LYTGOBI
(futibatinib) tablets

LYTGOBI® (futibatinib): safety profile and patient management

TAIHO ONCOLOGY

LYT-PM-UK-0016 | June 2026
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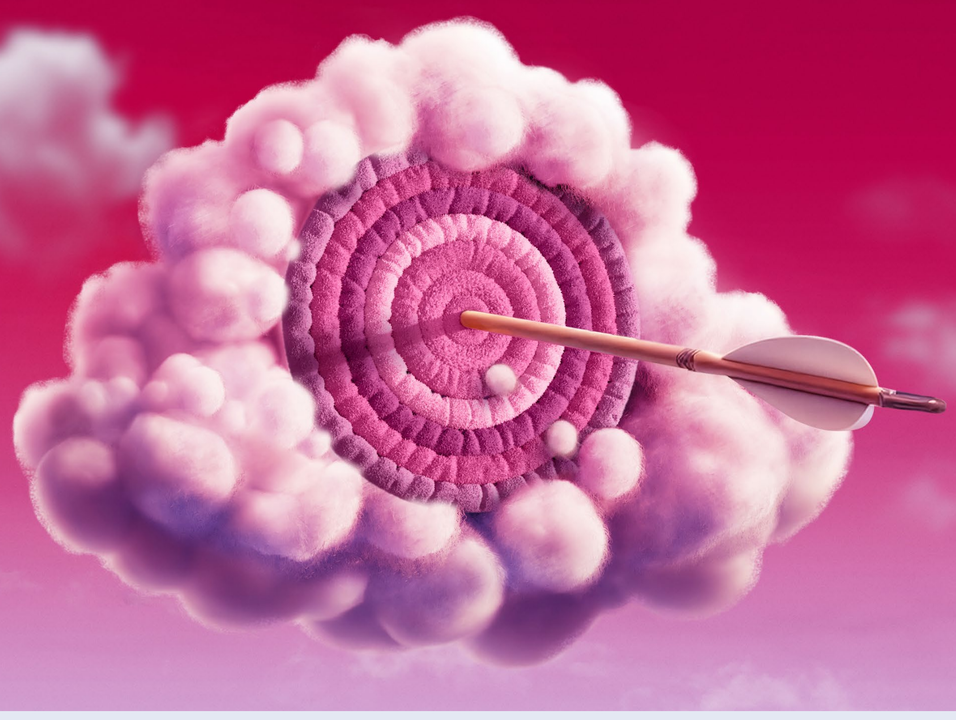

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LYTGOBI safety profile, categorised by incidence of treatment-emergent events[1]

Adverse reactions observed in the LYTGOBI safety population (N=145):[1]

System organ class	Frequency	Adverse reactions
Metabolism and nutrition disorders	Very common	Hyperphosphataemia Decreased appetite Hyponatraemia Hypophosphataemia
Nervous system disorders	Very common	Dysgeusia
	Common	Migraine
Eye disorders	Very common	Dry eye
	Common	Serous retinal detachment*
Gastrointestinal disorders	Very common	Stomatitis Diarrhoea Nausea Constipation Dry mouth Vomiting Abdominal pain
	Common	Intestinal obstruction
Skin and subcutaneous tissue disorders	Very common	Palmar-plantar erythrodysaesthesia syndrome Nail disorders† Dry skin Alopecia
Musculoskeletal and connective tissue disorders	Very common	Myalgia Arthralgia
General disorders and administration site conditions	Very common	Fatigue
Investigations	Very common	Liver transaminases increased

Frequency categories are: very common (≥ 1/10) and common (≥ 1/100 to < 1/10).[1]
*Includes serous retinal detachment, detachment of retinal pigment epithelium, subretinal fluid, chorioretinopathy, macular oedema, and maculopathy.
†Includes nail toxicity, nail bed tenderness, nail disorder, nail discolouration, nail dystrophy, nail hypertrophy, nail infection, nail pigmentation, onychalgia, onychoclasis, onycholysis, onychomadesis, onychomycosis and paronychia.

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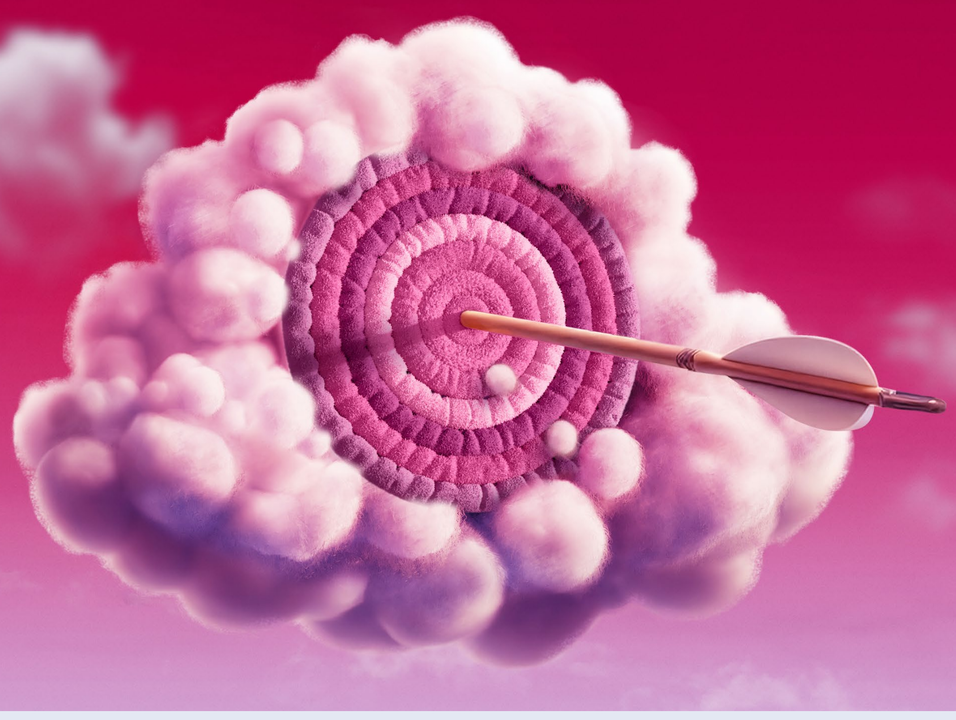

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LYTGOBI offers the flexibility of dose adjustments to help reduce the impact of adverse reactions[1]

Dose	Dose reduction levels	
	First	Second
20 mg taken orally once daily	16 mg taken orally once daily	12 mg taken orally once daily

Treatment should be permanently discontinued if the patient is unable to tolerate LYTGOBI 12 mg once daily.

On the following pages, we describe common side effects and the necessary monitoring and management of these, including dose modifications.

For a complete overview of scenarios where dose modifications may be required, see the LYTGOBI Dosing Guide.

LYTGOBI Dosing Guide

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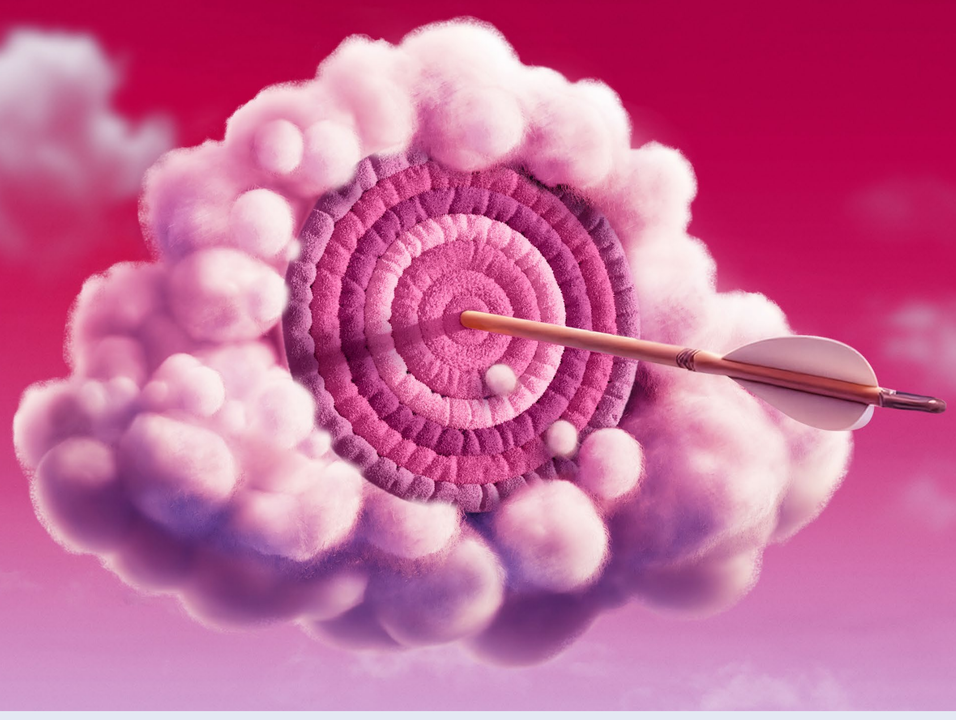

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Hyperphosphataemia is a very common, manageable side effect[1,2]

- **Risk of untreated hyperphosphataemia:** if left unmanaged, hyperphosphataemia can lead to soft tissue mineralisation (including cutaneous, vascular and myocardial calcification), hyperparathyroidism, anaemia and hypocalcaemia
- **Monitor for symptoms:** observe patients for muscle cramps, QT interval prolongation and arrhythmias
- **Hyperphosphataemia** may be managed with dose reductions/interruptions and careful monitoring. **If hyperphosphataemia occurs**, follow the guidance below:

Serum phosphate ≥5.5-≤7 mg/dL:

1. Initiate **phosphate-lowering therapy**

2. **Continue** current LYTGOBI dose

3. **Monitor serum phosphate levels weekly**

Serum phosphate >7-≤10 mg/dL:

1. Initiate or intensify **phosphate-lowering therapy**

2. **Reduce** to the next lowest LYTGOBI dose

3. **Monitor serum phosphate levels weekly**

- If it **resolves to ≤7.0 mg/dL within 2 weeks**, continue LYTGOBI at the reduced dose
- If it **is not ≤7.0 mg/dL within 2 weeks**, reduce the dose further to the next lowest dose
- If it **remains >7.0 mg/dL after the second dose reduction** (within 2 weeks), withhold LYTGOBI until serum phosphate is ≤7.0 mg/dL and then resume at the dose prior to suspension

Serum phosphate >10 mg/dL:

1. Initiate or intensify **phosphate-lowering therapy**

2. **Suspend** LYTGOBI

3. **Monitor serum phosphate levels weekly**

- If it is **≤7.0 mg/dL**, resume LYTGOBI at the next lowest dose
- If it **remains >7.0 mg/dL after two dose reductions** (within 2 weeks), **permanently discontinue LYTGOBI**

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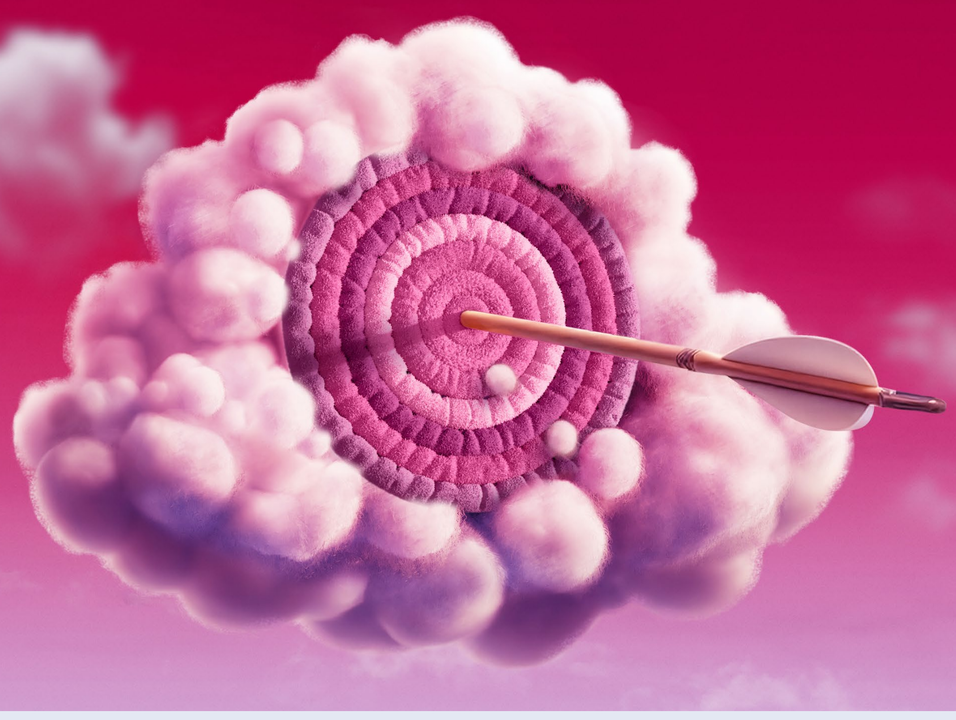

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Serous retinal detachment is a common, manageable adverse reaction[1,2]

- **Monitor for visual symptoms:** patients should be assessed for blurred vision, floaters or photopsia, as these may impair the ability to drive or operate machinery. Advise patients accordingly
- **Ophthalmological monitoring:** conduct an eye examination before starting treatment, at 6 weeks post initiation, and urgently if visual symptoms occur
- **Caution with eye conditions:** exercise extra care in patients with a history of significant retinal disorders (e.g. central serous retinopathy, macular/retinal degeneration, diabetic retinopathy or previous retinal detachment)
- **If serous retinal detachment occurs**, follow the guidance below:

Asymptomatic

1. Continue LYTGOBI at the current dose → **2.** Perform monitoring as described above

Moderate decrease in visual acuity

Criteria: best corrected visual acuity 20/40 or better or ≤3 lines of decreased vision from baseline; limiting instrumental activities of daily living:

1. Withhold LYTGOBI → **2.** If visual acuity improves on the next exam, resume LYTGOBI at the **next lowest dose** level → **3.** If symptoms recur, persist and do not improve upon examination, consider permanent discontinuation based on clinical status

Marked decrease in visual acuity

Criteria: best corrected visual acuity worse than 20/40 or >3 lines decreased from baseline, up to 20/200; limiting activities of daily living:

1. Withhold LYTGOBI → **2.** If visual acuity improves on the next exam, resume LYTGOBI at **2 dose levels lower** → **3.** If symptoms recur, persist or if examination does not improve, consider permanent discontinuation based on clinical status

Severe decrease in visual acuity

Criteria: visual acuity worse than 20/200 in the affected eye; limiting activities of daily living:

1. Consider **permanent discontinuation** of LYTGOBI based on clinical status

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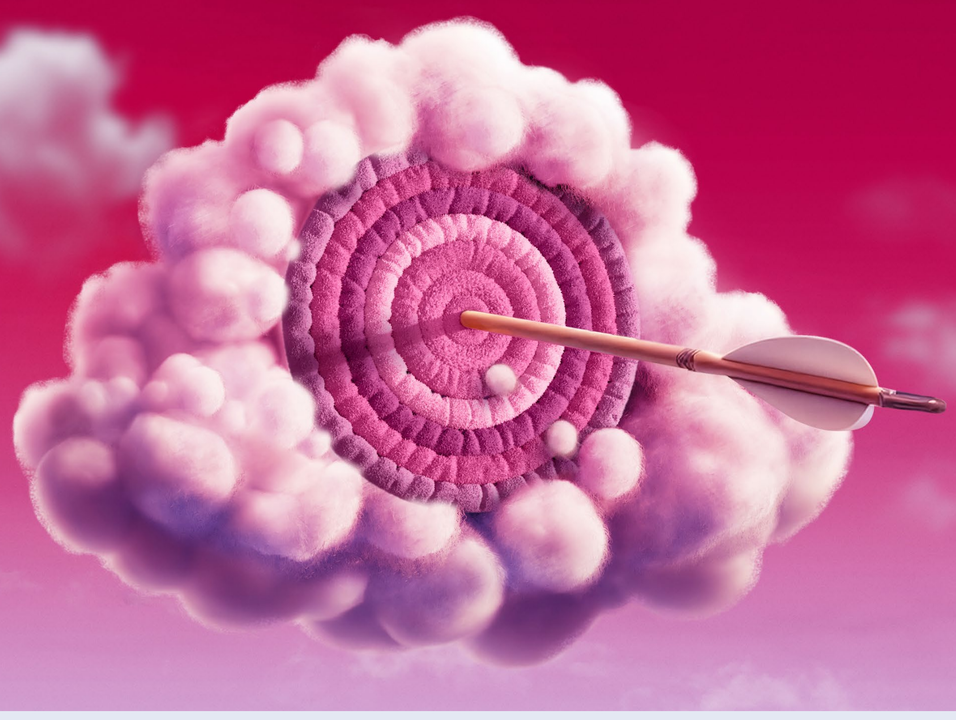

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Practical advice can help patients manage common adverse reactions like nail toxicity[2]

Nail toxicity

- **Inform** patients that they may experience changes in their nails, such as darkening, white streaks, ridges, brittleness, dryness, cracking or lifting
- **Advise** patients on measures to prevent nail infections, including gently trimming nails, moisturising hands regularly, avoiding professional manicures and pedicures, wearing gloves during house/garden chores, refraining from using nail-strengthening products and avoiding artificial nails
- **Instruct** patients to report any redness, pain or other changes around their cuticles to the healthcare team promptly

Advice for other common adverse reactions[2]

- **Palmar-plantar erythrodysesthesia**
  - Report redness, swelling or pain in hands/feet
  - Limit heat, avoid pressure and rubbing of the skin or wearing tight socks/gloves
  - Use thick creams (e.g. lanolin) or those with keratolytics (40% urea or salicylic acid)
  - Take only short walks and avoid prolonged standing
  - For grade 3+, consider cortisone creams and topical antibiotics

- **Stomatitis**
  - Report redness, swelling or sores around the mouth
  - Use baking soda rinses (every 2–3 hours, up to 6 times a day), mucosa-coating agents and topical anaesthetics
  - Opt for soft, moist foods, avoid spicy, acidic, very hot or very cold foods
  - For pain, use a straw or try pureed meals

- **Diarrhoea**
  - First-line: loperamide
  - Second-line: atropine/diphenoxylate
  - Recommend a low-fibre diet and stop taking stool softeners/laxatives
- **Dry mouth**
  - Encourage good oral hygiene, saliva substitutes/stimulants, dental checkups and high-fluoride toothpaste

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The efficacy and safety of LYTGOBI were reported in the FOENIX-CCA2 study.[3]

Scan the QR code to find out more.

Please refer to the SmPC for full Prescribing Information:

LYTGOBI® (futibatinib) 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 that have progressed after at least one prior line of systemic therapy.[1]

▼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 for MHRA Yellow Card in the Google Play or Apple App Store. Adverse events should also be reported to 0800 04 89 461 or medicalinformation@taihoeurope.com.

This medicinal product has been authorised under a so-called 'conditional approval' scheme. This means that further evidence on this medicinal product is awaited. The Medicines and Healthcare products Regulatory Agency will review new information on this medicinal product at least every year and the Summary of Product Characteristics will be updated as necessary.[1]

References: 1. LYTGOBI® (futibatinib) Summary of Product Characteristics; **2.** Subbiah V, Verstovsek S. *Cell Rep Med*. 2023;4(10):101204; **3.** Goyal L, et al. *N Engl J Med*. 2023;388(3):228-239.

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