

## Cosibelimab-ipdl (Unloxcyt)

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### About This Medicine

COSIBELIMAB-IPDL (koe si BEL i mab) treats skin cancer. It works by helping your immune system slow or stop the spread of cancer cells. It is a monoclonal antibody. It is given in the vein (IV).

This medicine may be used for other purposes; ask your care team if you have questions.

### Possible Side Effects

- Nausea
- Constipation (not able to move bowels)
- Diarrhea (loose bowel movements)
- Swelling of the hands, feet, or any other part of the body
- Infection
- Urinary tract infection
- Tiredness
- Changes in your thyroid function
- Muscle and bone pain
- Headache
- Rash
- Itching

**Note:** Each of the side effects above was reported in 10% or greater of people treated with cosibelimab-ipdl. All possible side effects are not included. Your side effects may be different depending on your cancer diagnosis, condition, or if you are receiving other medicines in combination. Please discuss any concerns or questions with your care team.

### Warnings and Precautions

- This medicine 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 care team.
- Inflammation of the lungs, which can be life-threatening. You may have a dry cough or trouble breathing.

- Colitis- inflammation in the colon. The symptoms are diarrhea, 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 care team know right away.**
- Severe changes in your liver function which can cause liver failure and be life-threatening.
- This medicine may affect your hormone glands (especially the 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 medicine.
- Changes in your kidney function
- Inflammation in the tissue of the heart
- 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 medicine in your vein (IV), you may have a reaction to the medicine. Sometimes you may be given medicine to stop or lessen these side effects. Your care team 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 people who undergo a stem cell transplant before or after receiving cosibelimab-ipdl.
- Increased risk of organ rejection in people 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 care team.

## Important Information

- This medicine may be present in the urine, stool and other body fluids such as blood, vomit, semen, and vaginal fluids. Take precautions to prevent others from coming in contact with your medicine or your body fluids. Follow safety precautions during your treatment and for as long as directed by your care team after your treatment. If you take a pill each day, follow these precautions every day.

## Treating Side Effects

- Drink enough fluids to keep your urine pale yellow.
- If you throw up or have diarrhea, you should drink more fluids so that you do not become dehydrated (lack of water in the body from losing too much fluid).
- To help with nausea and vomiting, eat small, frequent meals instead of three large meals a day. Choose foods and drinks that are at room temperature. Ask your care team about other helpful tips and medicine that is available to help stop or lessen these symptoms.



- 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.
- If you are not able to move your bowels, check with your care team before you use enemas, laxatives, or suppositories.
- Ask your care team about medicine that is available to help stop or lessen diarrhea and/or constipation.
- Manage tiredness by pacing your activities for the day.
- Be sure to include periods of rest between energy-draining activities.
- To decrease the risk of infection, wash your hands regularly.
- Avoid close contact with people who have a cold, the flu, or other infections.
- Take your temperature as your doctor or care team tells you, and whenever you feel like you may have a fever.
- Get regular exercise, with your care team's approval. If you feel too tired to exercise vigorously, try taking a short walk.
- 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.
- If you have numbness and tingling in your hands and feet, be careful when cooking, walking, and handling sharp objects and hot liquids.
- If you get a rash do not put anything on it unless your care team says you may. Keep the area around the rash clean and dry. Ask your care team for medicine if your rash bothers you.
- To help with itching, moisturize your skin several times a day.
- Avoid sun exposure and apply sunscreen routinely when outdoors.
- Infusion reactions may occur after your infusion. **If this happens, call 911 for emergency care.**
- Keeping your pain under control is important to your well-being. Please tell your care team if you are experiencing pain.

## Food and Medicine Interactions

- There are no known interactions of cosibelimab-ipdl with food.
- This medicine may interact with other medicines. Tell your care team 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 care team before starting any new prescription or over-the-counter medicines, or dietary supplements to make sure that there are no interactions.

## When to Call Your Care Team

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 respiration tract infection

**Call your care team 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
- Constipation
- Pain in your abdomen
- Inflammation of your colon
- Blood in your stool

**Call your care team 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 care team 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 care team 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 care team if you have any of these symptoms:**

- Decreased urine, or very dark urine
- Cloudy urine and/or urine that smells bad
- Trouble 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 care team 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
- Flu-like symptoms: fever, headache, muscle and joint aches, and tiredness

**Inflammation of the brain:**

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

**Call your care team 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 medicine
- Heart problems
- Electrolyte changes
- Muscle, bone, and joint pain

**Call your care team 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
- Weight gain of 5 pounds in one week (fluid retention)
- Swelling of the hands, feet, or any other part of the body

## Reproduction Warnings

- **Pregnancy warning:** This medicine can cause serious birth defects. If you can become pregnant, use birth control while taking this medicine and for 4 months after the last dose. Tell your care team right away if you think you might be pregnant.
- **Breastfeeding warning:** Do not breastfeed while taking this medicine and for 4 months after the last dose.
- **Fertility warning:** The effect of this medicine on fertility is not known. If you plan to have children, talk with your care team

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