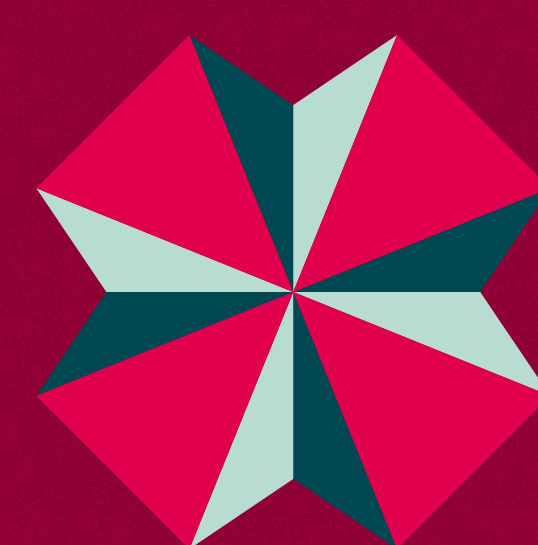
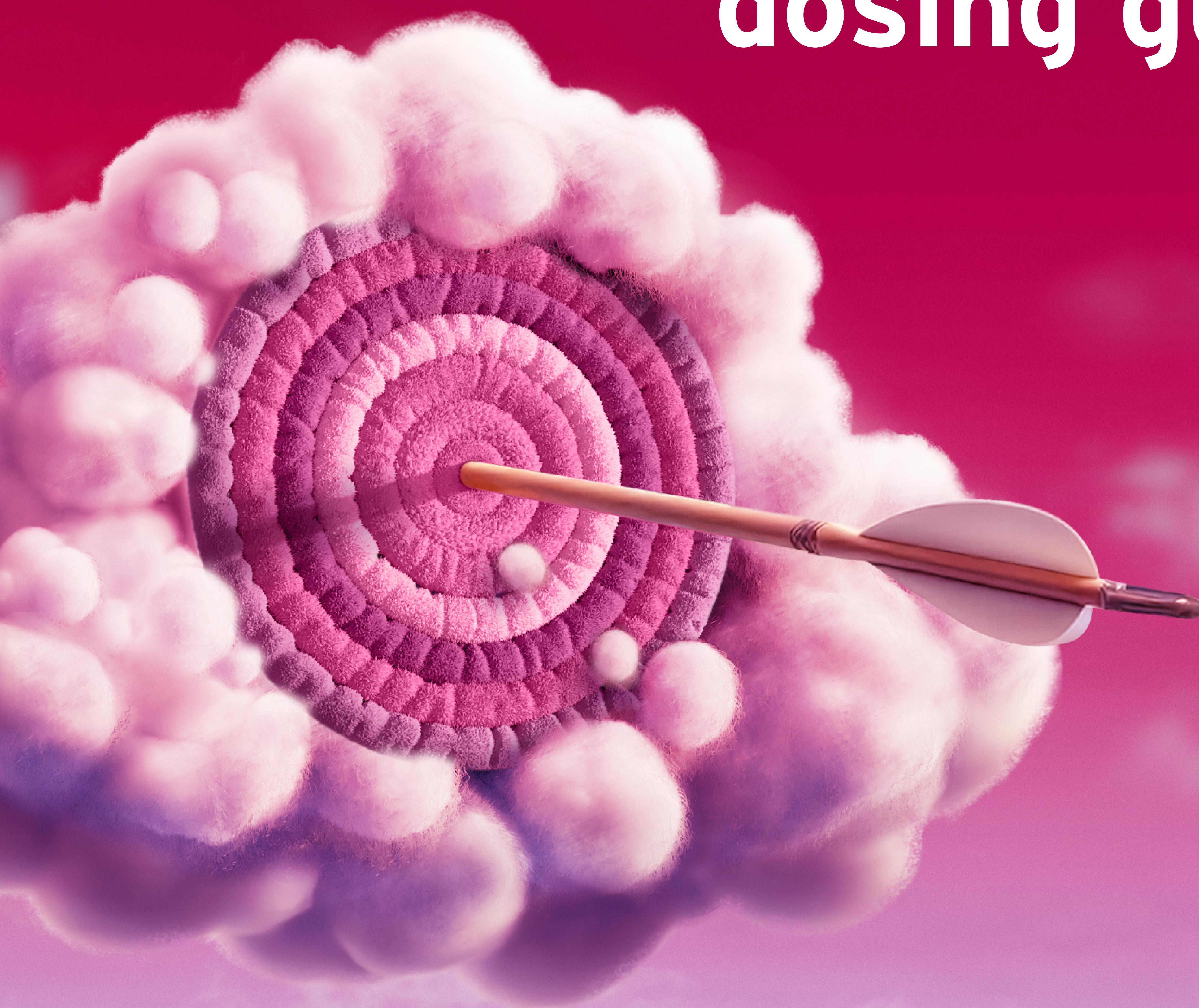




LYTGOBI[®] ▼
(futibatinib) tablets

LYTGOBI[®] (futibatinib): dosing guide



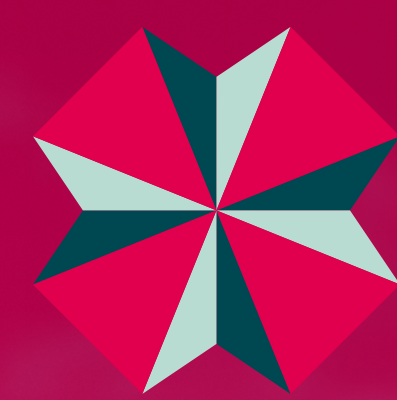
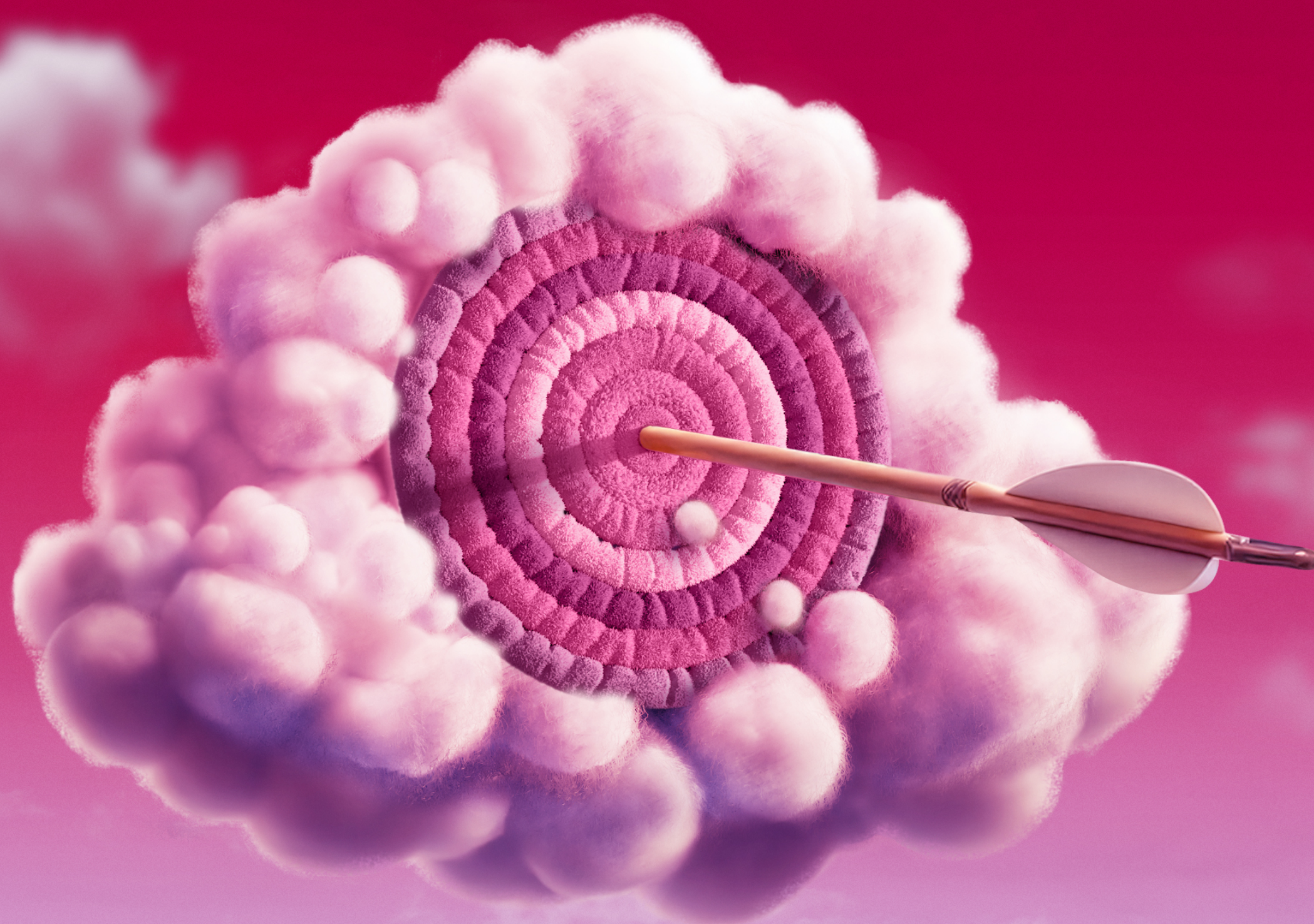
LYTGOBI[®] (futibatinib) monotherapy is indicated for the treatment of adult patients with locally advanced or metastatic cholangiocarcinoma with a fibroblast growth factor receptor 2 (FGFR2) fusion or rearrangement who have progressed after at least one prior line of systemic therapy.¹

Medicamento de uso hospitalario sujeto a seguimiento adicional.
El medicamento esta reembolsado por el SNS desde el 01/01/2024.
Precio de venta laboratorio notificado: 2.416 EUR.

▼ Este medicamento está sujeto a seguimiento adicional, es prioritaria la notificación de sospechas de reacciones adversas asociadas a este medicamento.

See section 4.8 of the LYTGOBI Summary of Product Characteristics for how to report adverse reactions.





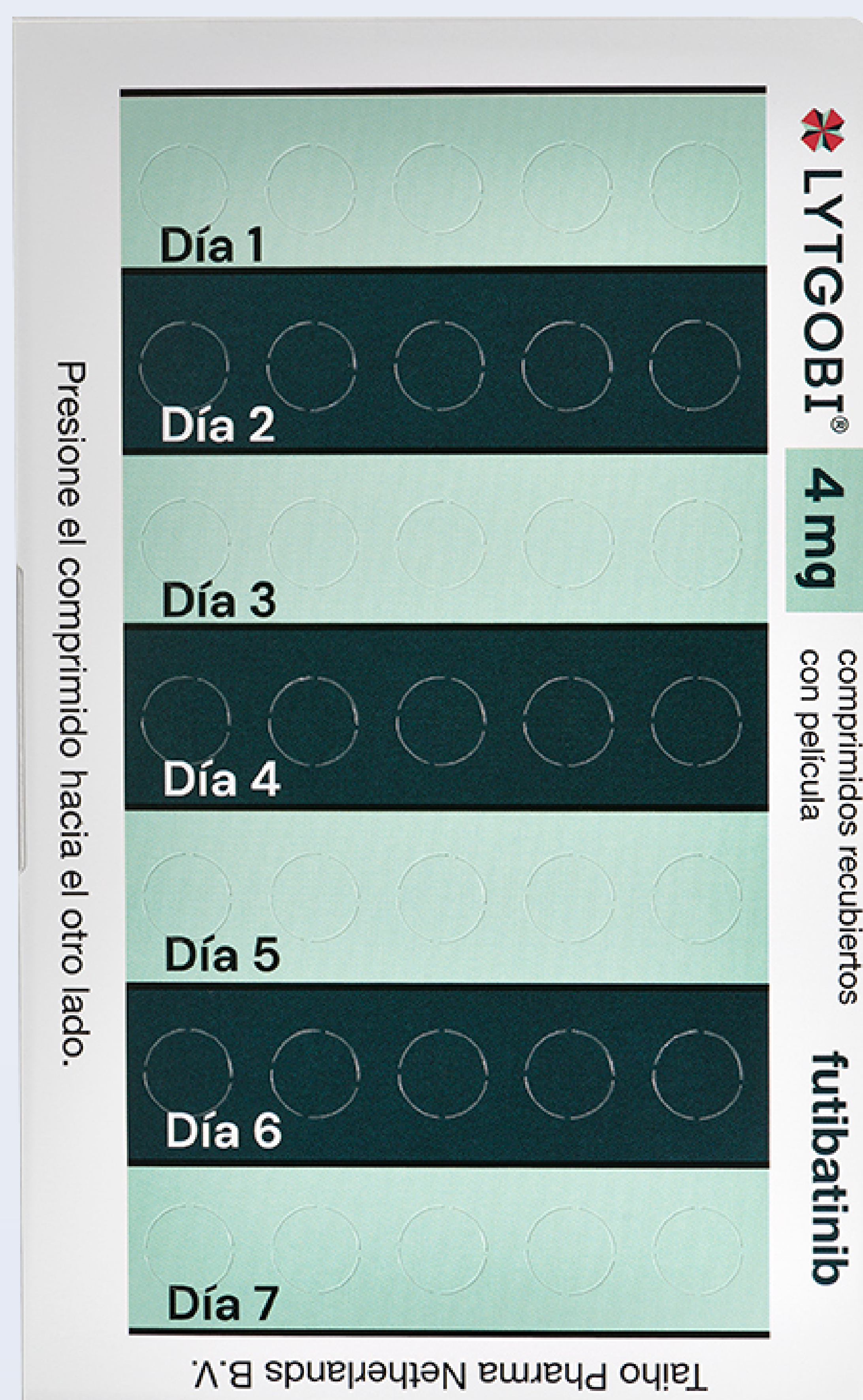
LYTGOBI® ▼
(futibatinib) tablets

LYTGOBI offers continuous once-daily oral dosing¹

LYTGOBI is taken:¹

- Orally at a recommended starting dose of 20 mg (five 4 mg tablets) once daily
- By swallowing whole with a glass of water at the same time every day, with or without food
- Continuously, without pre-planned treatment breaks
- Until disease progression or unacceptable toxicity. If a dose is missed by more than 12 hours or if vomiting occurs, dosing can resume with the next scheduled dose

LYTGOBI is packaged for patient convenience:¹



Day 1 is row 1.

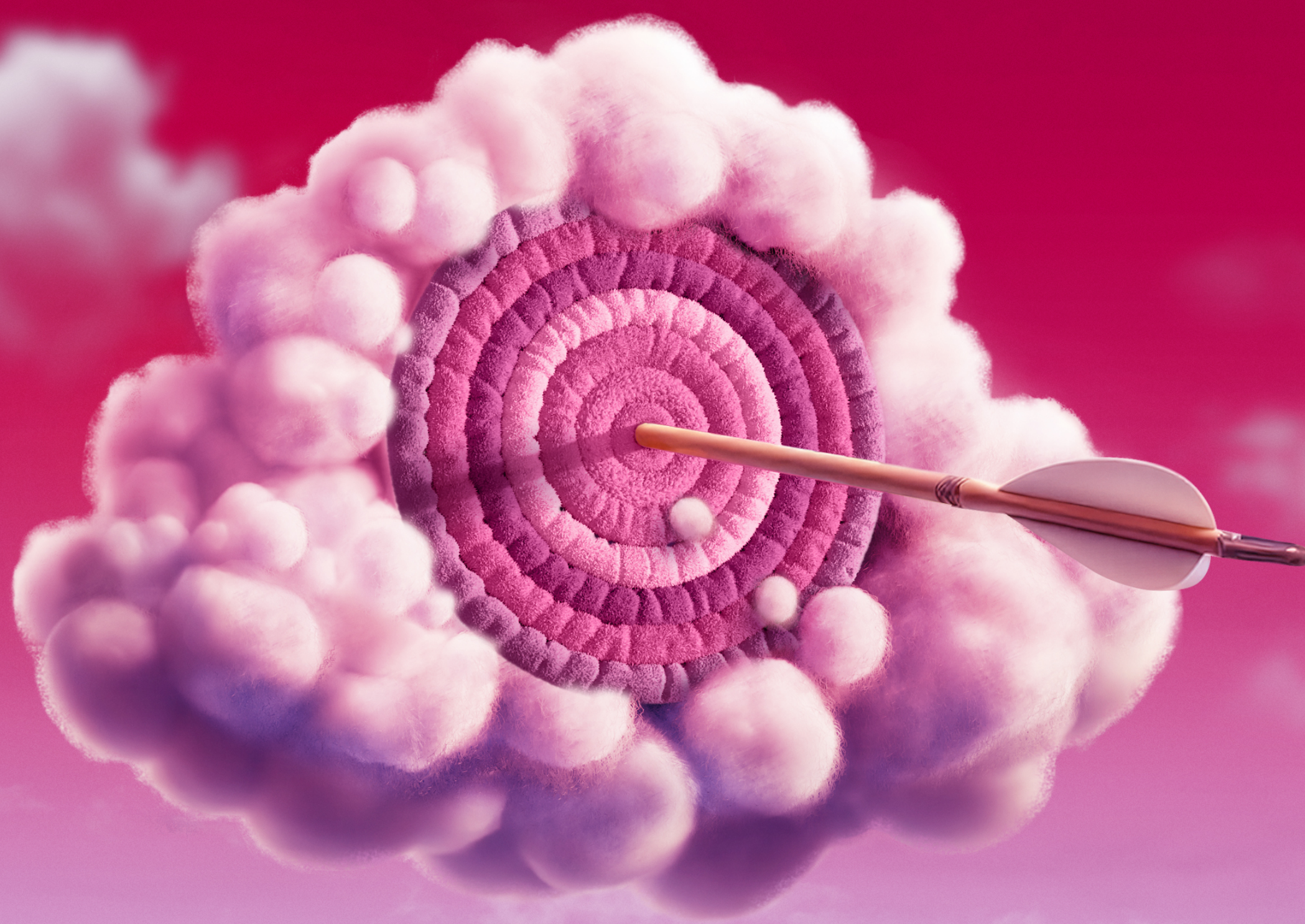
Each row of tablets equals one daily dose.

Each card contains one week's worth of LYTGOBI tablets.





LYTGOBI[®] ▼
(futibatinib) tablets



LYTGOBI offers the flexibility to adjust dosing as required¹

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

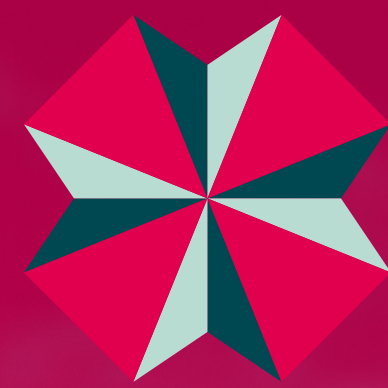
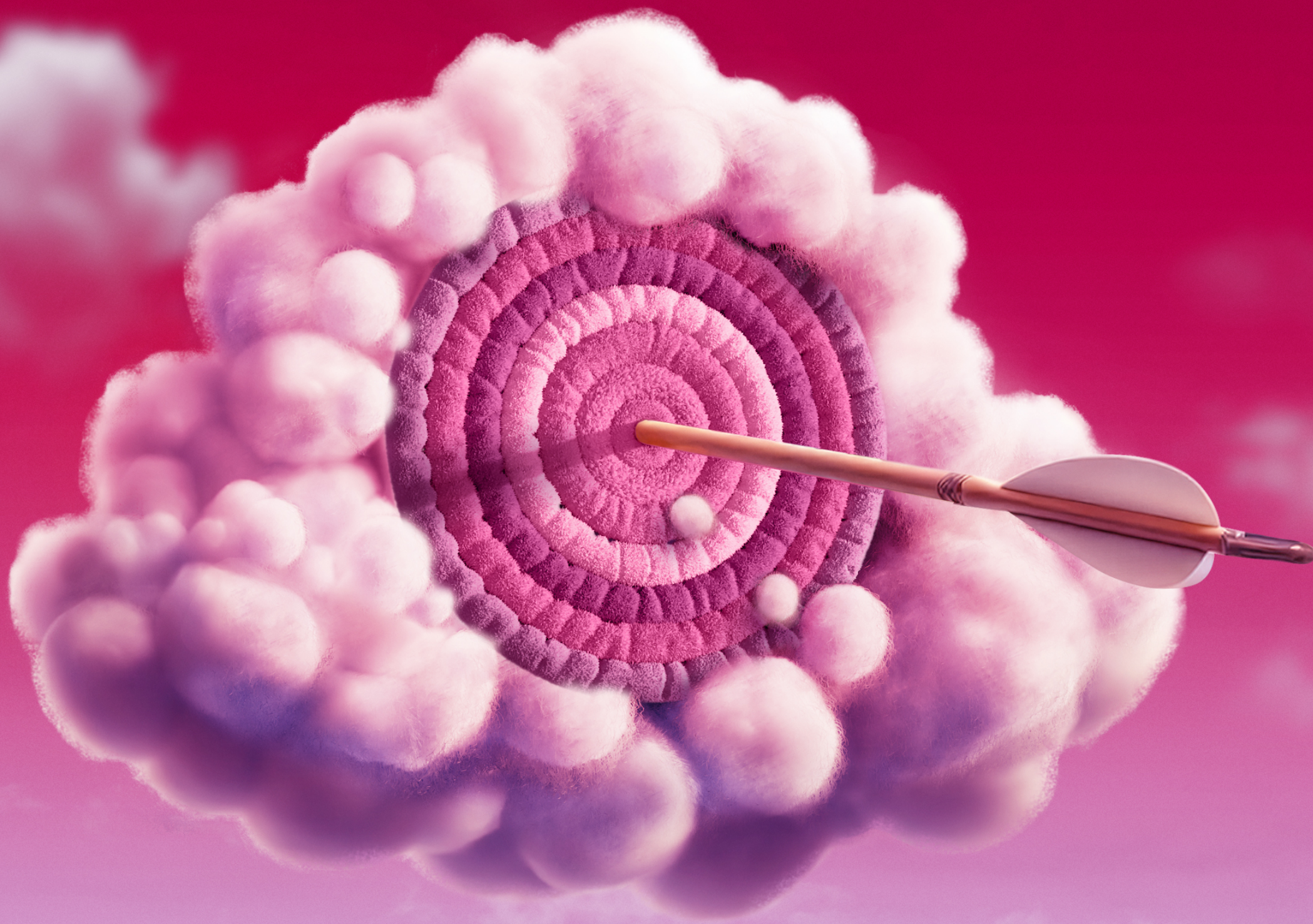
Dose adjustments may be required due to certain drug interactions:¹

- **Strong CYP3A4/P-gp inhibitors** (e.g. itraconazole) should be avoided. If this is not possible, consider **reducing the futibatinib dose** to the next lowest level based on careful monitoring of tolerability
- **Strong or moderate CYP3A4/P-gp inducers** (e.g. rifampicin) should be avoided. If avoidance is not possible, consider gradually **increasing the futibatinib dose**, with close monitoring of tolerability

Dose modifications or interruption of dosing can also be considered for the management of adverse reactions:¹

Hyperphosphatemia	LYTGOBI dose modifications
Serum phosphate ≥5.5 mg/dL to ≤7 mg/dL	• Initiate phosphate-lowering therapy and monitor serum phosphate weekly • LYTGOBI should be continued at current dose
Serum phosphate >7 mg/dL to ≤10 mg/dL	• Initiate/intensify phosphate-lowering therapy and monitor serum phosphate weekly AND • Dose-reduce LYTGOBI to next lower dose - If the serum phosphate resolves to ≤7.0 mg/dL within 2 weeks after dose reduction, continue at this reduced dose - If serum phosphate is not ≤7.0 mg/dL within 2 weeks, further reduce LYTGOBI to the next lower dose - If serum phosphate is not ≤7.0 mg/dL within 2 weeks after the second dose reduction, withhold LYTGOBI until serum phosphate is ≤7.0 mg/dL and resume at the dose prior to suspending
Serum phosphate >10 mg/dL	• Initiate/intensify phosphate-lowering therapy and monitor serum phosphate weekly AND • Suspend LYTGOBI until phosphate is ≤7.0 mg/dL and resume LYTGOBI at the next lower dose • Permanently discontinue LYTGOBI if serum phosphate is not ≤7.0 mg/dL within 2 weeks following 2 dose reductions





LYTGOBI[®] ▼
(futibatinib) tablets

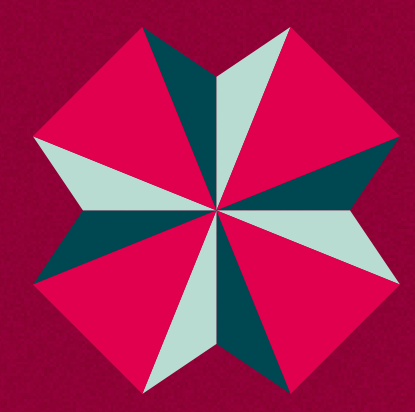
LYTGOBI offers the flexibility to adjust dosing as required¹

Serous retinal detachment	LYTGOBI dose modifications
Asymptomatic	• Continue LYTGOBI at current dose. Monitoring should be performed as described in section 4.4 of the SmPC
Moderate decrease in visual acuity (best corrected visual acuity 20/40 or better or ≤3 lines of decreased vision from baseline); limiting instrumental activities of daily living	• Withhold LYTGOBI. If improved on subsequent examination, LYTGOBI should be resumed at the next lower dose level • If symptoms recur or persist, or examination does not improve, permanent discontinuation of LYTGOBI should be considered based on clinical status
Marked decrease in visual acuity (best corrected visual acuity worse than 20/40 or >3 lines decreased vision from baseline up to 20/200); limiting activities of daily living	• Withhold LYTGOBI until resolution. If improved on subsequent examination, LYTGOBI may be resumed at 2 dose levels lower • If symptoms recur, persist or examination does not improve, permanent discontinuation of LYTGOBI should be considered based on clinical status
Visual acuity worse than 20/200 in affected eye; limiting activities of daily livin	• Permanent discontinuation of LYTGOBI should be considered based on clinical status

Other adverse reactions	LYTGOBI dose modifications
Other adverse reactions	Grade 3* • Withhold LYTGOBI until toxicity resolves to Grade 1 or baseline, then resume LYTGOBI - or haematological toxicities resolving within 1 week, at the dose prior to suspending - for other adverse reactions, at next lower dose Grade 4* • Permanently discontinue LYTGOBI *Severity as defined by National Cancer Institute Common Terminology Criteria for Adverse Events (NCI CTCAE version 4.03).

Treatment should be permanently discontinued if the patient is unable to tolerate LYTGOBI 12 mg once daily.¹





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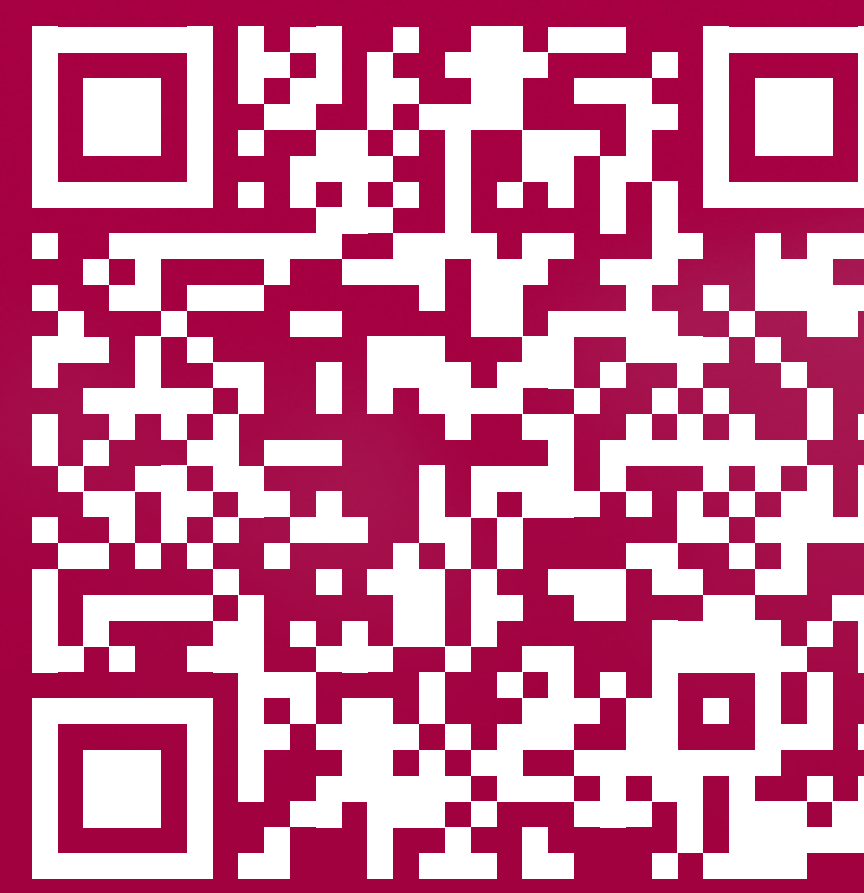
The efficacy and safety of
LYTGOBI were reported in
the FOENIX-CCA2 study.²
Find out more:



Please refer to the SmPC for full Prescribing Information:



EU



Spain (CIMA)

Prescribing Information is also available on the stand upon request. Registration conditions differ from country to country. Please refer to your local label.

References: **1.** LYTGOBI[®] Summary of Product Characteristics; **2.** Goyal L, et al. *N Engl J Med.* 2023;388(3):228-239.

Abbreviations

CIMA, Centro de Información online de Medicamentos de la AEMPS; CYP3A4, cytochrome P450 3A4; P-gp, P-glycoprotein.

