Pharma Europe, LTD
Taiho Pharmaceutical Europe, Ltd.
Building 2, Croxley Business Park
Watford, Hertfordshire, WD18 8YA
United Kingdom

21 February 2025

DIRECT HEALTHCARE PROFESSIONAL COMMUNICATION

Lytgobi▼ 4 mg film-coated tablets (futibatinib):
Interim Supply of Spain Stock to Mitigate Supply Disruption

Dear Healthcare Professional,

Summary: Taiho Pharma Europe Limited is currently experiencing supply disruption with Lytgobi 4 mg film-coated tablets (futibatinib) in the United Kingdom (UK).

To ensure continuity in supply, Taiho Pharma Europe Limited has obtained approval from the MHRA to supply Spanish product (batch number 2069740C (424 packs), batch number 2087957C (371 packs), batch number 2120213C (199 packs) and batch number 2130738C (385 packs)) which is expected to be on the UK market from January 2025.

Please note the following:

- This product is considered licensed in the UK.
- The product from EU/Spain has the same formulation as the UK product.
- The product from EU/Spain is manufactured according to the same manufacturing process and quality controls as the UK product.
- There are no differences between the Spain and UK product information other than the language. Please ensure the UK Summary of Product Characteristics (SPC) and UK Patient Information leaflet (PIL) is followed.
- Please refer to the paper copy of the UK approved PIL supplied with the Spanish packs. Discard the Spanish leaflet in the pack.
- For additional copies of the leaflet, please contact the company contact point (see below).
- The MHRA has agreed to an exemption granted in accordance with regulation 266(4)(a) and (b) of the Human Medicines Regulations (HMR) 2012, from the obligation that certain particulars should appear on the outer and immediate packaging of Lytgobi 4 mg film-coated tablets (futibatinib), and that the information must be given in English.

Please ensure all relevant staff are made aware of the content of this letter and that the information is communicated to the patients.

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Image of Spanish Lytgobi 4 mg film-coated tablets Wallet

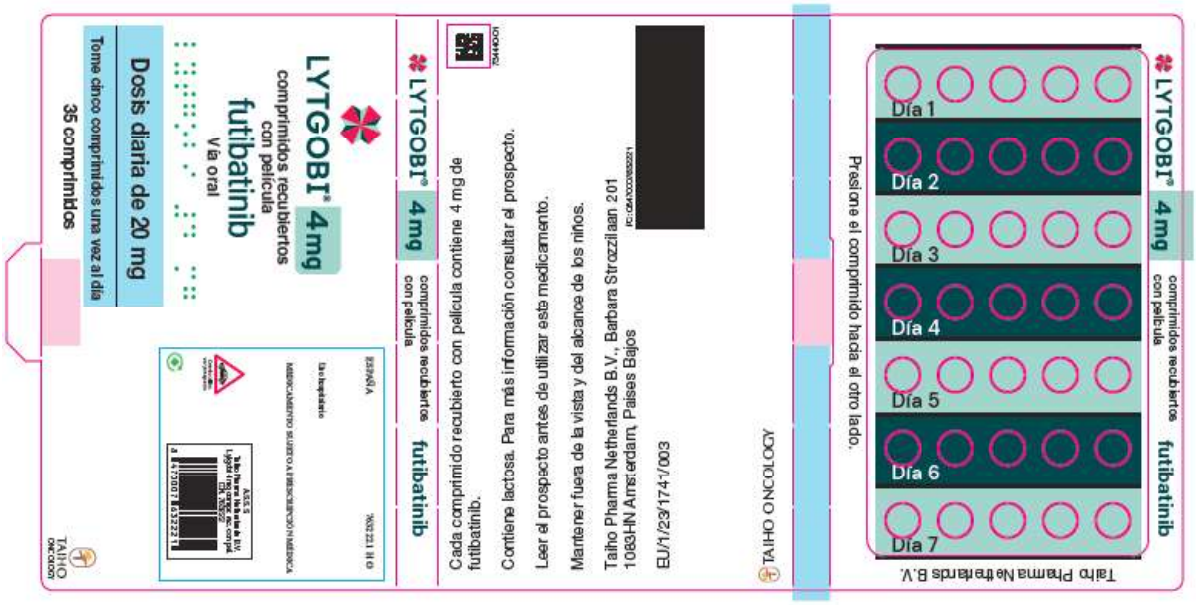
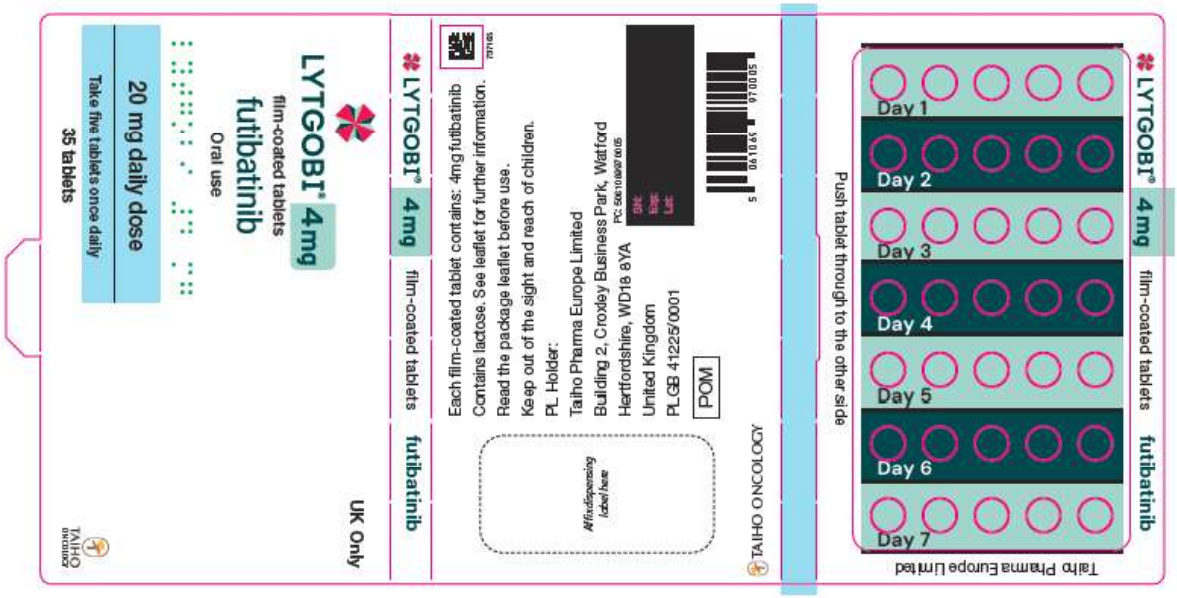


Image of United Kingdom Lytgobi 4 mg film-coated tablets Wallet



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Call for reporting
Please continue to report suspected adverse drug reactions (ADRs) to the MHRA through the Yellow Card scheme.

Please report:

- all suspected ADRs that are serious or result in harm. Serious reactions are those that are fatal, life-threatening, disabling or incapacitating, those that cause a congenital abnormality or result in hospitalisation, and those that are considered medically significant for any other reason
- all suspected ADRs associated with new drugs and vaccines identified by the black triangle ▼

You can report via:

- the Yellow Card website
- the free Yellow Card app available from the Apple App Store or Google Play Store
- some clinical IT systems (EMIS/SystmOne/Vision/MiDatabank) for healthcare professionals

Alternatively, you can report a suspected side effect to the Yellow Card scheme by calling 0800 731 6789 for free, Monday to Friday between 9am and 5pm.

When reporting please provide as much information as possible, including information about medical history, any concomitant medication, timing onset, treatment dates, and product brand name.

- Lytgobi 4 mg film-coated tablets▼ is subject to additional monitoring. This will allow quick identification of new safety information
- Please report ANY suspected adverse drug reactions (ADRs) to drugs and vaccines identified by the black triangle▼ to the MHRA through the Yellow Card Scheme.

Company contact point
If you have any questions about this letter or require more information about Lytgobi 4 mg film-coated tablets, please contact Taiho Pharma Europe Limited Medical Information at Building 2, Croxley Business Park, Watford, Hertfordshire, WD18 8YA, United Kingdom or telephone 0800 04 89 461 or via Website: Contact Us (taihooncology.eu) or via e-mail: medicalinformation@taiho.eu

Yours faithfully,

Olof Harlin, DVM, PhD
Senior Director Medical Affairs Europe North
Taiho Pharma Europe Limited