Package leaflet: Information for the patient

LOQTORZI 240 mg concentrate for solution for infusion
toripalimab

▼This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

Read all of this leaflet carefully before you are given this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- It is important that you keep the patient alert card with you during treatment.
- If you have any further questions, ask your doctor.
- If you get any side effects, talk to your doctor. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What LOQTORZI is and what it is used for
2. What you need to know before you are given LOQTORZI
3. How you are given LOQTORZI
4. Possible side effects
5. How to store LOQTORZI
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1. What LOQTORZI is and what it is used for

LOQTORZI contains the active substance toripalimab, which is a monoclonal antibody, a type of protein designed to recognise and attach to a specific target substance in the body.

LOQTORZI is used in adults to treat:
- a type of head and neck cancer called nasopharyngeal cancer that starts at the upper part of the throat behind the nose and near the base of the skull. It is used when the cancer has spread to other parts of the body, or has come back after previous treatment and cannot be removed by surgery.
- a type of oesophageal (gullet) cancer called oesophageal squamous cell cancer. It is used when the cancer cannot be removed by surgery, has come back after previous treatment or has spread to other parts of the body.

LOQTORZI is given in combination with other anti-cancer medicines. It is important that you also read the package leaflets for these medicines. If you have any questions about LOQTORZI or these other medicines, please ask your doctor.

The active substance in LOQTORZI, toripalimab, works by attaching to a target protein called programmed death-1 receptor (PD-1). PD-1 can switch off the activity of T cells (a type of white blood cell that forms part of the immune system, the body's natural defences), which prevents your immune system from fighting the cancer. By attaching to PD-1, toripalimab blocks its action and prevents it from switching off your T cells. This helps increase their activity against the cancer.

2. What you need to know before you are given LOQTORZI

You must not be given LOQTORZI

- if you are allergic to toripalimab or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions
Talk to your doctor or nurse before receiving LOQTORZI if you:
- have an autoimmune disease (an illness where the body attacks its own cells)
- have lung problems or breathing problems (called pneumonitis)
- have been told that your cancer has spread to your brain
- have active viral infection of the liver, including hepatitis B (HBV) or hepatitis C (HCV)
- have active tuberculosis (TB)
- have human immunodeficiency virus (HIV) infection or acquired immune deficiency syndrome (AIDS)
- have liver damage
- have kidney damage
- have had a solid organ transplant or a bone marrow (stem cell) transplant that used donor stem cells (allogeneic)
- are currently taking medicines to suppress your immune system. Examples of these may include corticosteroids, such as prednisone.

LOQTORZI acts on your immune system. It may cause inflammation in parts of your body. Your risk of these side effects may be higher if you already have an autoimmune disease (a condition where the body attacks its own cells). You may also experience frequent flares of your autoimmune disease, which in the majority of cases are mild.

If any of the above apply to you (or you are not sure), talk to your doctor before you are given LOQTORZI.

When you get LOQTORZI, you may develop some serious side effects. These side effects can be life-threatening and may happen anytime during treatment or even after your treatment has ended. You may experience more than one side effect at the same time.

If you have any of the following conditions, call or see your doctor immediately:

- inflammation of the lungs (pneumonitis), which may include symptoms of shortness of breath, chest pain or coughing.
- Inflammation of the large bowel (colitis), which may include symptoms of diarrhoea or more bowel movements than usual, black, tarry, sticky stools or stools with blood or mucus, severe stomach pain or tenderness.
- inflammation of the liver (hepatitis), which may include symptoms of nausea or vomiting, feeling less hungry, pain on the right side of stomach, yellowing of skin or whites of eyes, dark urine or bleeding or bruising more easily than normal.
- inflammation of hormone glands (especially the thyroid, pituitary and adrenal glands), which may include symptoms of rapid heartbeat, weight loss, increased sweating, weight gain, hair loss, feeling cold, constipation, deeper voice, muscle aches, dizziness or fainting, headaches that will not go away or unusual headache.
- type 1 diabetes, including diabetic ketoacidosis (acid in the blood produced from diabetes), which may include symptoms of feeling more hungry or thirsty than usual, need to urinate more often or weight loss, feeling tired or feeling sick, stomach pain, fast and deep breathing, confusion, unusual sleepiness, a sweet smell to your breath, a sweet or metallic taste in your mouth, or a different odour to your urine or sweat.
- inflammation of the kidneys (nephritis), which may include symptoms of changes in the amount or colour of your urine.
- inflammation of the skin, which may include symptoms of rash, itching, skin blistering, peeling or sores, and/or ulcers in mouth or in lining of nose, throat, or genital area
- inflammation of the heart muscle (myocarditis), which may include symptoms of shortness of breath, irregular heartbeat, feeling tired, or chest pain.

- inflammation in the muscles (myositis), which may include symptoms of muscle pain or weakness.
- inflammation of the uvea, the layer beneath the white of the eyeball (uveitis), which may include change in eyesight.
- inflammation of the pancreas (pancreatitis), which may include symptoms of abdominal pain, nausea and vomiting.
- inflammation of bladder (cystitis), which may include symptoms of painful urination and blood in the urine.
- inflammation of the joints (arthritis/arthralgia), which may include symptoms of painful, red, or swollen joints or permanent damage to the joints
- infusion reactions, which may include symptoms of fever, chills, itching or rash, nausea and low blood pressure.
- problems in other parts of the body (see section 4 'Possible side effects')

Your doctor may give you other medicines in order to prevent more severe complications and reduce your symptoms, withhold the next dose of LOQTORZI or stop your treatment with LOQTORZI. Please note that these signs and symptoms are sometimes delayed, and may develop weeks or months after your last dose. Before treatment, your doctor will check your general health. You will also have blood tests during your treatment.

Rejection of solid organ transplants (such as kidney, lung, heart or liver transplants) in patients who received such transplants or complications, including graft-versus-host-disease (GVHD), in people with bone marrow (stem cell) transplant that uses donor stem cells (allogeneic) may occur with use of LOQTORZI. These complications can be severe and can lead to death. They may occur if you had this kind of transplant in the past or if you get it in the future. Your doctor will monitor you for signs and symptoms of these complications, which may include skin rash, liver inflammation, abdominal pain, or diarrhoea.

Children and adolescents
LOQTORZI should not be used in children and adolescents below 18 years of age because it was not studied in patients less than 18 years of age.

Other medicines and LOQTORZI
Tell your doctor or nurse
- If you are taking medicines that suppress your immune system, such as corticosteroids (like prednisone). These medicines may interfere with the effect of LOQTORZI.
  However, once you are treated with LOQTORZI, your doctor may give you corticosteroids to reduce the side-effects that you may have with LOQTORZI. Corticosteroids may also be given to you before receiving LOQTORZI in combination with chemotherapy to prevent and/or treat nausea, vomiting, and other side effects caused by chemotherapy.
- If you are taking, have recently taken or might take any other medicines. Do not take any other medicines during your treatment without talking to your doctor first.

Pregnancy
- You must not be given LOQTORZI if you are pregnant unless your doctor specifically recommends it.
- If you are pregnant, think you may be pregnant or are planning to have a baby, ask your doctor for advice before you are given this medicine.
- LOQTORZI can cause harmful effects or death to your unborn baby.
- If you are a woman who could become pregnant, you must use effective contraception while you are being treated with LOQTORZI and for at least 4 months after your last dose.

Breast-feeding
- If you are breast-feeding, ask your doctor for advice before you are given this medicine.
- You must not breast-feed during treatment and for at least 4 months after your last dose of LOQTORZI.

- It is not known if LOQTORZI passes into your breast milk.

Driving and using machines
LOQTORZI may have a minor effect on your ability to drive or use machines, as feeling dizzy or tired are possible side effects. Do not drive or use machines unless you are sure you are feeling well.

LOQTORZI contains sodium
This medicine contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially 'sodium-free'. However, before LOQTORZI is given to you, it is mixed with a solution that contains sodium. Talk to your doctor if you are on a low salt diet.

LOQTORZI contains polysorbate 80
This medicine contains 1.2 mg of polysorbate 80 in each 6 ml vial which is equivalent to 0.2 mg/ml. Polysorbates may cause allergic reactions. Tell your doctor if you have any known allergies.

3. How LOQTORZI is given

LOQTORZI will be given to you in a hospital or clinic under the supervision of a doctor experienced in cancer treatment.

The recommended dose is 240 mg every 3 weeks. This will be given to you by your doctor as an infusion (drip) into a vein. The infusion will take about 60 minutes the first time. This may be lowered to about 30 minutes for subsequent doses.

Your doctor will decide how many treatments you need.

LOQTORZI is given in combination with other anti-cancer medicines. You will be given LOQTORZI first, followed by the other medicines.

If you forget an appointment to receive LOQTORZI
Contact your doctor or hospital immediately to reschedule your appointment. It is very important that you do not miss a dose of this medicine.

If you stop receiving LOQTORZI
Stopping your treatment may stop the effect of the medicine. Do not stop treatment with LOQTORZI unless you have discussed this with your doctor.

If you have any further questions on the use of this medicine, ask your doctor or nurse.

Patient alert card
Important information from this package leaflet can be found in the patient alert card you have been given by your doctor. It is important that you keep this patient alert card and show it to your partner or caregivers.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Serious side effects that can result in hospitalization or death are listed below by frequency.

Uncommon (may affect up to 1 in 100 people)
- Inflammation of lungs (pneumonitis)
- Inflammation of the skin (immune-related skin reactions)
- Inflammation of the liver (hepatitis)
- Inflammation of the heart muscle (myocarditis)

- Inflammation in the muscles (myositis)
- Inflammation of the large bowel (colitis)
- Inflammation of adrenal glands (adrenal insufficiency)
- Inflammation of the kidneys (nephritis)
- Decreased in number of platelet (immune mediated thrombocytopenia)
- Inflammation of thyroid (hyperthyroidism/thyroiditis)
- Inflammation of thyroid gland (hypothyroidism)
- Inflammation of insulin-producing cells (diabetes mellitus/ hyperglycaemia)
- Inflammation of pituitary gland (hypophysitis)
- Infusion reactions

Rare (may affect up to 1 in 1 000 people)
- Inflammation of the pancreas (pancreatitis)
- Inflammation of bladder (cystitis)
- Inflammation of the joints (arthritis/arthralgia)

Problems in other parts of the body/Other immune-related side effects (frequency cannot be estimated from the available toripalimab data but have been reported with this class of medicines)
- Inflammation of the brain (encephalitis) which may include symptoms of confusion, fever, memory problems or seizure.
- Myasthenic syndrome, a condition in which the muscles become weak and there is a rapid fatigue of the muscles
- Inflammation of the nerves, including Guillain Barré syndrome: symptoms may include weakness in the arm and leg muscles, or face muscles, double vision, and tingling in hands and feet
- Rhabdomyolysis, symptoms may include stiffness in muscles and joints, muscle spasm.
- Organ transplant rejection
- Inflammation of the uvea (uveitis)

If you experience any of these serious side effects, seek urgent medical attention or contact your healthcare provider immediately.

The following side effects have been reported in clinical studies with toripalimab:

Very common (may affect more than 1 in 10 people)
- decreased appetite;
- weight loss
- fatigue (feeling tired);
- pyrexia (fever);
- cough
- abdominal pain (pain in the belly)
- pain
- nausea (feeling sick)
- vomiting
- diarrhoea/ colitis (inflammation in the large bowel)
- constipation
- neuropathy (nerve damage)
- anaemia (low levels of red blood cells)
- thrombocytopenia (low levels of blood platelets, components which help the blood to clot)
- leucopenia (low levels of white blood cells)
- neutropenia (low levels of neutrophils, a type of white blood cell)
- upper respiratory tract infection (nose and throat infection)
- hyponatraemia (low blood sodium levels)
- hypoproteinaemia (low blood protein levels)

- hypokalaemia (low blood potassium levels which can cause weakness, muscle cramps, tingling and heart rhythm disturbance)
- hyperglycaemia (high blood glucose levels)
- hyperuricaemia (high blood levels of uric acid, a byproduct of metabolism)
- hyperbilirubinaemia (high blood levels of bilirubin, a breakdown product of red blood cells, which can cause yellowing of the skin and eyes)
- proteinuria (excess protein in the urine)
- haematuria (blood in the urine)
- rash including skin inflammation, itching, skin blistering, peeling or sores, acne-like skin problem
- pruritis (itching)
- musculoskeletal (muscle and bone) pain
- hypothyroidism (an underactive thyroid gland with tiredness, weight gain, and skin and hair changes)
- arrhythmia (abnormal or irregular heartbeat)
- abnormal results for tests of liver function
- abnormal results for tests of thyroid function
- abnormal results for tests of blood levels of lipids
- abnormal results for tests of urine analysis

Common (may affect up to 1 in 10 people)
- vomiting; bloating and distended belly; acid reflux; blood in the stool;
- decrease in flow of bowel content or bowel occlusion
- sores or burning sensation in the mouth, gums, throat or oesophagus; dry mouth; toothache
- overactive thyroid gland activity;
- chills; influenza like illness
- pain (in muscle, bones, lymph nodes, chest)
- eye disorder (dry or itchy eye, cataract)
- kidney damage
- shortness of breath; inflammation of the lungs, fluid around the lungs; nose bleeding, coughing up blood, upper respiratory tract congestion or irritation
- decrease in the number of platelets (bruising or bleeding more easily)
- trouble sleeping; change in mood
- night sweats; increased sweating
- inflammation of the nerves causing numbness, weakness, tingling or burning pain; headache; dizziness
- lung infection, urinary infection, infection (unknown type or location), ear infections, fungal infection of the mouth, herpes virus infection
- skin colour change in patches (including loss of pigmentation, vitiligo), hair loss, dry skin, hair colour changes, increased sensitivity to sunlight, skin peeling or sores
- muscle weakness
- inflammation of the liver
- high or low blood pressure; blood clots; cancer pain
- ear disorder, ear pain, ringing; hearing loss; blurred vision
- lung infection, upper respiratory tract infection, urinary infection

Uncommon (may affect up to 1 in 100 people)
- inflammation of the stomach
- inflammation of the pancreas
- type 1 diabetes, including diabetic ketoacidosis
- muscle pain
- temperature intolerance, thirst
- breathing difficulties, wheezing, hoarseness
- sinus congestion, abnormal speaking sound

- reactions related to the infusion of the medicine
- change in your sense of taste; drowsiness; speech disorder
- conjunctivitis, gingivitis, infections of skin and subcutaneous tissue
- inflammation of the joints; bulging disc; muscle spasms
- liver pain, gallbladder inflammation
- decreased secretion of hormones produced by the adrenal glands; inflammation of the pituitary gland situated at the base of the brain; inflammation of the thyroid
- accumulation of fluid around the heart; inflammation of the heart muscle; heart muscle damage
- tumour bleeding, tumour rupture
- oedema genital, scrotal oedema
- inflammation of the eye (which causes eye pain and redness), problems with coordinated eye movement; swelling of the optic nerve
- allergic reaction

Rare (may affect up to 1 in 1 000 people)
- gas in the intestinal wall, loss of sensation in the mouth, swollen or discoloured tongue
- inflammation of the layers that cover the lungs; increased amount of sputum
- vocal cord thickening
- diverticulitis
- inflammation of the skin (thickened, sometimes scaly skin growth; chronic itching or scaling; pain of skin)
- inflammation of the muscles which may include muscle pain or weakness (myositis) and could be associated with a rash (dermatomyositis)
- inflammation of subcutaneous fat, skin bruises
- overactive parathyroid gland activity; reduced pituitary gland activity
- paralysis in the extremities, disturbance in attention
- bulge in the aorta
- abnormal menstruation
- vaginal discharge or itching or pain of the skin outside vagina
- hearing loss; feeling off balance
- swelling, itching eyelid; farsightedness
- infection (flare of hepatitis B)

Contact your healthcare providers if you experience any of these side effects listed immediately above.

Changes in test results
LOQTORZI alone or in combination may cause changes in the results of tests carried out by your doctor. These include:
- abnormal liver function tests (including increased amounts of the liver enzymes aspartate aminotransferase, alanine aminotransferase, gamma-glutamyl transferase, or alkaline phosphatase in your blood)
- abnormal kidney function tests (increased amounts of creatinine or other waste products, uric acid, urea in your blood; increase in the number of cells or amount of protein in urine, abnormal amount of waste products in urine)
- an increased level of the enzyme that breaks down fats and of the enzyme that breaks down starch
- decreased amount of potassium, calcium, sodium, magnesium, chloride, phosphate, and protein in the blood
- increased amount of calcium, potassium, magnesium, sodium, or phosphate in the blood
- increased blood level of muscle enzymes
- abnormal thyroid function tests; anti-thyroid antibody positive; weight increased
- abnormal lipids and protein in the blood
- changes to the acid base balance in blood

- decreased in more than one type of blood cells (white blood cells, red blood cells, platelets)
- increased white blood cells, neutrophils; eosinophil count abnormal, platelet count increased;
- increase or decrease blood levels of endocrine gland hormones
- heart test abnormal

Reporting of side effects
If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store LOQTORZI

LOQTORZI will be given to you in a hospital or clinic and the healthcare professionals will be responsible for its storage.

If you are given a carton of LOQTORZI, this is how it should be stored:
- Keep this medicine out of the sight and reach of children.
- Do not use this medicine after the expiry date which is stated on the carton and vial label. The expiry date refers to the last day of that month.
- Store in a refrigerator (2 °C – 8 °C). Do not freeze. Store in the original carton in order to protect from light.
- After dilution, if the diluted solution is not used immediately, it may be stored at room temperature (20 °C to 25 °C) for up to 8 hours or at 2 °C to 8 °C for up to 24 hours from the time of dilution to the end of administration. These periods include the time from dilution until the end of administration.
- Do not use if this medicine contains visible particles.
- Do not store any unused medicine for reuse. Any unused medicine or waste material should be disposed of in accordance with local requirements. These measures will help protect the environment.

6. Contents of the pack and other information

What LOQTORZI contains
- The active substance is toripalimab.

One vial of 6 mL concentrate for solution for infusion contains 240 mg of toripalimab.

Each mL of concentrate for solution for infusion contains 40 mg of toripalimab.

- The other ingredients are citric acid monohydrate, mannitol, polysorbate 80, sodium chloride, sodium citrate dihydrate (Section 2 “LOQTORZI contains sodium”) and water for injections.

What LOQTORZI looks like and contents of the pack
LOQTORZI is supplied as a clear to slightly opalescent, colourless to slightly yellow solution, essentially free from visible particles.

It is available in cartons containing one glass vial containing 6 mL of concentrate for solution for infusion.

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The following information is intended for healthcare professionals only:

Preparation

- Visually inspect the solution for particulate matter and discoloration. The solution is clear to slightly opalescent, colourless to slightly yellow. Discard the vial if visible particles are observed.
- Dilute LOQTORZI prior to intravenous administration.
- Withdraw the required volume of LOQTORZI and inject slowly into a 100 mL infusion bag containing sodium chloride 9 mg/mL (0.9%) solution for injection. Mix diluted solution by gentle inversion. Do not shake. The final concentration of the diluted solution should be between 1 mg/mL to 3 mg/mL.

Administration

- Administer diluted solution intravenously via an infusion pump using a sterile in-line filter (0.2 micron or 0.22 micron pore size).
- First Infusion: infuse over at least 60 minutes.
- Subsequent infusions: if no infusion-related reactions occurred during the first infusion, subsequent infusions may be administered over 30 minutes.
- Do not co-administer other medicines through the same intravenous line.
- When administered on the same day as chemotherapy, LOQTORZI should be administered prior to chemotherapy.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.