

Medication Guide
LOQTORZI (lok tor zee)
(toripalimab-tpzi)
injection

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

LOQTORZI is a medicine that may treat nasopharyngeal cancer by working with your immune system. LOQTORZI 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 treatment has ended.

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

Lung problems

- cough
- shortness of breath
- chest pain

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 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

- headaches 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
- change in mood or behavior, such as decreased sex drive, irritability, or forgetfulness

Kidney problems

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

Skin problems

- rash
- itching
- skin blistering or peeling
- painful sores or ulcers in your mouth or in your nose, throat, or genital area
- fever or flu-like symptoms
- 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 LOQTORZI. Call or see your healthcare provider right away for any new or worsening signs or symptoms, which may include:

- chest pain, irregular heartbeat, shortness of breath, 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 or symptoms of infusion reactions may include:

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

Rejection of a transplanted organ. Your healthcare provider should tell you what signs and symptoms you should report and monitor, 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 LOQTORZI. 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 treatment with LOQTORZI. 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 LOQTORZI if you have severe side effects.

What is LOQTORZI?

LOQTORZI is a prescription medicine used to treat adults with a kind of cancer called nasopharyngeal carcinoma (NPC).

- LOQTORZI may be used in combination with the chemotherapy medicines cisplatin and gemcitabine, as your first treatment when your NPC has spread to other parts of your body (metastatic) or has returned (recurrent) in nearby tissues (locally advanced).
- LOQTORZI may be used alone to treat your NPC when it:
 - has returned and cannot be removed with surgery **or**
 - has spread (metastatic), **and**
 - you received chemotherapy that contains platinum, and it did not work or is no longer working.

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

Before receiving LOQTORZI, tell your healthcare provider about all of your medical conditions, including if you:

- have immune system problems such as Crohn's disease, ulcerative colitis, or lupus
- have received an organ 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 had a condition that affects your nervous system, such as myasthenia gravis or Guillain-Barré syndrome
- are pregnant or plan to become pregnant. LOQTORZI can harm your unborn baby.

Females who are able to become pregnant:

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

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 LOQTORZI?

- Your healthcare provider will give you LOQTORZI into your vein through an intravenous (IV) line over 30 or 60 minutes.
- LOQTORZI is usually given every two or three weeks as an intravenous (IV) infusion.
- Your healthcare provider will decide how many treatments you need.
- Your healthcare provider will test your blood to check you for certain side effects.
- If you miss any appointments, call your healthcare provider as soon as possible to reschedule.

What are the possible side effects of LOQTORZI?

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

Common side effects of LOQTORZI when used with cisplatin and gemcitabine include:

- nausea
- vomiting
- decreased appetite
- constipation
- low levels of thyroid hormone
- rash
- fever
- diarrhea
- burning or feeling of pins and needles in feet and toes
- cough
- muscle and bone pain
- upper respiratory infection
- sleep problems
- dizziness
- feeling generally unwell

Common side effects of LOQTORZI when used alone include:

- tiredness
- low levels of thyroid hormone
- muscle and bone pain

These are not all the possible side effects of LOQTORZI.

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 LOQTORZI.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. You can ask your pharmacist or healthcare provider for information about LOQTORZI that is written for health professionals.

What are the ingredients in LOQTORZI?

Active ingredient: toripalimab-tpzi

Inactive ingredients: citric acid monohydrate, mannitol, polysorbate 80, sodium chloride, sodium citrate, and Water for Injection.

Manufactured and Distributed by: Coherus BioSciences, Inc. 333 Twin Dolphin Drive, Suite 600 Redwood City, CA 94065, USA

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For more information, call 1-800-483-3692 or go to www.coherus.com

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