

MEDICATION GUIDE
KEYTRUDA[®] (key-true-duh)
(pembrolizumab)
injection

What is the most important information I should know about KEYTRUDA?

KEYTRUDA is a medicine that may treat certain cancers by working with your immune system. KEYTRUDA can cause your immune system to attack normal organs and tissues in any area of your body and can affect the way they work. These problems can sometimes become severe or life-threatening and can lead to death. These problems may happen anytime during treatment or even after your treatment has ended.

Call or see your doctor right away if you develop any symptoms of the following problems or these symptoms get worse:

Lung problems (pneumonitis). Symptoms of pneumonitis may include:

- shortness of breath
- chest pain
- new or worse cough

Intestinal problems (colitis) that can lead to tears or holes in your intestine. Signs and symptoms of colitis may include:

- diarrhea or more bowel movements than usual
- stools that are black, tarry, sticky, or have blood or mucus
- severe stomach-area (abdomen) pain or tenderness

Liver problems, including hepatitis. Signs and symptoms of liver problems may include:

- yellowing of your skin or the whites of your eyes
- nausea or vomiting
- pain on the right side of your stomach area (abdomen)
- dark urine
- bleeding or bruising more easily than normal

Hormone gland problems (especially the thyroid, pituitary, adrenal glands, and pancreas). Signs and symptoms that your hormone glands are not working properly may include:

- rapid heart beat
- weight loss or weight gain
- increased sweating
- feeling more hungry or thirsty
- urinating more often than usual
- hair loss
- feeling cold
- constipation
- your voice gets deeper
- muscle aches
- feeling very weak
- dizziness or fainting
- headaches that will not go away or unusual headache

Kidney problems, including nephritis and kidney failure. Signs of kidney problems may include:

- change in the amount or color of your urine

Skin problems. Signs of skin problems may include:

- rash
- itching
- blisters, peeling or skin sores
- painful sores or ulcers in your mouth or in your nose, throat, or genital area

Problems in other organs. Signs and symptoms of these problems may include:

- changes in eyesight
- severe or persistent muscle or joint pains
- severe muscle weakness
- low red blood cells (anemia)
- swollen lymph nodes, rash or tender lumps on skin, cough, shortness of breath, vision changes, or eye pain

(sarcoidosis)

- confusion, fever, muscle weakness, balance problems, nausea, vomiting, stiff neck, memory problems, or seizures (encephalitis)
- pain, numbness, tingling, or weakness in your arms or legs, or bladder or bowel problems, including the need to urinate more often, leaking of urine, trouble urinating, or constipation (myelitis)
- shortness of breath, irregular heartbeat, feeling tired, or chest pain (myocarditis)

Infusion (IV) reactions that can sometimes be severe and life-threatening. Signs and symptoms of infusion reactions may include:

- chills or shaking
- shortness of breath or wheezing
- itching or rash
- flushing
- dizziness
- fever
- feeling like passing out

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 who have received a bone marrow (stem cell) transplant that uses donor stem cells (allogeneic). These complications can be severe and can lead to death. These complications may happen if you underwent transplantation either before or after being treated with KEYTRUDA. Your doctor will monitor you for the following signs and symptoms: skin rash, liver inflammation, stomach-area (abdominal) pain, and diarrhea.

Getting medical treatment right away may help keep these problems from becoming more serious.

Your doctor will check you for these problems during treatment with KEYTRUDA. Your doctor may treat you with corticosteroid or hormone replacement medicines. Your doctor may also need to delay or completely stop treatment with KEYTRUDA, if you have severe side effects.

What is KEYTRUDA?

KEYTRUDA is a prescription medicine used to treat:

- a kind of skin cancer called melanoma. KEYTRUDA may be used:
 - when your melanoma has spread or cannot be removed by surgery (advanced melanoma), **or**
 - to help prevent melanoma from coming back after it and lymph nodes that contain cancer have been removed by surgery.
- a kind of lung cancer called non-small cell lung cancer (NSCLC).
 - KEYTRUDA may be used with the chemotherapy medicines pemetrexed and a platinum as your first treatment when your lung cancer:
 - has spread (advanced NSCLC), **and**
 - is a type called “nonsquamous”, **and**
 - your tumor does not have an abnormal “EGFR” or “ALK” gene.
 - KEYTRUDA may be used with the chemotherapy medicines carboplatin and either paclitaxel or paclitaxel protein-bound as your first treatment when your lung cancer:
 - has spread (advanced NSCLC), **and**
 - is a type called “squamous”.
 - KEYTRUDA may be used alone as your first treatment when your lung cancer:
 - has not spread outside your chest (stage III) and you cannot have surgery or chemotherapy with radiation **or**
 - your NSCLC has spread to other areas of your body (advanced NSCLC), **and**
 - your tumor tests positive for “PD-L1”, **and**
 - does not have an abnormal “EGFR” or “ALK” gene.
 - KEYTRUDA may also be used alone when:
 - you have received chemotherapy that contains platinum to treat your advanced NSCLC, and it did not work or it is no longer working, **and**
 - your tumor tests positive for “PD-L1”, **and**
 - if your tumor has an abnormal “EGFR” or “ALK” gene, you have also received an EGFR or ALK inhibitor medicine and it did not work or is no longer working.
- a kind of lung cancer called small cell lung cancer (SCLC). KEYTRUDA may be used when your lung cancer:
 - has spread (advanced SCLC), **and**

- you have received 2 or more types of chemotherapy, including one that contains platinum, and it did not work or is no longer working.
- a kind of cancer called head and neck squamous cell cancer (HNSCC).
 - KEYTRUDA may be used with the chemotherapy medicines fluorouracil and a platinum as your first treatment when your head and neck cancer has spread or returned and cannot be removed by surgery.
 - KEYTRUDA may be used alone as your first treatment when your head and neck cancer:
 - has spread or returned and cannot be removed by surgery, **and**
 - your tumor tests positive for “PD-L1”.
 - KEYTRUDA may be used alone when your head and neck cancer:
 - has spread or returned, **and**
 - you have received chemotherapy that contains platinum and it did not work or is no longer working.
- a kind of cancer called classical Hodgkin Lymphoma (cHL) in adults and children when:
 - you have tried a treatment and it did not work **or**
 - your cHL has returned after you received 3 or more types of treatment.
- a kind of cancer called primary mediastinal B-cell lymphoma (PMBCL) in adults and children when:
 - you have tried a treatment and it did not work **or**
 - your PMBCL has returned after you received 2 or more types of treatment.
- a kind of bladder and urinary tract cancer called urothelial carcinoma.
 - KEYTRUDA may be used when your cancer has not spread to nearby tissue in the bladder, but is at high-risk for spreading (high-risk non-muscle-invasive bladder cancer [NMIBC]) when:
 - your tumor is a type called “carcinoma in situ” (CIS), **and**
 - you have tried treatment with Bacillus Calmette-Guerin (BCG) and it did not work, **and**
 - you are not able to or have decided not to have surgery to remove your bladder.
 - KEYTRUDA may be used when your bladder or urinary tract cancer:
 - has spread or cannot be removed by surgery (advanced urothelial cancer) **and**,
 - you are not able to receive chemotherapy that contains a medicine called cisplatin, and your tumor tests positive for “PD-L1”, **or**
 - you are not able to receive a medicine called cisplatin or carboplatin, **or**
 - you have received chemotherapy that contains platinum, and it did not work or is no longer working.
- a kind of cancer that is shown by a laboratory test to be a microsatellite instability-high (MSI-H) or a mismatch repair deficient (dMMR) solid tumor. KEYTRUDA may be used in adults and children to treat:
 - cancer that has spread or cannot be removed by surgery (advanced cancer), **and**
 - has progressed following treatment, and you have no satisfactory treatment options, **or**
 - you have colon or rectal cancer, and you have received chemotherapy with fluoropyrimidine, oxaliplatin, and irinotecan but it did not work or is no longer working.

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

- a kind of cancer called colon or rectal cancer. KEYTRUDA may be used as your first treatment when your cancer:
 - has spread or cannot be removed by surgery (advanced colon or rectal cancer), **and**
 - has been shown by a laboratory test to be microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR).
- a kind of stomach cancer called gastric or gastroesophageal junction (GEJ) adenocarcinoma that tests positive for “PD-L1.” KEYTRUDA may be used when your stomach cancer:
 - has returned or spread (advanced gastric cancer), **and**
 - you have received 2 or more types of chemotherapy including fluoropyrimidine and chemotherapy that contains platinum, and it did not work or is no longer working, **and**
 - if your tumor has an abnormal “HER2/neu” gene, you also received a HER2/neu-targeted medicine and it did not work or is no longer working.
- a kind of cancer called squamous cell carcinoma of the esophagus. KEYTRUDA may be used when:
 - your cancer has returned or spread (advanced esophageal cancer), **and**
 - your tumor tests positive for “PD-L1” and you have received one or more types of treatment and it did not work or is no longer working.
- a kind of cancer called cervical cancer that tests positive for “PD-L1.” KEYTRUDA may be used when your cervical cancer:
 - has returned, or has spread or cannot be removed by surgery (advanced cervical cancer), **and**
 - you have received chemotherapy, and it did not work or is no longer working.
- a kind of liver cancer called hepatocellular carcinoma, after you have received the medicine sorafenib.
- a kind of skin cancer called Merkel cell carcinoma (MCC) in adults and children. KEYTRUDA may be used to treat your skin cancer when it has spread or returned.
- a kind of kidney cancer called renal cell carcinoma (RCC). KEYTRUDA may be used with the medicine axitinib as

- your first treatment when your kidney cancer has spread or cannot be removed by surgery (advanced RCC).
- a kind of uterine cancer called endometrial carcinoma. KEYTRUDA may be used with the medicine lenvatinib:
 - when your tumors are not microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR), **and**
 - you have received anti-cancer treatment, and it did not work or is no longer working, **and**
 - your cancer cannot be cured by surgery or radiation (advanced endometrial carcinoma).
 - a kind of cancer that is shown by a test to be tumor mutational burden-high (TMB-H). KEYTRUDA may be used in adults and children to treat:
 - solid tumors that have spread or cannot be removed by surgery (advanced cancer), **and**
 - you have received anti-cancer treatment, and it did not work or is no longer working, **and**
 - you have no satisfactory treatment options.

It is not known if KEYTRUDA is safe and effective in children with TMB-H cancers of the brain or spinal cord (central nervous system cancers).
 - a kind of skin cancer called cutaneous squamous cell carcinoma (cSCC). KEYTRUDA may be used when your skin cancer:
 - has returned or spread, **and**
 - cannot be cured by surgery or radiation.

What should I tell my doctor before receiving KEYTRUDA?

Before you receive KEYTRUDA, tell your doctor if you:

- have immune system problems such as Crohn’s disease, ulcerative colitis, or lupus
- have received an organ transplant, such as a kidney or liver
- have received or plan to receive a stem cell transplant that uses donor stem cells (allogeneic)
- have lung or breathing problems
- have liver problems
- have any other medical problems
- are pregnant or plan to become pregnant
 - KEYTRUDA can harm your unborn baby.

Females who are able to become pregnant:

- Your doctor will give you a pregnancy test before you start treatment with KEYTRUDA.
- You should use an effective method of birth control during and for at least 4 months after the final dose of KEYTRUDA. Talk to your doctor about birth control methods that you can use during this time.
- Tell your doctor right away if you think you may be pregnant or if you become pregnant during treatment with KEYTRUDA.
- are breastfeeding or plan to breastfeed.
 - It is not known if KEYTRUDA passes into your breast milk.
 - Do not breastfeed during treatment with KEYTRUDA and for 4 months after your final dose of KEYTRUDA.

Tell your doctor about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

Know the medicines you take. Keep a list of them to show your doctor and pharmacist when you get a new medicine.

How will I receive KEYTRUDA?

- Your doctor will give you KEYTRUDA into your vein through an intravenous (IV) line over 30 minutes.
- In adults, KEYTRUDA is usually given every 3 weeks or 6 weeks depending on the dose of KEYTRUDA that you are receiving.
- In children, KEYTRUDA is usually given every 3 weeks.
- Your doctor will decide how many treatments you need.
- Your doctor will do blood tests to check you for side effects.
- If you miss any appointments, call your doctor as soon as possible to reschedule your appointment.

What are the possible side effects of KEYTRUDA?

KEYTRUDA can cause serious side effects. See “What is the most important information I should know about KEYTRUDA?”

Common side effects of KEYTRUDA when used alone include: feeling tired, pain, including pain in muscles, bones or joints and stomach-area (abdominal) pain, decreased appetite, itching, diarrhea, nausea, rash, fever, cough, shortness of breath, and constipation.

Common side effects of KEYTRUDA when given with certain chemotherapy medicines include: feeling tired or weak, nausea, constipation, diarrhea, decreased appetite, rash, vomiting, cough, trouble breathing, fever, hair loss, inflammation of the nerves that may cause pain, weakness, and paralysis in the arms and legs, swelling of the lining of the mouth, nose, eyes, throat, intestines, or vagina, and mouth sores.

Common side effects of KEYTRUDA when given with axitinib include: diarrhea, feeling tired or weak, 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, and constipation.

Common side effects of KEYTRUDA when given with lenvatinib include: feeling tired, high blood pressure, joint and muscle pain, diarrhea, 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, and rash.

In children, feeling tired, vomiting and stomach-area (abdominal) pain, and increased levels of liver enzymes and decreased levels of salt (sodium) in the blood are more common than in adults.

These are not all the possible side effects of KEYTRUDA. For more information, ask your doctor or pharmacist.

Tell your doctor if you have any side effect that bothers you or that does not go away.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

General information about the safe and effective use of KEYTRUDA

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. If you would like more information about KEYTRUDA, talk with your doctor. You can ask your doctor or nurse for information about KEYTRUDA that is written for healthcare professionals. For more information, go to www.keytruda.com.

What are the ingredients in KEYTRUDA?

Active ingredient: pembrolizumab

Inactive ingredients:

KEYTRUDA injection: L-histidine, polysorbate 80, sucrose, and Water for Injection, USP.

Manufactured by: Merck Sharp & Dohme Corp., a subsidiary of
 **MERCK & CO., INC.**, Whitehouse Station, NJ 08889, USA

For KEYTRUDA injection, at:
MSD Ireland (Carlow), County Carlow, Ireland
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