

# LYTGOBI AND YOU

A guide to help you through treatment for intrahepatic cholangiocarcinoma (bile duct cancer) with LYTGOBI® (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.

LYTGOBI is approved based on tumor response and duration of response. There are ongoing studies to show if LYTGOBI improves survival or symptoms.

## Selected Important Safety Information

**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 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.

**Please see Important Safety Information throughout and full Prescribing Information in pocket or at [LYTGOBI.com/PI](https://www.lytgo.com/PI).**



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(futibatinib) tablets 4 mg

## ABOUT THIS GUIDE

This guide is a resource for you as you start oral treatment (taken by mouth) with LYTGObI® (futibatinib) tablets for bile duct cancer (which is sometimes called cholangiocarcinoma, or CCA).

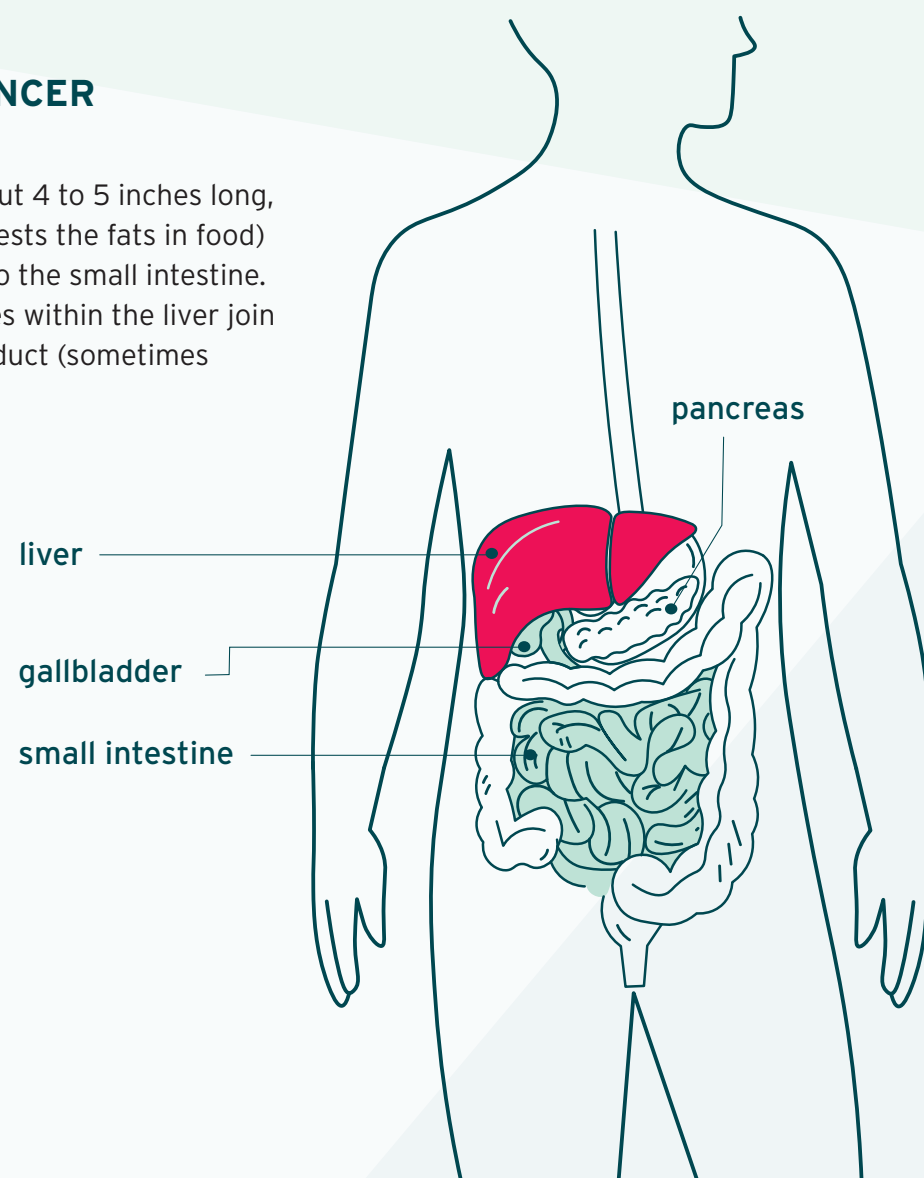
It's important to follow your healthcare provider's instructions for taking LYTGObI. This guide serves as a reminder of those instructions. Always contact your healthcare provider if you have questions, or if you have any problems taking your medication as instructed.

The terms in **purple** are defined at bottom of the pages, throughout this brochure.

## ABOUT BILE DUCT CANCER

### What are bile ducts?

The bile duct is a thin tube, about 4 to 5 inches long, that moves bile (a fluid that digests the fats in food) from the liver and gallbladder to the small intestine. Many smaller ducts and ductules within the liver join together to form the main bile duct (sometimes called the "common bile duct").



## GLOSSARY

**Extrahepatic** bile duct cancer starts outside of the liver. The category is split into 2 types, called distal and perihilar.

**Intrahepatic** bile duct cancer is found inside the liver.

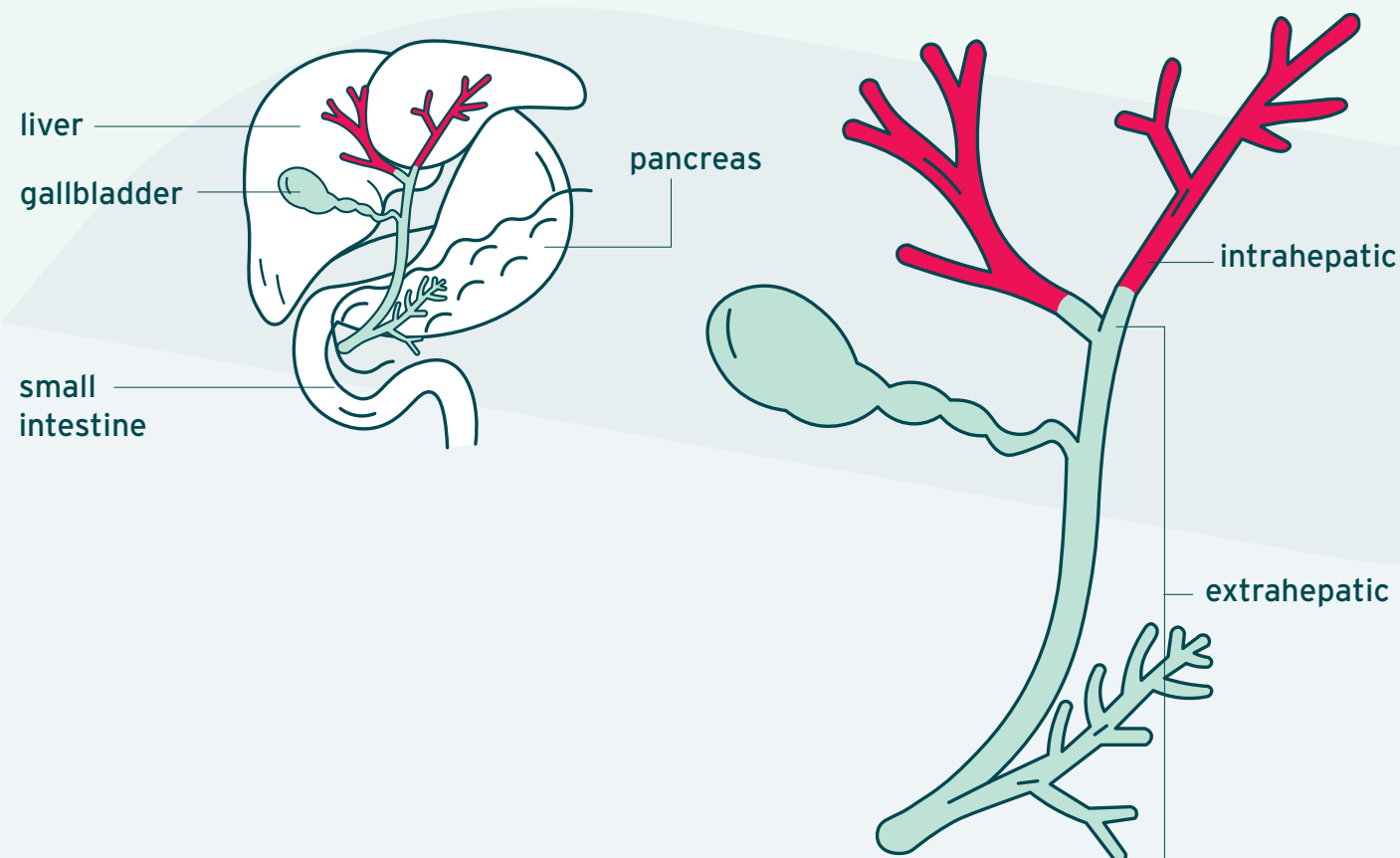
Please see Important Safety Information throughout and full Prescribing Information in pocket or at [LYTGObI.com/PI](https://www.lytgo.com/PI).

### How common is bile duct cancer?

Bile duct cancer is a rare cancer, with about 8,000 new cases in the United States per year. Rare cancers are those with fewer than 40,000 new cases nationally per year.

### Types of bile duct cancer

There are 2 different types of bile duct cancer, based on where the cancer is found in the bile duct system. **Intrahepatic** bile duct cancer forms in bile ducts inside the liver, while **extrahepatic** bile duct cancer forms outside the liver.



### Selected Important Safety Information

- **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 tear substitutes or hydrating or lubricating eye gels during treatment with LYTGObI to help prevent or treat dry eyes.
- **High phosphate levels in your blood (hyperphosphatemia) and buildup 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.



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## TREATING BILE DUCT CANCER

If you were prescribed LYTGObI® (futibatinib) tablets, that means you have already been through **biomarker** testing and your tumor has an abnormal **FGFR2** gene.

Whether or not a tumor has gene mutations (and the kind of mutations, if any) is what makes each case of bile duct cancer unique.

- There are about 25 known mutations associated with bile duct cancer, including **FGFR2** gene mutations
- **FGFR2** gene mutations are found in 10%-16% of intrahepatic bile duct cases

### Types of treatment for bile duct cancer

Treatment options may vary depending on the size, location, and stage of the tumor, and if you have previously been treated for bile duct cancer. You may have heard of **chemotherapy** as a treatment for bile duct cancer. Chemotherapy cannot distinguish between healthy and unhealthy cells, so it sometimes causes harm while trying to kill cancer cells.

There is another type of therapy for bile duct cancer that may be used alongside or after chemotherapy, called **targeted therapy**. In bile duct cancer, targeted therapy works by aiming for cells that have specific mutations, which is intended to target cancer cells while limiting damage to healthy cells.

Targeted therapy can do different things to the cancer cells they target, such as:

- Block or turn off signals that tell cancer cells to grow and divide
- Prevent cells from living longer than normal
- Destroy cancer cells

## GLOSSARY

An **abnormal gene** is a mutation, which can include fusions (when parts of two different genes join together), rearrangements (when genetic materials get reshuffled), and aberrations (when the DNA in the gene changes).

**Biomarkers** are characteristics of the body that can be measured to help identify if a specific disease is present. Biomarker testing is a way to look for genes, proteins, and other substances (called biomarkers or tumor markers) that can provide information about cancer.

**Chemotherapy** The use of cytotoxic agents, or medicines that kill cells. Chemotherapy works by controlling abnormal cells, but it may harm healthy cells in the process. Side effects can occur as a result. Chemotherapy is working well when normal blood cells start to grow again.

**FGFR2** is a type of fibroblast growth factor receptor, a group of genes that act as important biomarkers.

**Metastatic** means that the cancer has spread to other parts of the body.

**Previously treated** means that you have taken a treatment for your bile duct cancer in the past, such as chemotherapy or another targeted therapy.

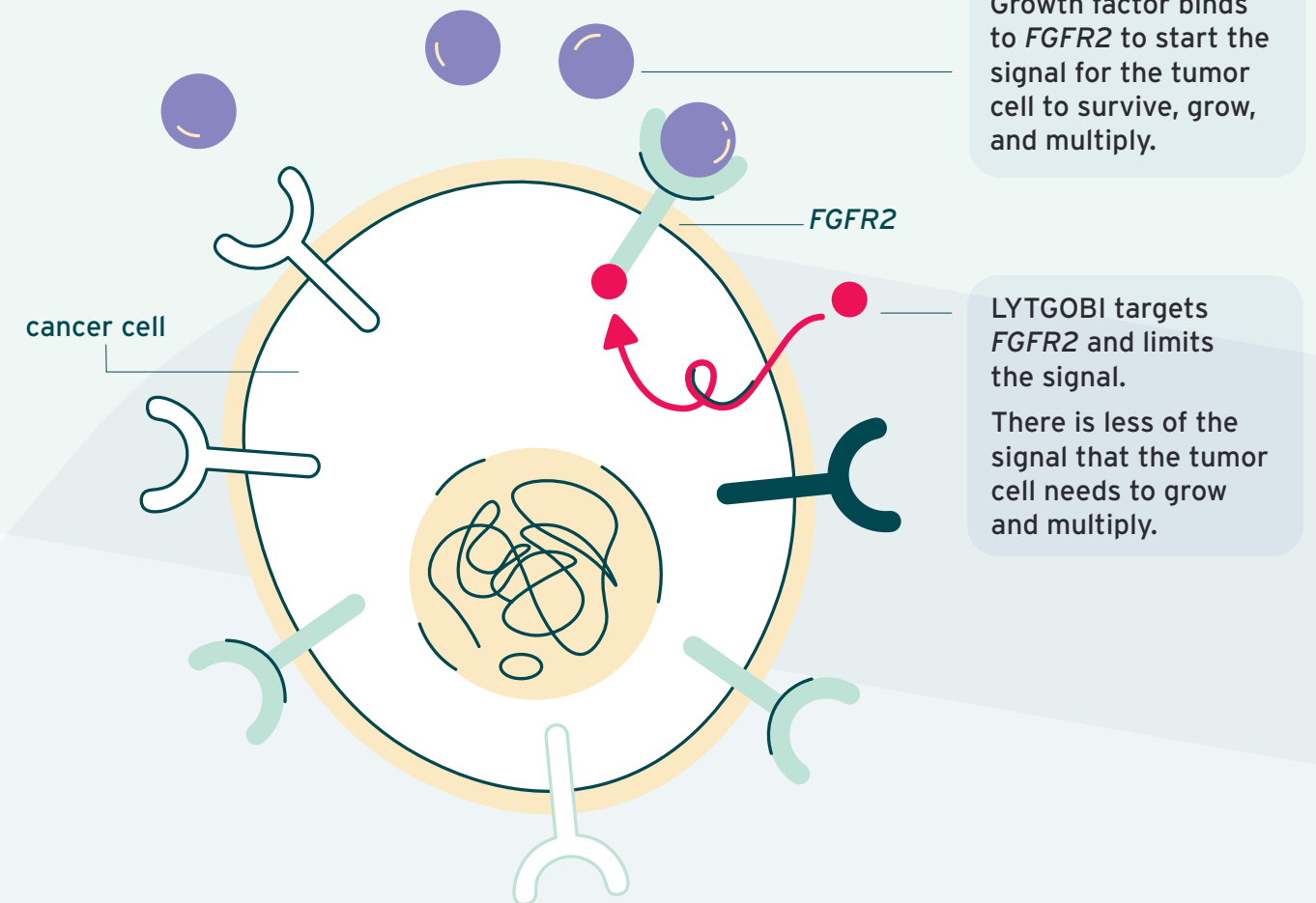
**Targeted therapy** uses medicine to target specific genes and proteins that are involved in the growth and survival of cancer cells while limiting damage to healthy cells.

**Please see Important Safety Information throughout and full Prescribing Information in pocket or at [LYTGObI.com/PI](https://www.lytgo.com/PI).**

## ABOUT LYTGObI

### How LYTGObI works

Growth factors help cancer cells grow and make copies. As a targeted therapy, LYTGObI blocks **FGFR2** receptors on the tumor cells (or cancer cells) from receiving the growth factor signal, in order to help keep the cancer cells from growing.



### Who should take LYTGObI?

LYTGObI is indicated for the treatment of adult patients with locally advanced or **metastatic** bile duct cancer (intrahepatic cholangiocarcinoma), whose tumor has an **abnormal FGFR2 gene** that cannot be removed by surgery and who have been **previously treated**.

You should talk to your healthcare provider about the type of bile duct cancer you have, and whether LYTGObI is an appropriate treatment option for you.

## Selected Important Safety Information

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

- changes in kidney function
- increased blood glucose level
- decreased red blood cell, white blood cell, and platelet counts
- increased calcium level in the blood
- decreased sodium and phosphate levels in the blood
- changes in liver function blood tests
- nails separate from the bed or poor formation of the nail; change in the color of nails
- muscle pain
- constipation
- diarrhea
- feeling tired or weak
- changes in tests used to measure your blood clotting time
- dry mouth



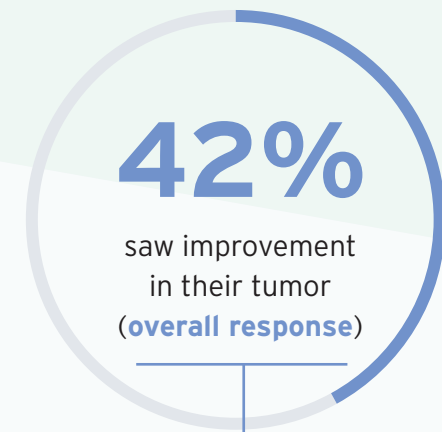
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## TREATMENT WITH LYTGOBI

### LYTGOBI in a clinical trial

In a clinical trial of 103 patients with locally advanced or metastatic bile duct cancer (intrahepatic cholangiocarcinoma) that has been previously treated and that cannot be removed by surgery, LYTGOBI® (futibatinib) tablets were shown to provide a response for some patients.



- 42% saw their tumor shrink in size (partial response)

The **median** time for them to see a response with LYTGOBI was **2.5 months** (range 0.7-7.4 months).

The median duration of response was **9.7 months**.

Of those patients that responded to treatment:

- **72%** or 31 people had responses that lasted 6 months or more.
- **14%** or 6 people had responses that lasted up to a year or longer

LYTGOBI is approved based on tumor response and duration of response. There are ongoing studies to show if LYTGOBI improves survival or symptoms.

## GLOSSARY

A **complete response** is the disappearance of all signs of cancer in response to treatment. This does not always mean the cancer has been cured.

The **median** is the middle value of a range of values.

An **overall response** is the percentage of people in a study who have a partial or complete response to the treatment within a certain period of time.

A **partial response** is a decrease in the size of a tumor, or in the extent or amount of cancer in the body, in response to treatment.

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## HOW TO TAKE LYTGOBI

### Straightforward, continuous, once-daily dosing



Tablets shown are at actual size.



Swallow 5 LYTGOBI tablets (4 mg each, 20 mg total) once a day at about the same time, with or without food. Do not change your dose or stop taking LYTGOBI unless your healthcare provider tells you to.

LYTGOBI can be taken with or without food. You should not eat or drink grapefruit products during treatment with LYTGOBI. You may want to take it when you first wake up or right before you go to sleep. Take your LYTGOBI dose at the same time each day, unless otherwise instructed by your healthcare provider.

If you miss a dose, you can take it within 12 hours on the same day. If it has been more than 12 hours, or if you vomit a dose, do not make up for that dose. Continue with the next scheduled dose. Always advise your healthcare provider if you accidentally miss a dose of LYTGOBI.

Remember to swallow the tablets whole—do not crush, chew, split, or dissolve them.

**Remember: Day one is row 1. Each row of tablets equals one daily dose.** Each card contains one week's worth of LYTGOBI tablets. Alternative dose packs are available if your healthcare provider prescribes a new dose.

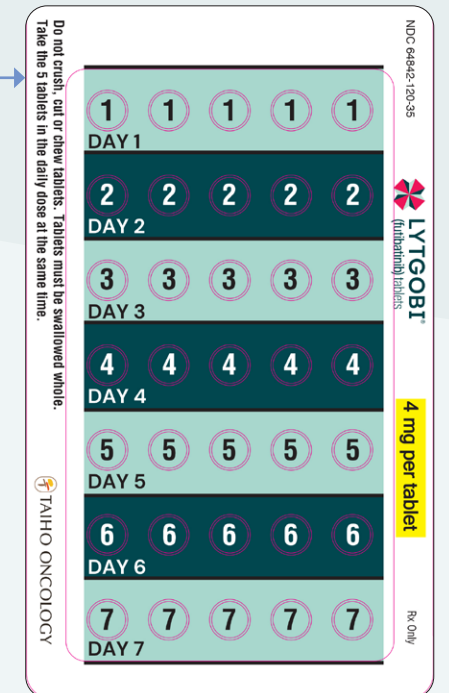
## HOW TO STORE LYTGOBI

- Store LYTGOBI at room temperature between 68°F and 77°F (20°C and 25°C)
- Do not store LYTGOBI outside of the original packaging
- Talk to your healthcare provider about how to safely dispose of LYTGOBI

## Selected Important Safety Information

### The most common side effects of LYTGOBI include (continued):

- hair loss
- decreased protein level (albumin) in the blood
- mouth sores
- stomach area (abdominal) pain
- dry skin
- decreased glucose and potassium level in the blood
- joint pain
- changes in sense of taste
- dry eye
- nausea
- decrease in appetite
- urinary tract infection
- redness, swelling, peeling or tenderness, mainly on the hands or feet ("hand-foot syndrome")
- vomiting



## POSSIBLE SIDE EFFECTS

You may experience side effects during treatment with LYTGOBI® (futibatinib) tablets. Talk to your healthcare provider if you notice anything out of the ordinary with your health while taking LYTGOBI. Serious side effects with LYTGOBI include eye problems\* and high phosphate levels in your blood.†

Below is a list of some of the additional possible side effects of LYTGOBI.

- nails separated from the bed or poor formation of the nail
- change in the color of nails
- muscle pain
- constipation
- diarrhea
- feeling tired or weak
- dry mouth
- hair loss
- mouth sores
- stomach area (abdominal) pain
- dry skin
- joint pain
- changes in sense of taste
- dry eye
- nausea
- decrease in appetite
- urinary tract infection
- redness, swelling, peeling or tenderness, mainly on the hands or feet (hand-foot syndrome)
- vomiting

Your healthcare provider may use blood tests and other laboratory tests to monitor possible side effects such as changes in kidney or liver function, increased blood glucose level, and decreased red blood cell, white blood cell, and platelet counts.‡

**These are not all the possible side effects of LYTGOBI.**

\*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. Please see the full Prescribing Information for instructions.

†Tell your healthcare provider right away if you develop any muscle cramps, or numbness or tingling around your mouth, as this is a more serious side effect.

‡See the Prescribing Information for a full list of possible side effects that your healthcare provider will monitor with blood tests.

## MANAGEMENT OF SOME COMMON SIDE EFFECTS

You should always talk to your healthcare provider about any side effects you experience. Your healthcare provider will know the best way to help manage side effects, including prescribe an additional medication, lower your dose of LYTGOBI, or may temporarily or completely stop treatment with LYTGOBI.

**Some side effects can be managed at home.** In addition to your healthcare provider's advice, here are some tips to help manage some of the common side effects of LYTGOBI.

### Diarrhea

- Try eating smaller meals throughout the day instead of 3 large meals
- Eat foods that are low in fiber and high in sodium or potassium. You can ask your healthcare provider for suggestions on specific foods
- Contact your healthcare provider if your diarrhea lasts more than 24 hours, or if you have pain or cramping

### Dry mouth

- Sip water throughout the day or suck on ice chips, sugar-free candy, or chew sugar-free gum
- If your mouth is always dry, ask your healthcare provider about saliva substitutes

### Hair loss

- Be gentle when you wash your hair; use mild shampoo and pat dry
- Avoid items that can hurt your scalp, such as heat-powered styling tools, hairspray or hair dye, or hair bands and clips
- Protect your scalp during and after hair loss by wearing a hat, turban, or scarf while you are outside, and avoid extreme temperatures
- Use a satin pillowcase to avoid friction while sleeping

### Dry skin

- Take quick showers or sponge baths using a mild, moisturizing soap
- Pat yourself dry and apply moisturizing lotion while your skin is still damp after bathing
- Avoid toiletries containing alcohol

### Constipation

- Try to be active every day by walking or doing light exercise
- Eat foods that are high in fiber, such as whole-grain breads and cereals. You can also ask your healthcare provider for suggestions on specific foods
- Talk to your healthcare provider if you do not have a bowel movement for 2 days. They may suggest a fiber supplement, laxative, stool softener, or enema. Do not use these treatments without your healthcare provider's approval

### Tiredness

- Try relaxing activities like meditation or yoga
- Plan time to rest during the day
- Try to get at least 8 hours of sleep at night
- Try low-effort exercises like short walks to stay active

**HEALTHY REMINDER**  
**Try to eat well and drink at least 8 cups of water or other fluids each day.**

## Selected Important Safety Information

These are not all the possible side effects of LYTGOBI. For more information, talk to your healthcare provider or pharmacist. You may report side effects to FDA at 1-800-FDA-1088.



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## PATIENT SUPPORT

### Taiho Oncology Patient Support™

Taiho Oncology Patient Support™ is here to help you obtain access to your Taiho Oncology medicine.



The program offers a benefits review to confirm coverage, co-pay assistance enrollment,\* specialty pharmacy prescription coordination, and personalized nurse support for patients taking LYTGOBI® (futibatinib) tablets. Visit [TaihoPatientSupport.com](https://www.taihopatient.com) to find support now.

### Financial assistance

We offer financial support, depending on the type of insurance you have, including:

- **\$0 Co-pay assistance enrollment\***
- Alternate funding education and support for publicly insured patients (such as patients with low-income subsidy and those on Medicare)
- Patient Assistance program that provides financial assistance for eligible patients who have insufficient or no prescription insurance

Talk to your healthcare provider about personalized nurse support† to help with dose refills and education about treatment with LYTGOBI.

### Additional services include:

- Insurance support: Taiho Oncology Patient Support™ will welcome you and explain your insurance benefits
- Reimbursement support: A reimbursement specialist will confirm your access to LYTGOBI or assist you in applying for financial assistance
- Specialty pharmacy program: The specialty pharmacy will call you to discuss payment and shipment
- You will receive your prescription of LYTGOBI from the specialty pharmacy, physician, or hospital, and it will have instructions for use to begin your treatment



Talk to your healthcare provider about how to enroll.  
To learn more, visit [TaihoPatientSupport.com](https://www.taihopatient.com) or call  
**1-844-TAIHO-4U** (1-844-824-4648) Monday to Friday, 8 AM to 8 PM ET

\*For commercially insured, eligible patients. Visit [TaihoPatientSupport.com](https://www.taihopatient.com) to see full eligibility criteria.

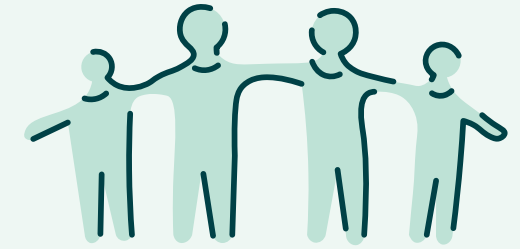
†If selected on the Patient Enrollment Form, a Nurse Navigator will be assigned to provide telephone support and will address general inquiries about LYTGOBI treatment.

Please see Important Safety Information throughout and full Prescribing Information in pocket or at [LYTGOBI.com/PI](https://www.lytgo.com/PI).

## COMMUNITY SUPPORT

You may not know anyone else with bile duct cancer, but you are not alone. It is important to have someone to talk to about bile duct cancer and how it affects you.

The following organizations can support you on your treatment journey and connect you with other bile duct cancer patients and caregivers. They also offer educational resources, as well as opportunities for financial support.



### Bile duct cancer support

#### Cholangiocarcinoma Foundation

- Visit [cholangiocarcinoma.org](https://www.cholangiocarcinoma.org)
- Call 1-888-936-6731, ext. 8
- Email [advocacy@curecca.org](mailto:advocacy@curecca.org) for general information

#### TargetCancer Foundation

- Visit [targetcancerfoundation.org](https://www.targetcancerfoundation.org)
- Call 1-617-765-4881
- Email [info@targetcancerfoundation.org](mailto:info@targetcancerfoundation.org) for general information

### General cancer support

#### American Society of Clinical Oncology

- Visit [Cancer.net](https://www.cancer.net)
- Call 1-888-651-3038
- Email [contactus@cancer.net](mailto:contactus@cancer.net)

#### American Cancer Society

- Visit [Cancer.org](https://www.cancer.org)
- Call 1-800-227-2345
- Online chat available Monday to Friday, 7:00 AM to 6:30 PM CT

#### National Cancer Institute

- Visit [Cancer.gov](https://www.cancer.gov)
- Call 1-800-4-CANCER (1-800-422-6237) Monday to Friday, 9:00 AM to 9:00 PM ET
- LiveHelp online chat available Monday to Friday, 9:00 AM to 9:00 PM ET
- Email [NClinfo@nih.gov](mailto:NClinfo@nih.gov) for general information

## Selected Important Safety Information

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.



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For more information about treatment with LYTGOBI® (futibatinib) tablets, visit [LYTGOBI.com](https://LYTGOBI.com)

For financial support or help with insurance, visit [TaihoPatientSupport.com](https://TaihoPatientSupport.com) or call **1-844-TAIHO-4U** (1-844-824-4648) Monday to Friday, 8 AM to 8 PM ET.



## Selected Important Safety Information

### 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 final 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 final 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.

**Please see Important Safety Information throughout and full Prescribing Information in pocket or at [LYTGOBI.com/PI](https://LYTGOBI.com/PI).**



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