

## PATIENT INFORMATION

LYTGOBI (light-GOH-bee)

(futibatinib)

tablets

### What is LYTGOBI?

LYTGOBI is a prescription medicine that is used to treat adults with bile duct cancer (intrahepatic cholangiocarcinoma) that has spread or cannot be removed by surgery:

- who have already received a previous treatment, **and**
- whose tumor has a certain type of abnormal "FGFR2" gene.

Your healthcare provider will test your cancer for a certain type of abnormal FGFR2 gene and make sure that LYTGOBI is right for you.

It is not known if LYTGOBI is safe and effective in children.

### Before you take LYTGOBI, tell your healthcare provider about all of your medical conditions, including if you:

- have vision or eye problems.
- are pregnant or plan to become pregnant. LYTGOBI can harm your unborn baby or cause loss of your pregnancy (miscarriage). You should not become pregnant during treatment with LYTGOBI.

#### Females who can become pregnant:

- Your healthcare provider should do a pregnancy test before you start treatment with LYTGOBI.
- You should use an effective method of birth control during treatment and for 1 week after your final dose of LYTGOBI. Talk to your healthcare provider about birth control methods that may be right for you.
- Tell your healthcare provider right away if you become pregnant or think that you may be pregnant.

#### Males with female partners who can become pregnant:

- You should use effective birth control when sexually active during treatment with LYTGOBI and for 1 week after your last dose of LYTGOBI.
- are breastfeeding or plan to breastfeed. It is not known if LYTGOBI passes into your breast milk. Do not breastfeed during treatment and for 1 week after your last dose of LYTGOBI.

**Tell your healthcare provider about all the medicines you take**, including prescription and over-the-counter medicines, vitamins, and herbal supplements. LYTGOBI and other medicines may affect each other causing side effects. LYTGOBI may affect the way other medicines work, and other medicines may affect how LYTGOBI works.

### How should I take LYTGOBI?

- Take LYTGOBI exactly as your healthcare provider tells you.
- Take LYTGOBI 1 time each day with or without food at about the same time each day. You will continue for as long as your healthcare provider tells you to.
- Swallow LYTGOBI tablets whole. **Do not** crush, chew, split, or dissolve LYTGOBI tablets. Tell your healthcare provider if you have problems swallowing LYTGOBI tablets whole.
- You should not eat or drink grapefruit products during treatment with LYTGOBI.
- Your healthcare provider may change your dose of LYTGOBI, or may temporarily or completely stop treatment if you get certain side effects.
- If you miss a dose of LYTGOBI, you can take the missed dose within 12 hours on the same day. If more than 12 hours have passed, do not make up the dose. Take your regular dose of LYTGOBI the next day at the usual time. **Do not** take more LYTGOBI than prescribed to make up for the missed dose.
- If you vomit after taking LYTGOBI, **do not** take another LYTGOBI tablet. Take your regular dose of LYTGOBI the next day at the usual time.

### What are the possible side effects of LYTGOBI?

#### LYTGOBI may cause serious side effects, including:

- **Eye problems.** Certain eye problems are common with LYTGOBI but can also be serious. Eye problems include dry eye or inflamed eyes, inflamed cornea (front part of the eye), increased tears, and a disorder of the retina (an internal part of the eye). You will need to see an eye specialist for a complete eye exam before you begin treatment with LYTGOBI, every 2 months for the first 6 months, and every 3 months thereafter during treatment with LYTGOBI.

- **Tell your healthcare provider right away** if you develop any changes in your vision during treatment with LYTGObI, including blurred vision, flashes of light, or seeing black spots. You may need to see an eye specialist right away.
- You should use artificial tears or substitutes, or hydrating or lubricating eye gels during treatment with LYTGObI to prevent or treat dry eyes.
- **High phosphate levels in your blood (hyperphosphatemia) and build up of minerals in different tissues in your body.** Hyperphosphatemia is common with LYTGObI but can also be serious. High levels of phosphate in your blood may lead to buildup of minerals such as calcium, in different tissues in your body. Your healthcare provider will check your blood phosphate levels during treatment with LYTGObI.
  - Your healthcare provider may prescribe changes in your diet or phosphate lowering therapy, or change, interrupt or stop LYTGObI if needed.
  - Tell your healthcare provider right away if you develop any muscle cramps, or numbness or tingling around your mouth.

**The most common side effects of LYTGObI include:**

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| <ul style="list-style-type: none"> <li>• changes in kidney function blood tests</li> <li>• increased blood glucose level</li> <li>• decreased red blood cell, white blood cell, and platelet counts</li> <li>• increased calcium level in the blood</li> <li>• decreased sodium and phosphate levels in the blood</li> <li>• changes in liver function blood tests</li> <li>• nails separate from the bed or poor formation of the nail; change in the color of nails</li> <li>• muscle pain</li> <li>• constipation</li> <li>• diarrhea</li> <li>• feeling tired or weak</li> <li>• changes in tests used to measure your blood clotting time</li> <li>• dry mouth</li> </ul> | <ul style="list-style-type: none"> <li>• hair loss</li> <li>• decreased protein level (albumin) in the blood</li> <li>• mouth sores</li> <li>• stomach area (abdominal) pain</li> <li>• dry skin</li> <li>• decreased glucose and potassium level in the blood</li> <li>• joint pain</li> <li>• changes in sense of taste</li> <li>• dry eye</li> <li>• nausea</li> <li>• decrease in appetite</li> <li>• urinary tract infection</li> <li>• redness, swelling, peeling or tenderness, mainly on the hands or feet (hand-foot syndrome)</li> <li>• vomiting</li> </ul> |
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These are not all the possible side effects of LYTGObI. For more information, ask your healthcare provider or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

**How should I store LYTGObI?**

- Store LYTGObI at room temperature between 68°F to 77°F (20°C to 25°C).

**Keep LYTGObI and all medicines out of the reach of children.**

**General information about the safe and effective use of LYTGObI.**

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use LYTGObI for a condition for which it is not prescribed. Do not give LYTGObI to other people, even if they have the same symptoms you have. It may harm them. If you would like more information, talk with your healthcare provider. You can ask your pharmacist or healthcare provider for information that is written for healthcare professionals.

**What are the ingredients in LYTGObI?**

**Active ingredient:** futibatinib

**Inactive ingredients:** corn starch, crospovidone, hydroxypropyl cellulose, lactose monohydrate, magnesium stearate, mannitol, microcrystalline cellulose, and sodium lauryl sulfate.

The film coating material contains: hypromellose, magnesium stearate, polyethylene glycol, and titanium dioxide.

Manufactured for: Taiho Pharmaceutical Co., Ltd. Japan

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For more information, go to [www.LYTGObI.com](http://www.LYTGObI.com) or call 1-844-878-2446.

This Patient Information has been approved by the U.S. Food and Drug Administration.

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