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Pembrolizumab Injection

pronounced as (pem" broe liz' ue mab)

Why is this medication prescribed?

Pembrolizumab injection is used: Pembrolizumab injection is in a class of medications called monoclonal antibodies. It works by helping your immune system to slow or stop the growth of cancer cells.

- to treat melanoma (a type of skin cancer) that cannot be treated with surgery or has spread to other parts of the body, or in combination with other chemotherapy medications to treat and prevent the return of melanoma after surgery to remove it and any affected lymph nodes;
- to treat certain types of non-small-cell lung cancer (NSCLC) that cannot be treated with surgery, other chemotherapy medications, or radiation therapy or that has spread to other parts of the body or worsened during or after it was treated with platinum containing chemotherapy medications (cisplatin, carboplatin), or in combination with other chemotherapy medications (paclitaxel, pemetrexed) to treat certain types of NSCLC that has spread to other parts of the body;
- to treat a certain type of head and neck cancer that keeps coming back or has spread to other parts of the body and cannot be removed by surgery. It can also be used in combination with fluorouracil and a platinum containing chemotherapy medications (cisplatin, carboplatin) to treat a certain type of head and neck cancer that keeps coming back or has spread to other parts of the body and cannot be treated with surgery. Pembrolizumab is also used to treat a certain type of head and neck cancer that has worsened or spread to other parts of the body during or after treatment with chemotherapy medications;
- to treat a certain type of Hodgkin's lymphoma (Hodgkin's disease) in adults that did not get better with other chemotherapy treatments or got better but returned after treatment with other chemotherapy medications. It also is used to treat a certain type of Hodgkin's lymphoma (Hodgkin's disease) in children that did not get better with other chemotherapy treatments or got better but returned after being treated two or more times with other chemotherapy medications;
- to treat a certain type of primary mediastinal B-cell lymphoma (PMBCL; non-Hodgkin lymphoma) in children and adults that did not get better with other chemotherapy treatments or returned after being treated two or more times with other chemotherapy medications;
- to treat a certain type of urothelial cancer (cancer of the lining of the bladder and other parts of the urinary tract) that has spread to nearby tissues or other parts of the body in people who cannot receive platinum containing chemotherapy medications (cisplatin, carboplatin), or whose cancer worsened during or after it was treated with these chemotherapy medications;
- to treat a certain type of bladder cancer in people who did not get better with another medication (Bacillus Calmette-Guerin; BCG therapy) and who are unable to or who have decided not to be treated by surgery to remove the bladder;

- to treat certain types of colorectal cancer (cancer that begins in the large intestine) and certain types of solid tumors as a first treatment in children and adults that cannot be treated by surgery or that has spread to other parts of the body or in those that worsened after it was treated with other chemotherapy medications;
- alone to treat certain types of gastric cancer (cancer of the stomach) or cancer located in the area where the stomach meets the esophagus (the tube between the throat and stomach) that has returned or that has spread to other parts of the body during or after 2 or more chemotherapy treatments. Also used in combination with trastuzumab (Herceptin), a fluoropyrimidine chemotherapy medication (fluorouracil), and a platinum containing chemotherapy medication an initial treatment for a certain type of gastric cancer that cannot be treated with surgery or that has spread to other parts of the body;
- alone or in combination with a fluoropyrimidine chemotherapy medication and a platinum-containing chemotherapy medication to treat a certain type of esophageal cancer that has returned and has spread to nearby tissues or other parts of the body after treatment with one or more other chemotherapy medications and cannot be treated with surgery or radiation therapy;
- to treat certain types of cervical cancer (cancer that begins in the opening of the uterus [womb]) that has returned or has spread to other parts of the body during or after treatment with another chemotherapy medication; Also used in combination with chemotherapy (with or without bevacizumab [Avastin]) to treat a certain type of cervical cancer that is persistent or has returned or has spread to other parts of the body.
- to treat certain types of hepatocellular carcinoma (HCC; a type of liver cancer) in people who were previously treated unsuccessfully with sorafenib (Nexafar);
- to treat Merkel cell carcinoma (MCC; a type of skin cancer) in children and adults that has returned and spread to nearby tissues or other parts of the body;
- in combination with axitinib (Inlyta) or lenvatinib (Lenvima) to treat advanced renal cell carcinoma (RCC; a type of cancer that begins in the kidneys);
- in combination with lenvatinib (Lenvima) to treat a certain type of cancer of the endometrium (lining of the uterus) that has spread to other parts of the body or worsened during or after treatment with chemotherapy medications or that cannot be treated with surgery or radiation therapy;
- to treat certain types of solid tumors that has spread to other parts of the body or cannot be treated by surgery in adults and children who were previously treated unsuccessfully with another chemotherapy medication and do not have other satisfactory treatment options;
- to treat certain types of cutaneous squamous cell carcinoma (CSCC; skin cancer) that has returned or has spread to other parts of the body and cannot be treated with surgery or radiation therapy;
- and in combination with chemotherapy to treat a certain type of breast cancer that has returned to nearby tissues or has spread to other parts of the body and cannot be treated with surgery.

How should this medicine be used?

Pembrolizumab injection comes as a powder to be mixed with liquid and injected intravenously (into a vein) over 30 minutes by a doctor or nurse in a hospital or medical facility. It is usually injected once every 3 or 6 weeks for as long as your doctor recommends that you receive treatment.

Pembrolizumab injection may cause serious reactions during, or shortly after the infusion of the medication. If you experience any of the following symptoms, tell your doctor immediately: flushing, fever, chills, shaking, dizziness, feeling faint, shortness of breath, difficulty breathing, itching, rash, or hives.

Your doctor may delay or stop your treatment with pembrolizumab injection, or treat you with additional medications, depending on your response to the medication and any side effects that you experience. Talk to your doctor about how you are feeling during your treatment.

Your doctor or pharmacist will give you the manufacturer's patient information sheet (Medication Guide) when you begin treatment with pembrolizumab injection and each time you receive a dose. Read the information carefully and ask your doctor or pharmacist if you have any questions. You can also visit the Food and Drug Administration (FDA) website (<http://www.fda.gov/Drugs/DrugSafety/ucm085729.htm> [<http://www.fda.gov/Drugs/DrugSafety/ucm085729.htm>]) or the manufacturer's website to obtain the Medication Guide.

Other uses for this medicine

This medication may be prescribed for other uses; ask your doctor or pharmacist for more information.

What special precautions should I follow?

Before receiving pembrolizumab injection,

- tell your doctor and pharmacist if you are allergic to pembrolizumab, any other medications, or any of the ingredients in pembrolizumab injection. Ask your pharmacist or check the Medication Guide for a list of the ingredients.
- tell your doctor and pharmacist what other prescription and nonprescription medications, vitamins, nutritional supplements, and herbal products you are taking or plan to take. Your doctor may need to change the doses of your medications or monitor you carefully for side effects.
- tell your doctor if you have ever had an organ or bone marrow transplant and if you have or have ever had radiation therapy to your chest area; an autoimmune disease (condition in which the immune system attacks a healthy part of the body) such as Crohn's disease (condition in which the immune system attacks the lining of the digestive tract causing pain, diarrhea, weight loss, and fever), ulcerative colitis (condition which causes swelling and sores in the lining of the colon [large intestine] and rectum), or lupus (condition in which the immune system attacks many tissues and organs including the skin, joints, blood, and kidneys); diabetes; thyroid problems; any type of lung disease or breathing problems; any condition that affects your nervous system such as myasthenia gravis (a disorder of the nervous system that causes muscle weakness) or Guillain-Barré syndrome (weakness, tingling, and possible paralysis due to sudden nerve damage); or kidney or liver disease.
- tell your doctor if you are pregnant or plan to become pregnant. You will have to take a pregnancy test before starting treatment. You should not become pregnant while you are receiving pembrolizumab injection and for 4 months after your final dose. Talk to your doctor about birth control methods that will work for you. If you become pregnant while receiving pembrolizumab injection, call your doctor immediately. Pembrolizumab injection may harm the fetus.
- tell your doctor if you are breastfeeding or plan to breastfeed. Your doctor may tell you not to breastfeed while receiving pembrolizumab injection, and for 4 months after your final dose.

What special dietary instructions should I follow?

Unless your doctor tells you otherwise, continue your normal diet.

What side effects can this medication cause?

Pembrolizumab injection may cause side effects. Tell your doctor if any of these symptoms are severe or do not go away:

- joint or back pain
- swelling of body or face
- changes in skin color
- extreme tiredness or lack of energy
- nausea
- vomiting
- constipation

Some side effects can be serious. If you experience any of these symptoms, call your doctor immediately or get emergency medical treatment:

- blisters or peeling skin; skin redness; rash; or itching
- painful sores or ulcers in mouth, nose, throat, or genital area
- fever or flu-like symptoms
- shortness of breath
- swollen glands
- chest pain
- new or worsening cough
- diarrhea
- stools that are black, tarry, sticky, or contain blood or mucus
- severe abdominal pain
- severe nausea and vomiting
- increased or decreased appetite
- increased thirst
- pain in upper right part of the stomach
- yellowing of the skin or eyes
- easy bleeding or bruising
- fast heartbeat
- changes in weight (gain or loss)
- hair loss
- increased sweating
- feeling cold
- deepening of voice or hoarseness

- changes in mood or behavior
- decreased sex drive
- swelling in front of the neck (goiter)
- tingling and weakness in the feet, legs, hands, and arms
- stiff neck
- severe or persistent headache, muscle aches
- severe muscle weakness
- dizziness or lightheadedness
- fainting
- change in amount or color of urine
- pain or a burning sensation while urinating
- blood in urine
- swelling of feet, ankles, or lower legs
- changes in vision
- feeling confused

Pembrolizumab injection may cause other side effects. Call your doctor if you have any unusual problems while receiving this medication.

If you experience a serious side effect, you or your doctor may send a report to the Food and Drug Administration's (FDA) MedWatch Adverse Event Reporting program online (<http://www.fda.gov/Safety/MedWatch>) or by phone (1-800-332-1088).

In case of emergency/overdose

In case of overdose, call the poison control helpline at 1-800-222-1222. Information is also available online at <https://www.poisonhelp.org/help>. If the victim has collapsed, had a seizure, has trouble breathing, or can't be awakened, immediately call emergency services at 911.

What other information should I know?

Keep all appointments with your doctor and the laboratory. Your doctor will order certain lab tests to check your body's response to pembrolizumab injection. For some conditions, your doctor will order a lab test before you begin your treatment to see whether your cancer can be treated with pembrolizumab.

It is important for you to keep a written list of all of the prescription and nonprescription (over-the-counter) medicines you are taking, as well as any products such as vitamins, minerals, or other dietary supplements. You should bring this list with you each time you visit a doctor or if you are admitted to a hospital. It is also important information to carry with you in case of emergencies.

Brand names

- Keytruda®

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