

Cemiplimab-rwlc (Libtayo)

About This Drug

Cemiplimab-rwlc is used to treat cancer. It is given in the vein (IV).

Possible Side Effects

- Diarrhea (loose bowel movements)
- Tiredness
- Bone and muscle pain
- Rash

Note: Each of the side effects above was reported in 15% or greater of patients treated with cemiplimab-rwlc. Not all possible side effects are included above.

Warnings and Precautions

- This drug works with your immune system and can cause inflammation (swelling) in any of your organs and tissues and can change how they work. This may put you at risk for developing serious medical problems, which can be life-threatening. These side effects may require treatment with steroids at the discretion of your doctor.
- Inflammation of the lungs which can be life-threatening. You may have a dry cough or trouble breathing.
- Colitis which is swelling (inflammation) in the colon. You may have diarrhea (loose bowel movements), stomach cramping, and sometimes blood in the bowel movements
- Changes in your central nervous system can happen. The central nervous system is made up of your brain and spinal cord. You could feel extreme tiredness, agitation, confusion, hallucinations (see or hear things that are not there), trouble understanding or speaking, loss of control of your bowels or bladder, eyesight changes, numbness, or lack of strength to your arms, legs, face, or body, and coma. **If you start to have any of these symptoms let your doctor know right away.**
- Severe changes in your liver function, which can cause liver failure and be life-threatening.
- This drug may affect your hormone glands (thyroid, adrenals, pituitary, and pancreas).
- Blood sugar levels may change, and you may develop diabetes. If you already have diabetes, changes may need to be made to your diabetes medication.
- Changes in your kidney function
- Allergic skin reaction, which can be life-threatening. You may develop blisters on your skin that are filled with fluid or a severe red rash all over your body that may be painful.

- While you are getting this drug in your vein (IV), you may have a reaction to the drug. Sometimes you may be given medication to stop or lessen these side effects. Your nurse will check you closely for these signs: fever or shaking chills, flushing, facial swelling, feeling dizzy, headache, trouble breathing, rash, itching, chest tightness, or chest pain. These reactions may happen after your infusion. **If this happens, call 911 for emergency care.**
- Increased risk of serious complications which can be life-threatening such as graft versus host disease (GVHD) in patients who undergo a stem cell transplant before or after receiving cemiplimab-rwlc.
- Increased risk of organ rejection in patients who have received donor organs

Note: Some of the side effects above are very rare. If you have concerns and/or questions, please discuss them with your medical team.

Important Information

- This drug may be present in the saliva, tears, sweat, urine, stool, vomit, semen, and vaginal secretions. Talk to your doctor and/or your nurse about the necessary precautions to take during this time.

Treating Side Effects

- Manage tiredness by pacing your activities for the day.
- Be sure to include periods of rest between energy-draining activities.
- To help decrease the risk of bleeding, use a soft toothbrush. Check with your nurse before using dental floss.
- Be very careful when using knives or tools.
- Use an electric shaver instead of a razor.
- Drink plenty of fluids (a minimum of eight glasses per day is recommended).
- To help with nausea, eat small, frequent meals instead of three large meals a day. Choose foods and drinks that are at room temperature.
- If you have diarrhea, eat low-fiber foods that are high in protein and calories, and avoid foods that can irritate your digestive tracts or lead to cramping. You should also drink more fluids so that you do not become dehydrated (lack of water in the body from losing too much fluid).
- Ask your doctor or nurse about medicine that is available to help stop or lessen diarrhea and/or nausea.
- If you have diabetes, keep good control of your blood sugar level. Tell your nurse or your doctor if your glucose levels are higher or lower than normal.
- Keeping your pain under control is important to your well-being. Please tell your doctor or nurse if you are experiencing pain.
- If you get a rash do not put anything on it unless your doctor or nurse says you may. Keep the area around the rash clean and dry. Ask your doctor for medicine if your rash bothers you.
- If you have numbness and tingling in your hands and feet, be careful when cooking, walking, and handling sharp objects and hot liquids.



- Infusion reactions may happen after your infusion. **If this happens, call 911 for emergency care.**

Food and Drug Interactions

- There are no known interactions of cemiplimab-rwlc with food.
- This drug may interact with other medicines. Tell your doctor and pharmacist about all the prescription and over-the-counter medicines and dietary supplements (vitamins, minerals, herbs, and others) that you are taking at this time. Also, check with your doctor or pharmacist before starting any new prescription or over-the-counter medicines, or dietary supplements to make sure that there are no interactions.

When to Call the Doctor

Not all possible side effects are included. Some of these side effects, although rare, can be life-threatening.

Lung problems:

- Inflammation of the lungs
- Cough
- Trouble breathing
- Upper respiratory tract infection

Call your doctor or nurse if you have any of these symptoms:

- Wheezing or trouble breathing
- New or worsening cough
- Coughing up yellow, green, or bloody mucus
- Chest pain

Stomach problems:

- Decreased appetite (decreased hunger)
- Nausea and vomiting (throwing up)
- Diarrhea (loose bowel movements)
- Constipation (unable to move bowels)
- Pain in your abdomen
- Inflammation of your colon



- Blood in your stool

Call your doctor or nurse if you have any of these symptoms:

- Nausea that stops you from eating or drinking or is not relieved by prescribed medicine
- Throwing up more than 3 times a day
- Lasting loss of appetite or rapid weight loss of five pounds in a week
- Diarrhea, 4 times in one day or diarrhea with lack of strength or a feeling of being dizzy
- No bowel movement for 3 days or when you feel uncomfortable
- Pain in your abdomen that does not go away
- Blood in your stool (bright red, or black/tarry)

Liver problems:

- Changes in your liver function

Call your doctor or nurse if you have any of these symptoms:

- Yellowing of the eyes or skin
- Dark urine
- Pale bowel movements
- Pain on the right side of your abdomen that does not go away
- Feeling very tired and weak
- Unusual itching
- Easy bleeding or bruising

Hormone gland problems:

- Changes in some of your hormone glands (especially the thyroid, adrenals, pituitary, and pancreas)
- Blood sugar levels may change, and you may develop diabetes

Call your doctor or nurse if you have any of these symptoms:

- Headache that does not go away
- Tiredness that interferes with your daily activities
- Feeling dizzy or lightheaded
- Changes in mood or behavior such as irritability and/or feeling forgetful



- Shakiness
- Weight loss or weight gain
- Nausea
- Abnormal blood sugar
- Unusual thirst or passing urine often
- Feeling cold

Kidney problems:

- Changes in your kidney function
- Urinary tract infection

Call your doctor or nurse if you have any of these symptoms:

- Decreased or very dark urine
- Cloudy urine and/or urine that smells bad
- Difficulty urinating
- Pain or burning when you pass urine
- Feeling like you have to pass urine often, but not much comes out when you do
- Tender or heavy feeling in your lower abdomen
- Pain on one side of your back under your ribs

Skin problems:

- Rash and itching
- Soreness of the mouth and throat
- Allergic skin reaction

Call your doctor or nurse if you have any of these symptoms:

- New rash and/or itching
- Fluid-filled bumps/blisters
- Rash that is not relieved by prescribed medicines
- Red areas, white patches, or sores in your mouth that hurt

Inflammation of the brain:

- Changes in your brain and spinal cord
- Headache
- Effects on the nerves

Call your doctor or nurse if you have any of these symptoms:

- Headache that does not go away
- Extreme tiredness, agitation, or confusion
- Seizures
- Hallucinations
- Trouble understanding or speaking
- Loss of control of bowels or bladder
- Numbness or lack of strength to your arms, legs, face, or body
- Numbness, tingling, pins, and needles, or pain in your arms, hands, legs, or feet

Other problems:

- Low red blood cells, and platelets
- Fever
- Inflammation of your eye and/or other changes in vision
- Allergic reaction to the drug
- Heart problems
- Electrolyte changes
- Muscle, bone, and joint pain

Call your doctor or nurse if you have any of these symptoms:

- Fever of 100.4° F (38° C) or higher
- Chills, flushing
- Easy bleeding or bruising
- Blurred vision or other changes in eyesight
- Sensitivity to light
- Feeling that your heart is beating fast or in a not normal way (palpitations)
- Signs of infusion reaction: fever or shaking chills, flushing, facial swelling, feeling dizzy, headache, trouble breathing, rash, itching, chest tightness, or chest pain. **If this happens, call 911 for emergency care.**
- Pain that does not go away, or is not relieved by prescribed medicines



- Extreme muscle weakness

Reproduction Warnings

- **Pregnancy warning:** This drug can have harmful effects on the unborn baby. Women of childbearing potential should use effective methods of birth control during your cancer treatment and for at least 4 months after stopping treatment. Let your doctor know right away if you think you may be pregnant.
- **Breastfeeding warning:** Women should not breastfeed during treatment and for at least 4 months after stopping treatment because this drug could enter the breast milk and cause harm to a breastfeeding baby.
- **Fertility warning:** Fertility studies have not been done with this drug. Talk with your doctor or nurse if you plan to have children. Ask for information on sperm or egg banking.

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