Package leaflet: Information for the patient

Lytgobi 4 mg film-coated tablets
futibatinib

▼This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Lytgobi is and what it is used for

Lytgobi contains the active substance futibatinib, which belongs to a group of cancer medicines called tyrosine kinase inhibitors. It blocks the action of a protein in the cell, called fibroblast growth factor receptor (FGFR), that helps regulate cell growth. Cancer cells may have an abnormal form of this protein. By blocking FGFR, futibatinib can prevent the growth of such cancer cells.

Lytgobi is used on its own (monotherapy) to treat adults with bile duct cancer (also known as cholangiocarcinoma) that has spread or cannot be removed by surgery in patients who have already received previous treatment, and whose tumour has a certain type of abnormal "FGFR".

2. What you need to know before you take Lytgobi

Do not take Lytgobi if you are allergic to futibatinib or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions
Talk to your doctor or pharmacist before taking Lytgobi if you have:
- been told you have high levels of phosphate in your blood (a condition known as hyperphosphataemia) based on a blood test result
- vision or eye problems such as problems with the retina (light-sensitive layers of nerve tissue at the back of the eye)

Eye examinations are recommended:
- before starting treatment with Lytgobi
- 6 weeks thereafter or at any time if any visual or eye problems occur.

Lytgobi can cause serous retinal detachment (retina pulls away from its normal position). Symptoms include blurred vision, flashes of light in the field of vision (photopsia) and small dark shapes moving in the field of vision (floaters). Tell your doctor straight away if you get any problems with your vision.

Lytgobi can cause high levels of phosphate in your blood and may lead to a build-up of minerals such as calcium in different tissues in your body. Your doctor may prescribe changes in your diet, phosphate lowering therapy, or change or stop treatment with Lytgobi if needed. Tell your doctor straight away if you develop painful skin lesions, any muscle cramps, numbness or tingling around your mouth, or an abnormal heartbeat.

Lytgobi may harm the unborn baby. If you are a woman of childbearing age or your partner is of childbearing capacity, you must use an effective contraception during treatment and for 1 week after the last dose of Lytgobi. Because it is not known if Lytgobi decreases the effectiveness of birth control medication, barrier methods should be applied in addition to such medication to avoid pregnancy.

Children and adolescents

Lytgobi should not be given to children or adolescents under 18 years. It is not known whether it is safe and effective in this age group.

Other medicines and Lytgobi
Tell your doctor or pharmacist if you are taking, have recently taken, or might take any other medicines.

In particular, you should tell your doctor if you are taking any of the following medicines so that the doctor can decide if your treatment needs to change:
- **itraconazole**: a medicine to treat fungal infections
- **clarithromycin**: medicines to treat certain infections
- **rifampicin**: a medicine to treat tuberculosis or certain other infections
- **carbamazepine**, **phenytoin**, **phenobarbital**: medicines to treat epilepsy
- **efavirenz**: medicine to treat HIV infection
- **digoxin**: a medicine to treat heart disease
- **dabigatran**: a medicine to prevent blood clots
- **colchicine**: a medicine to treat gout attacks
- **rosuvastatin**: a medicine to treat high cholesterol
- **theophylline:** a medicine to treat breathing problems
- **olanzapine:** a medicine to manage symptoms of mental health conditions

Pregnancy and breast-feeding
If you are pregnant or breast-feeding, think you may be pregnant, or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

- **Pregnancy /Contraception -information for women**
  You should not become pregnant during the treatment with Lytgobi because this medicine could harm your baby. A pregnancy test should be performed before initiating treatment, and women who could become pregnant must use effective contraception during treatment and for 1 week after the last dose of Lytgobi. Barrier methods should be applied as a second form of contraception to avoid pregnancy. Talk to your doctor about the most suitable contraception for you.
- **Contraception -information for men**
  You should not conceive a child during treatment with Lytgobi because this medicine may harm the baby. You must use effective contraception during treatment and for 1 week after the last dose of Lytgobi.

- **Breast-feeding**
  Do not breast-feed during treatment with Lytgobi and for 1 week after the last dose. This is because it is not known if Lytgobi can pass into breast milk and could therefore harm your baby.

Driving and using machines
Lytgobi can cause side effects such as fatigue or visual disturbances. Do not drive or operate machinery if this happens.

Lytgobi contains lactose and sodium
This medicine contains lactose (found in milk or dairy products). If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.
This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially "sodium-free".

3. How to take Lytgobi

Lytgobi treatment should be started by a doctor who is experienced in the diagnosis and treatment of bile duct cancer. Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose is
5 tablets of Lytgobi 4 mg (20 mg futibatinib in total) taken orally once daily. Your doctor will adjust the dose or stop treatment if needed. For patients with dose adjustments relative to the recommended 5 tablets per day, specific pack sizes are available to meet their dosage requirements. See section 6.

Method of administration
Swallow the tablet whole with one glass of water at the same time every day. Lytgobi may be taken with food or between meals. The tablets should be swallowed whole to ensure that the full dose is taken.

Duration of treatment
Take Lytgobi for as long as it is prescribed by the doctor.

If you take more Lytgobi than you should
Tell your doctor straight away if you have taken more Lytgobi than you should have.

If you forget to take Lytgobi
- If you miss a dose of Lytgobi by 12 hours or less, take the missed dose as soon as you remember.
- If you miss a dose of Lytgobi by more than 12 hours, skip the missed dose. Take your next dose at the usual time.
- Do not take a double dose of Lytgobi if you experience vomiting. Take the next dose at your scheduled usual time.
- Do not take a double dose to make up for a missed dose.

If you stop taking Lytgobi
Do not stop taking Lytgobi without discussing it with your doctor, as stopping treatment could reduce the success of therapy.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

If you have any of the serious side effects below, tell your doctor immediately. These side effects

listed below are common (may affect up to 1 in 10 people).
- Migraine
- Intestinal obstruction

Other side effects
Talk to your doctor if you get any other side effects. These may occur with the following frequencies:

Very common (may affect more than 1 in 10 people)
- high or low phosphate levels seen in blood tests
- low sodium levels seen in blood tests
- nails separating from the nail bed, poor formation of the nail, change in colour of the nails
- constipation
- diarrhoea
- dry mouth
- vomiting
- abdominal pain
- hair loss (alopecia)
- feeling tired or weak
- dry skin
- high levels of liver enzyme seen in blood tests
- nausea
- inflammation of the lining of the mouth (stomatitis)
- decreased appetite
- dry eye
- redness, swelling, peeling or tenderness, mainly on the hands or feet ('hand-foot' syndrome)
- change in sense of taste
- muscle pain
- joint pain

Common (may affect up to 1 in 10 people)
- Eye problems including inflammation of the eyes or cornea (front part of the eye), blurred vision, sudden appearance of small dark shapes moving in the field of vision (floaters) and flashes of light in the field of vision (photopsia).

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly 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.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Lytgobi

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and blister after EXP. The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Lytgobi contains

- The active substance is futibatinib.
  Each film-coated tablet contains 4 mg futibatinib.

- The other ingredient(s) are:
  Tablet core: maize starch, crospovidone, hydroxypropylcellulose, lactose monohydrate, magnesium stearate, mannitol, cellulose microcrystalline and sodium lauril sulfate (see section 2, "Lytgobi contains lactose and sodium")
  Film coating: hypromellose, macrogols, and titanium dioxide
  Lustering agent: magnesium stearate

What Lytgobi looks like and contents of the pack

Lytgobi 4 mg is supplied as round, white, film-coated tablets, debossed on one side with "4MG" and "FBN" on the other side.

Lytgobi tablets are packaged in a blister card sealed inside a folding wallet containing a 7-day supply as follows:

- 20 mg daily dose: Each wallet contains 35 tablets (5 tablets once daily).
- 16 mg daily dose: Each wallet contains 28 tablets (4 tablets once daily).
- 12 mg daily dose: Each wallet contains 21 tablets (3 tablets once daily).

Marketing Authorisation Holder

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This leaflet was last revised in 12/2024.

This medicine has been given 'conditional approval'.
This means that there is more evidence to come about this medicine.
The Medicines and Healthcare products Regulatory Agency (MHRA) will review new information on this medicine at least every year and this leaflet will be updated as necessary.

Other sources of information

Detailed information on this medicine is available on the Medicines and Healthcare products Regulatory Agency (MHRA) web site: www.mhra.gov.uk.