

MEDICATION GUIDE
UNLOXYCT (un-LOX-sit)
(cosibelimab-ipdl)
injection

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

UNLOXYCT is a medicine that may treat a type of skin cancer by working with your immune system. UNLOXYCT 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. You can have more than one of these problems at the same time. These problems may happen anytime during treatment or even after your treatment has ended.

Call or see your healthcare provider right away if you develop any new or worsening signs or symptoms, including:

Lung problems.

- cough
- chest pain
- shortness of breath

Intestinal problems.

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

Liver problems.

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

Hormone gland problems.

- headache that will not go away or unusual headaches
- eye sensitivity to light
- eye problems
- rapid heartbeat
- increased sweating
- extreme tiredness
- weight gain or weight loss
- feeling more hungry or thirsty than usual
- urinating more often than usual
- hair loss
- feeling cold
- constipation
- your voice gets deeper
- dizziness or fainting
- changes in mood or behavior, such as decreased sex drive, irritability, or forgetfulness

Kidney problems:

- decrease in your amount urine
- blood in your urine
- swelling of your ankles
- loss of appetite

Skin problems.

- rash
- itching
- fever or flu-like symptoms
- skin blistering or peeling
- painful sores or ulcers in mouth or nose, throat, or genital area
- swollen lymph nodes

Problems can also happen in other organs and tissues. These are not all of the signs and symptoms of immune system problems that can happen with UNLOXYCT. Call or see your healthcare provider right way for any new or worsening signs or symptoms which may include:

- chest pain, irregular heartbeat, shortness of breath or swelling of ankles
- confusion, sleepiness, memory problems, changes in mood or behavior, stiff neck, balance problems, tingling or numbness of the arms or legs
- double vision, blurry vision, sensitivity to light, eye pain, changes in eyesight
- persistent or severe muscle pain or weakness, muscle cramps
- low red blood cells, bruising

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

- nausea
- chills or shaking
- itching or rash
- flushing
- shortness of breath or wheezing
- dizziness
- feel like passing out
- fever
- back or neck pain

Rejection of a transplanted organ. Your healthcare provider 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 serious and can lead to death. These complications may happen if you underwent transplantation either before or after being treated with UNLOXYCT. Your healthcare provider will monitor you for these complications.

Getting medical treatment right away may help keep these problems from becoming more serious. Your healthcare provider will check you for these problems during your treatment with UNLOXYCT. Your healthcare provider may treat you with corticosteroid or hormone replacement medicines. Your healthcare provider may also need to delay or completely stop treatment with UNLOXYCT if you have severe side effects.

What is UNLOXYCT?

UNLOXYCT is a prescription medicine used to treat adults with a type of skin cancer called cutaneous squamous cell carcinoma (CSCC). UNLOXYCT may be used to treat CSCC that has spread or cannot be cured by surgery or radiation.

It is not known if UNLOXYCT is safe and effective in children.

Before you receive UNLOXYCT, tell your healthcare provider about all your medical conditions, including if you:

- have immune system problems such as Crohn's disease, ulcerative colitis, or lupus
- have received an organ transplant, including corneal transplant.
- have received or plan to receive a stem cell transplant that uses donor stem cells (allogeneic)
- have received radiation treatment to your chest area
- have a condition that affects your nervous system, such as myasthenia gravis or Guillain-Barré syndrome.
- are pregnant or plan to become pregnant. UNLOXYCT can harm your unborn baby.

Females who are able to become pregnant:

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

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

How will I receive UNLOXYCT?

- Your healthcare provider will give you UNLOXYCT into your vein through an intravenous (IV) line over 60 minutes.
- UNLOXYCT is usually given every 3 weeks.
- Your healthcare provider will decide how many treatments you will need.
- Your healthcare provider will do blood tests to check you for side effects.
- If you miss any appointments, call your healthcare provider as soon as possible to reschedule your appointment.

What are the possible side effects of UNLOXYCT?

UNLOXYCT can cause serious side effects.

- See “**What is the most important information I should know about UNLOXYCT?**”

The most common side effects of UNLOXYCT include tiredness or weakness, muscle or bone pain, rash, diarrhea, low thyroid hormone levels (hypothyroidism), constipation, nausea, headache, itchy skin, swelling, infection, and urinary tract infection.

These are not all the possible side effects of UNLOXYCT.

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 UNLOXYCT.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. If you would like more information about UNLOXYCT, talk with your healthcare provider. You can ask your healthcare provider for information about UNLOXYCT that is written for healthcare professionals.

What are the ingredients of UNLOXYCT?

Active Ingredient: cosibelimab-ipdl

Inactive ingredients: acetic acid, mannitol, polysorbate 80, sodium acetate, sodium chloride, and Water for Injection.

Manufactured for:

Checkpoint Therapeutics, Inc.

Waltham, MA, 02453

U.S. License No 2275, Product of Korea

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Sun Pharmaceutical Industries, Inc.

Cranbury, NJ 08512

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