Information for the chemotherapy agents administered in combination with this drug for recommended dosing information.

Uses:
-As a single agent for first line treatment of patients with metastatic or unresectable recurrent head and neck squamous cell cancer (HNSCC) whose tumors express PD-L1 (Combined Positive Score [CPS] greater than or equal to 1) as determined by an FDA-approved test
-As a single agent for treatment of patients with recurrent or metastatic HNSCC with disease progression on or after platinum-containing chemotherapy
-In combination with platinum and fluorouracil (FU) for first-line treatment of patients with metastatic or with unresectable, recurrent head and neck squamous cell carcinoma (HNSCC)

Usual Adult Dose for Hodgkin's Disease:

200 mg IV over 30 minutes every 3 weeks until disease progression, unacceptable toxicity, or up to 24 months in patients without disease progression

Use: For the treatment of patients with refractory classical Hodgkin lymphoma (cHL), or who have relapsed after 3 or more prior lines of therapy

Usual Adult Dose for Urothelial Carcinoma:

Locally advanced or metastatic urothelial carcinoma:
200 mg IV over 30 minutes every 3 weeks until disease progression, unacceptable toxicity, or up to 24

months in patients without disease progression

High-risk BCG-unresponsive non-muscle invasive bladder cancer:
200 mg IV over 30 minutes every 3 weeks until persistent or recurrent high-risk NMIBC, disease progression or unacceptable toxicity, or up to 24 months in patients without disease progression

Uses:
-For the treatment of patients with locally advanced or metastatic urothelial carcinoma who are not eligible for cisplatin-containing chemotherapy and whose tumors express PD-L1 10 or greater) as determined by an FDA-approved test, or in patients who are not eligible for any platinum-containing chemotherapy regardless of PD-L1 status.
-For the treatment of patients with locally advanced or metastatic urothelial carcinoma who have disease progression during or following platinum-containing chemotherapy or within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy.
-For the treatment of patients with Bacillus Calmette-Guerin (BCG)-unresponsive, high-risk, non-muscle invasive bladder cancer (NMIBC) with carcinoma in situ (CIS) with or without papillary tumors who are ineligible for or have elected not to undergo cystectomy

Usual Adult Dose for Colorectal Cancer:

200 mg IV over 30 minutes every 3 weeks until disease progression, unacceptable toxicity, or up to 24 months in patients without disease progression

Uses: For the treatment of patients with unresectable or metastatic, microsatellite instability-high (MSI-H) or mismatch repair deficient solid tumors that have progressed following prior treatment and who have no satisfactory alternative treatment options OR colorectal cancer that has progressed following treatment with a fluoropyrimidine, oxaliplatin, and irinotecan

Usual Adult Dose for Solid Tumors:

200 mg IV over 30 minutes every 3 weeks until disease progression, unacceptable toxicity, or up to 24 months in patients without disease progression

Uses: For the treatment of patients with unresectable or metastatic, microsatellite instability-high (MSI-H) or mismatch repair deficient solid tumors that have progressed following prior treatment and who have no satisfactory alternative treatment options OR colorectal cancer that has progressed following treatment with a fluoropyrimidine, oxaliplatin, and irinotecan

Usual Adult Dose for Gastric Cancer:

200 mg IV over 30 minutes every 3 weeks until disease progression, unacceptable toxicity, or up to 24 months in patients without disease progression

Use: For patients with recurrent locally advanced or metastatic gastric or gastroesophageal junction adenocarcinoma whose tumors express PD-L1 Positive Score (CPS) 1 or greater as determined by an FDA-approved test, with disease progression on or after 2 or more prior lines of therapy including fluoropyrimidine-and platinum-containing chemotherapy and if appropriate, HER2/neu-targeted therapy

Usual Adult Dose for Cervical Cancer:

200 mg IV over 30 minutes every 3 weeks until disease progression, unacceptable toxicity, or up to 24 months in patients without disease progression

Use: For the treatment of patients with recurrent or metastatic cervical cancer with disease

progression on or after chemotherapy whose tumors express PD-L1 (CPS 1 or greater) as determined by an FDA-approved test

Usual Adult Dose for Lymphoma:

200 mg IV over 30 minutes every 3 weeks until disease progression, unacceptable toxicity, or up to 24 months in patients without disease progression

Use: For the treatment of patients with refractory primary mediastinal large B-cell lymphoma (PMBCL) or who have relapsed after 2 or more prior lines of therapy (not recommended for treatment of patients with PMBCL who require urgent cytoreductive therapy)

Usual Adult Dose for Hepatocellular Carcinoma:

200 mg IV over 30 minutes every 3 weeks until disease progression, unacceptable toxicity, or up to 24 months in patients without disease progression

Use: For the treatment of patients with hepatocellular carcinoma (HCC) who have been previously treated with sorafenib

Usual Adult Dose for Merkel Cell Carcinoma:

200 mg IV over 30 minutes every 3 weeks until disease progression, unacceptable toxicity, or up to 24 months in patients without disease progression

Use: For the treatment of patients with recurrent locally advanced or metastatic Merkel cell carcinoma (MCC)

Usual Adult Dose for Renal Cell Carcinoma:

200 mg IV over 30 minutes every 3 weeks in combination with 5 mg axitinib orally 2 times a day until disease progression, unacceptable toxicity, or for pembrolizumab up to 24 months in patients without disease progression

Comments:
-When axitinib is used in combination with this drug, dose escalation of axitinib above the initial 5 mg dose may be considered at intervals of 6 weeks or longer.
-See the prescribing information for recommended axitinib dosing information.

Use: In combination with axitinib for the first-line treatment of advanced renal cell carcinoma (RCC)

Usual Adult Dose for Esophageal Carcinoma:

200 mg IV over 30 minutes every 3 weeks in combination until disease progression, unacceptable toxicity, or up to 24 months in patients without disease progression

Use: For patients with recurrent locally advanced or metastatic squamous cell carcinoma of the esophagus whose tumors express PD-L1 (CPS 10 or greater) as determined by an FDA-approved test, with disease progression after one or more prior lines of systemic therapy

Usual Adult Dose for Endometrial Carcinoma:

200 mg IV over 30 minutes every 3 weeks in combination with lenvatinib 20 mg orally once daily until disease progression, unacceptable toxicity, or up to 24 months in patients without disease progression

Comments:

-Refer to the lenvatinib prescribing information for recommended dosing.

Use: In combination with lenvatinib for the treatment of patients with advanced endometrial carcinoma that is not MSI-H or dMMR, who have disease progression following prior systemic therapy, and are not candidates for curative surgery or radiation

Usual Pediatric Dose for Hodgkin's Disease:

2 years and older:
2 mg/kg (up to a maximum of 200 mg) IV 30 minutes every 3 weeks until disease progression, unacceptable toxicity, or up to 24 months in patients without disease progression

Use: For the treatment of pediatric patients 2 years and older with refractory classical Hodgkin lymphoma (cHL), or who have relapsed after 3 or more prior lines of therapy

Usual Pediatric Dose for Colorectal Cancer:

2 years and older:
2 mg/kg (up to a maximum of 200 mg) IV over 30 minutes every 3 weeks until disease progression, unacceptable toxicity, or up to 24 months in patients without disease progression

Uses: For the treatment of pediatric patients with unresectable or metastatic, microsatellite instability-high (MSI-H) or mismatch repair deficient solid tumors that have progressed following prior treatment and who have no satisfactory alternative treatment options OR colorectal cancer that has progressed following treatment with a fluoropyrimidine, oxaliplatin, and irinotecan

Usual Pediatric Dose for Solid Tumors:

2 years and older:
2 mg/kg (up to a maximum of 200 mg) IV over 30 minutes every 3 weeks until disease progression, unacceptable toxicity, or up to 24 months in patients without disease progression

Uses: For the treatment of pediatric patients with unresectable or metastatic, microsatellite instability-high (MSI-H) or mismatch repair deficient solid tumors that have progressed following prior treatment and who have no satisfactory alternative treatment options OR colorectal cancer that has progressed following treatment with a fluoropyrimidine, oxaliplatin, and irinotecan

Usual Pediatric Dose for Lymphoma:

2 years and older:
2 mg/kg (up to a maximum of 200 mg) IV over 30 minutes every 3 weeks until disease progression, unacceptable toxicity, or up to 24 months in patients without disease progression

Use: For the treatment of pediatric patients 2 years and older with refractory primary mediastinal large B-cell lymphoma (PMBCL) or who have relapsed after 2 or more prior lines of therapy (not recommended for treatment of patients with PMBCL who require urgent cytoreductive therapy)

Usual Pediatric Dose for Merkel Cell Carcinoma:

2 years and older:
2 mg/kg (up to a maximum of 200 mg) IV over 30 minutes every 3 weeks until disease progression, unacceptable toxicity, or up to 24 months in patients without disease progression

Use: For the treatment of patients with recurrent locally advanced or metastatic Merkel cell carcinoma (MCC)

See also:
Keytruda dosage information (in more detail)

What happens if I miss a dose?

Call your doctor for instructions if you miss an appointment for your Keytruda injection.

What happens if I overdose?

Seek emergency medical attention or call the Poison Help line at 1-800-222-1222.

What should I avoid while receiving Keytruda?

Pembrolizumab can pass into body fluids (urine, feces, vomit). For at least 48 hours after you receive a dose, avoid allowing your body fluids to come into contact with your hands or other surfaces. Caregivers should wear rubber gloves while cleaning up a patient's body fluids, handling contaminated trash or laundry or changing diapers. Wash hands before and after removing gloves. Wash soiled clothing and linens separately from other laundry.

Keytruda side effects

Get emergency medical help if you have **signs of an allergic reaction to Keytruda:** (hives, difficult breathing, swelling in your face or throat) **or a severe skin reaction** (fever, sore throat, burning eyes, skin pain, red or purple skin rash with blistering and peeling).

Some side effects may occur during the injection. Tell your caregiver if you feel dizzy, light-headed, itchy, hot, sweaty, chilled, or have trouble breathing.

Pembrolizumab affects your immune system, and can cause side effects in many different parts of your body. Some side effects may need to be treated with other medicine.

Call your doctor at once if you have:

- sores in your mouth, throat, or nose, or on your genital area;
- eye pain or vision problems;
- numbness, tingling, burning pain, redness, rash, or blisters on your hands or feet;
- severe muscle weakness, severe or ongoing muscle or joint pain;
- fever, swollen glands, neck stiffness;
- diarrhea or increased stools, severe stomach pain, bloody or tarry stools;
- a change in the amount or color of your urine;
- **liver problems** - loss of appetite, right-sided stomach pain, easy bruising or bleeding, dark urine, **jaundice** (yellowing of the skin or eyes);
- **low levels of sodium in the body** - confusion, slurred speech, severe weakness, loss of coordination, feeling unsteady; or
- **signs of a hormonal disorder** - frequent or unusual headaches, feeling light-headed, rapid heartbeats, hoarse or deepened voice, increased hunger or thirst, increased urination, **constipation**, **hair loss**, muscle pain, sweating, feeling cold, weight changes.

Your cancer treatments may be delayed or permanently discontinued if you have certain side effects.

Common Keytruda side effects (some are more likely with combination chemotherapy) may include:

- **nausea**, **vomiting**, stomach pain, loss of appetite, diarrhea, constipation;
- low sodium levels, abnormal **liver function** or thyroid function tests;
- fever, feeling weak or tired;
- cough, hoarse voice, feeling short of breath;
- itching, rash, or hair loss;
- increased blood pressure;
- pain in your muscles, bones, or joints; or
- soreness in or around your mouth, nose, eyes, throat, or vagina.

This is not a complete list of side effects and others may occur. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

See also:
Keytruda side effects (in more detail)

What other drugs will affect Keytruda?

Other drugs may interact with Keytruda, including prescription and over-the-counter medicines, **vitamins**, and **herbal products**. Tell your doctor about all your current medicines and any medicine you start or stop using.

See also:
Keytruda drug interactions (in more detail)

Further information

Remember, keep this and all other medicines out of the reach of children, never share your medicines with others, and use Keytruda only for the indication prescribed.

Always consult your healthcare provider to ensure the information displayed on this page applies to your personal circumstances.

Popular FAQ

Pembrolizumab vs. nivolumab: how do they compare?

How are axitinib and pembrolizumab used in kidney cancer?

How does pembrolizumab affect the immune system?

What type of cancer is pembrolizumab used for?

How does pembrolizumab kill cancer cells?

How is pembrolizumab (Keytruda) administered?