Lytgobi▼ (futibatinib) Prescribing Information – UK

Please refer to the Summary of Product Characteristics for further information.
Product name: Lytgobi▼ 4 mg film-coated tablets.
Composition: Each film-coated tablet contains 4 mg of futibatinib.
Indication: Lytgobi monotherapy is indicated for the treatment of adult patients with locally advanced or metastatic cholangiocarcinoma with a fibroblast growth factor receptor 2 (FGFR2) fusion or rearrangement who have progressed after at least one prior line of systemic therapy.
Posology and administration: Lytgobi should be initiated by a physician experienced in the diagnosis and treatment of patients with biliary tract cancer. Presence of FGFR2 gene fusions or rearrangements should be confirmed prior to initiation of Lytgobi. The recommended starting dose is 20 mg orally once daily. Treatment should be continued until progression or unacceptable toxicity. Lytgobi should be taken with or without food at about the same time each day and the tablets should be swallowed whole. Dietary restrictions that limit phosphate intake are recommended as part of hyperphosphataemia management. Dose modifications or interruption should be considered for the management of toxicities. *Special populations:* No dose adjustment is required for elderly patients. No dose adjustment is required for mild or moderate renal impairment; no data are available in patients with severe renal impairment or haemodialysis. No dose adjustment is required for hepatic impairment; no safety data are available in patients with severe hepatic impairment. No data in children are available.
Contraindications: Hypersensitivity to the active substance or any of the excipients listed in the summary of product characteristics.
Special warnings and precautions: Hyperphosphataemia: Recommendations include dietary phosphate restriction, administration of phosphate-lowering therapy, and dose modification when required. Serous retinal detachment: Ophthalmological examination should be performed prior to initiation of therapy, at 6 weeks thereafter, and urgently if visual symptoms occur. Dry eye: Use ocular demulcents as needed. Embryo-foetal toxicity: Exclude pregnancy before treatment initiation. Contraception should be used in women of childbearing potential and in men with women partners of childbearing potential during treatment and for 1 week following completion of therapy. Women using systemically acting hormonal contraceptives should add a barrier method during Lytgobi treatment and for at least 1 week after the last dose. Interactions: Concomitant use of strong CYP3A inhibitors, or strong or moderate CYP3A inducers should be avoided. If this is not possible then dose modifications should be considered. Lactose: Lytgobi contains lactose and should not be taken by patients with galactose intolerance, total lactase deficiency or glucose-galactose malabsorption.
Adverse reactions: *Very common (≥1/10):* hyperphosphataemia, decreased appetite, hyponatraemia, hypophosphataemia, dysgeusia, dry eye, stomatitis, diarrhoea, nausea, constipation, dry mouth, vomiting, abdominal pain, palmar-plantar erythrodysaesthesia syndrome, nail disorders, dry skin, alopecia, myalgia, arthralgia, fatigue, increased liver transaminases. *Common (≥1/100 to <1/10):* migraine, serous retinal detachment, intestinal obstruction.
Legal classification: Prescription only medicine.
Marketing authorisation holder: Taiho Pharma Europe Ltd, Building 2, Croxley Business Park, Watford, Hertfordshire, WD18 8YA.
MA number: PLGB 41225/0001.
UK list price: £2,386.33 per pack (excl. VAT).
PI date of revision: April 2026.
Additional monitoring: ▼ 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 via the Yellow card Scheme, website: www.mhra.gov.uk/yellowcard or search MHRA Yellow Card in the Google Play or Apple Play Store. Adverse events should also be reported to Taiho Pharma Europe Ltd, tel. 0800 04 89 461, email: medicalinformation@taiho.eu

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