

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

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

LOQTORZI is a medicine that may treat your 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 they may sometimes be delayed and develop weeks or months after your treatment has ended.

Your doctor will monitor you for these problems during treatment with LOQTORZI. Your doctor may give you other medicines in order to keep these problems from becoming more serious, delay the next dose of LOQTORZI, or stop your treatment with LOQTORZI.

Getting medical treatment right away may help keep these problems from becoming more serious. Do not attempt to diagnose or treat these problems yourself without consulting a healthcare professional first.

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

Chest problems (lung or heart)

- cough
- chest pain
- shortness of breath
- irregular heartbeat

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 (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-(abdomen)
- dark urine (tea colored)
- bleeding or bruising more easily than normal

Hormone gland problems, including diabetes

- 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

Muscle problems

- persistent or severe muscle pain or weakness, muscle cramps

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 doctor right away for any new or worsening signs or symptoms, which may include:

- 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
- bruising

Infusion reactions. Signs or symptoms of infusion reactions may include:

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

Rejection of a transplanted organ. Your doctor 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 doctor will monitor you for these complications.

What is LOQTORZI?

LOQTORZI is a prescription medicine used to treat adults with two types of cancer: nasopharyngeal carcinoma (NPC) and oesophageal squamous cell cancer (OSCC).

- 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) and cannot be treated with surgery or more radiation.
- LOQTORZI may be used in combination with the chemotherapy medicines cisplatin and paclitaxel, as your first treatment when your OSCC has spread to other parts of your body (metastatic) or has returned (recurrent) and cannot be treated with surgery or more radiation.

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

Before receiving LOQTORZI, tell your doctor 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 had a condition that affects your nervous system, such as myasthenia gravis
- are pregnant or plan to become pregnant. LOQTORZI can harm your unborn baby.

Females who are able to become pregnant:

- 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 doctor about birth control methods that you can use during this time.
- Tell your doctor 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 doctor about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

How will I receive LOQTORZI?

- Your doctor will give you LOQTORZI into your vein through an intravenous (IV) line over 30 or 60 minutes.
- LOQTORZI is usually given every three weeks as an intravenous (IV) infusion.
- Your doctor will decide how many treatments you need.
- Your doctor will test your blood to check you for certain side effects.
- If you miss any appointments, call your doctor 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
- diarrhea
- burning or feeling of pins and needles in feet and toes

- decreased appetite
- constipation
- low levels of thyroid hormone
- rash
- fever
- cough
- muscle and bone pain
- upper respiratory infection
- sleep problems
- dizziness
- feeling generally unwell

These are not all the possible side effects of LOQTORZI.

For more information on LOQTORZI, consult your doctor.

What are the ingredients in LOQTORZI?

Active ingredient: toripalimab

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

For more information, consult your doctor.