United Kingdom
Prescribing Information for LOQTORZI®▼ (TORIPALIMAB) 240 mg concentrate for solution for infusion

Please refer to the full Summary of Product Characteristics (SmPC) (www.medicines.org.uk/emc) before prescribing.

▼This medicinal product is subject to additional monitoring. This will allow quick identification of new safety information. Healthcare professionals are asked to report any suspected adverse reactions.

Indications: Nasopharyngeal carcinoma (NPC): In combination with cisplatin and gemcitabine, for the first line treatment of adult patients with recurrent, not amenable to surgery or radiotherapy, or metastatic nasopharyngeal carcinoma.

Oesophageal squamous cell carcinoma (OSCC): In combination with cisplatin and paclitaxel, for the first line treatment of adult patients with unresectable advanced, recurrent, or metastatic oesophageal squamous cell carcinoma.

Active ingredients: One vial of concentrate for solution for infusion contains 240 mg of toripalimab. Each mL of concentrate for solution for infusion contains 40 mg of toripalimab.

Dosage and administration: Posology: The recommended dose of toripalimab for adults is 240 mg every 3 weeks (Q3W) as an intravenous infusion over 60 minutes via an infusion pump through an in-line filter (0.2 micron or 0.22 micron pore size) for the first infusion. If no significant infusion related reactions occurred during the first infusion, the subsequent infusions may be administered over 30 minutes. Treatment should continue until disease progression, unacceptable toxicity or up to a maximum duration of 24 months. Dose modifications: Recommended modifications to manage adverse reaction are provided in Table 1 of section 4.2 of the SmPC. Patient card: All prescribers should inform patients about the patient card, explaining what to do should they experience any symptom of immune related adverse reactions. Special populations: No dose adjustment is recommended for patients who are aged 65 years or over. No dose adjustment is needed for patients with mild or moderate renal impairment. There are insufficient data in patients with severe renal impairment for dosing recommendations. No dose adjustment is recommended for patients with mild hepatic impairment. There are insufficient data in patients with moderate or severe hepatic impairment. The safety and efficacy in children and adolescents aged under 18 years have not been established. No data are available. Method of administration: For intravenous use only and must be administered by infusion. Do not co-administer other medicinal products through the same intravenous line. When administered on the same day as chemotherapy, toripalimab should be administered prior to chemotherapy. For instructions on dilution of the medicinal product before administration, see section 6.6 of the SmPC.

Contraindications: Hypersensitivity to the active substance or to any of the excipients.

Precautions and special warnings: Immune related adverse reactions, which may be severe or fatal, can occur in patients treated with antibodies blocking the PD 1/PD L1 pathway, including toripalimab. Immune related adverse reactions can also manifest after discontinuation of treatment. Immune related adverse reactions may affect more than one body system simultaneously. Patients should be monitored closely for symptoms and signs of immune related adverse reactions. Liver enzymes, creatinine, and thyroid function should be evaluated at baseline and periodically during treatment. Toripalimab should be withheld or permanently discontinued depending on the type and severity of the adverse reaction. Systemic corticosteroid therapy (1 to 2 mg/kg/day prednisone or equivalent) should be administered until improvement to Grade 1 or less, followed by corticosteroid taper. Treatment with toripalimab may be restarted within 12 weeks after last dose if the adverse reaction recovers to Grade ≤1 and corticosteroid dose has been reduced to ≤10 mg prednisone or equivalent per day.

Treatment with toripalimab must be permanently discontinued for any Grade 3 immune related adverse reaction that recurs and for any Grade 4 immune related adverse reaction toxicity, except for endocrinopathies that are controlled with replacement hormones.

Toxicity management guidelines for the following adverse reactions are discussed in section 4.4 of the SmPC: immune-related pneumonitis, immune-related colitis, hepatotoxicity and immune-related hepatitis, immune-related endocrinopathies, immune-related nephritis, immune-related skin adverse reactions, immune-related myocarditis, immune-related myositis, other adverse reactions (including but not limited to neurologic toxicities, pancreatitis, iritis, uveitis, immune-related cystitis, and immune-related inflammatory arthritis). Patients should be monitored for signs and symptoms of pneumonitis. Suspected pneumonitis should be confirmed with radiographic imaging and other causes excluded. CMV infection/reactivation has been reported with corticosteroid-refractory colitis. Hypothyroidism may be managed with replacement therapy without toripalimab interruption. Withhold for Grade ≥3 thyroiditis or hyperthyroidism until controlled with medical management.

Solid organ transplant rejection has been reported with PD 1 inhibitors. Treatment with toripalimab may increase the risk of rejection in solid organ transplant recipients. Fatal and other serious complications, including graft versus host disease (GVHD), may occur. Severe and potentially life-threatening infusion related reactions can occur.

Drug interactions: See SmPC for full details on interactions.

Fertility, pregnancy and lactation: Toripalimab should not be used during pregnancy or in women of childbearing potential not using effective contraception unless the clinical benefit outweighs the potential risk. Toripalimab can cause harmful effects or death to the unborn baby. Women of childbearing potential should use effective contraception during treatment with toripalimab and for at least 4 months after the last dose. It is unknown whether toripalimab is secreted in human milk. Women should not breast-feed during treatment and for at least 4 months after the last dose of toripalimab. Studies to evaluate the effect of toripalimab on fertility have not been performed.

Side effects: *Very common (≥1/10):* upper respiratory tract infection, anaemia, leukopenia, neutropenia, thrombocytopenia, hypothyroidism, decreased appetite, hyponatraemia, weight decreased, hypoproteinaemia, hyperglycaemia, hypokalaemia, hyperuricaemia/gout, neuropathy, cough, diarrhoea/colitis, vomiting, nausea/ dyspepsia/eructation, abdominal pain, constipation/dyschezia, hyperbilirubinaemia/jaundice, proteinuria, haematuria, rash, pruritus, musculoskeletal pain, hypothyroidism, arrhythmia, fatigue, pyrexia, pain, liver function test abnormal, thyroid function test abnormal, increased or decreased lipids, urine analysis abnormal; *Common (≥1/100 to <1/10):* pneumonia, urinary tract infection, infection (not specified by site or pathogen), ear infections, dental and oral soft tissue infections, herpes simplex/herpes zoster infection, tumour pain, leukocytosis, neutrophilia, lymphopenia, hypersensitivity, hyperthyroidism, hypochloraemia, hypomagnesaemia, hypocalcaemia, hypophosphataemia, hyperkalaemia, hypercalcaemia, hypoglycaemia, dehydration, hypersomnia/ insomnia, dizziness, headache, neurotoxicity, dysgeusia, vision blurred, ear disorder, dyspnoea, hypotension/orthostatic hypotension, embolism and thrombosis, pneumonitis/immune-mediated lung disease/ interstitial lung disease, upper respiratory tract disorders, haemoptysis, epistaxis, pleural effusion, hiccups, dysphonia, rhinitis allergic, stomatitis, abdominal distension/flatulence, dry mouth, dysphagia, toothache, gastrointestinal haemorrhage, gastrooesophageal reflux disease/hyperchlorhydria, hepatitis, total bile acids increased, alopecia, vitiligo, pigmentation disorder, muscular weakness, arthritis/joint range of motion decreased, renal injury/ nephropathy, creatinine renal clearance decreased, oedema, influenza like illness, face oedema, chills, eye disorder, blood creatine phosphokinase decreased/increased, blood lactate dehydrogenase increased, amylase increased, lymphocyte count abnormal/monocyte count abnormal, blood alkaline phosphatase increased, blood urea increased, weight increased, lipase increased, electrocardiogram abnormal, C-reactive protein increased, occult blood positive, cardiac investigation abnormal.

Immune-related adverse reactions which can be serious: Data for immune-related adverse reactions are based on 403 patients who received toripalimab 240 mg Q3W in combination with platinum-based chemotherapy. Immune-related pneumonitis: 3.2% (Grade 3: 0.5%, Grade 2: 1.7%), Immune-related colitis: 0.7% (Grade 3: 0.5%, Grade 2: 0.2%), Immune-related hepatitis: 2.0% (Grade 4: 0.5%, Grade 3: 1.2%, Grade 2: 0.2%), Adrenal insufficiency: 0.2% (Grade 3: 0.2%), Thyroiditis: 2.0% (Grade 2: 1.0%), Hyperthyroidism: 2.0% (all Grade 1), Hypothyroidism: 17.1% (Grade 2: 11.4%), Diabetes mellitus: 0.2% (Grade 3: 0.2%), Hypophysitis: 0.2% (Grade 2: 0.2%), Immune-related skin adverse reactions: 9.4% (Grade 3: 3.0%, Grade 2: 2.0%), Immune-related myocarditis: 0.7% (Grade 4: 0.5%, Grade 3: 0.2%), Immune-related myositis: 0.5% (Grade 3: 0.5%), Immune-related nephritis: 0.2% (Grade 4: 0.2%), Immune-related cystitis: 0.5% (Grade 3: 0.2%), Infusion-related reactions: 2.7% (Grade 4: 0.2%, Grade 3: 0.2%, Grade 2: 0.5%).

Please see SmPC for full list of side effects.

Precautions for storage: Store in a refrigerator (2°C – 8°C). Do not freeze. Store in the original carton in order to protect from light.

Legal category: POM.

Marketing authorisation number and holder: PL 60874/0001; Topalliance Biosciences Europe Limited, Ground Floor, Two Dockland Central, Guild Street, I.f.s.c., Dublin 1, Co. Dublin, D01 K2C5, Ireland.

List price: LOQTORZI 240 mg / 6 mL concentrate for solution for infusion, 1 vial £7,525.00.

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Further information can be found in the Summary of Product Characteristics or from: Topalliance Biosciences Europe Limited, Ground Floor, Two Dockland Central, Guild Street, I.f.s.c., Dublin 1, Co. Dublin, D01 K2C5, Ireland, email: regulatory@topalliancebio.com.

Reporting of Suspected Adverse Reactions

Adverse events should be reported.

Reporting forms and information can be found at: https://yellowcard.mhra.gov.uk/ or search for MHRA Yellow Card in the Google Play or Apple App Store.

Adverse events should also be reported to Drug Safety at LEO Pharma by calling +44 (0) 1844 347333 or emailing medical-info.uk@leo-pharma.com

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