

Futibatinib (Lytgobi)

About This Medicine

FUTIBATINIB (FUE ti BA ti nib) treats bile duct cancer. It works by blocking a protein that causes cancer cells to grow and multiply. This helps to slow or stop the spread of cancer cells. It is given orally (by mouth).

This medicine may be used for other purposes; ask your care team if you have questions.

Possible Side Effects

- Bone marrow suppression. This is a decrease in the number of white blood cells, red blood cells, and platelets. This may raise your risk of infection, make you tired and weak, and raise your risk of bleeding
- Decrease in a blood protein called albumin
- Dry eyes
- Soreness of the mouth and throat. You may have red areas, white patches, or sores that hurt.
- Dry mouth
- Nausea and vomiting (throwing up)
- Constipation (not able to move bowels)
- Diarrhea (loose bowel movements)
- Tiredness
- Pain in your abdomen
- Decreased appetite (decreased hunger)
- Urinary tract infection
- Blood sugar levels may change
- Changes in your kidney and liver function
- Changes in tests that measures how long it takes for your blood to clot
- Electrolytes changes
- Joint, bone and muscle pain
- Changes in the way food and drinks taste
- Dry skin
- Hair loss. Hair loss is often temporary, although with certain medicine, hair loss can sometimes be permanent. Hair loss may happen suddenly or gradually. If you lose hair, you may lose it from your head, face, armpits, pubic area, chest, and/or legs. You may also notice your hair getting thin.
- Changes in your nails and/or nail loss

- Hand-foot syndrome. The palms of your hands or soles of your feet may tingle, become numb, painful, swollen, or red.

Note: Each of the side effects above was reported in 20% or greater of people treated with futibatinib. All possible side effects are not included. Your side effects may be different depending on your cancer diagnosis, condition, or if you are receiving other medicines in combination. Please discuss any concerns or questions with your care team.

Warnings and Precautions

- Blurred vision or other changes in eyesight such as dry or inflamed eyes, increased tears, inflamed cornea, and/or problems with the retina (thin membrane that covers the back of the eye). Eye exams are recommended during your treatment.
- Increased phosphate level in your blood. You may require phosphate lowering treatment such as medicines and/or a low phosphate diet.

Note: Some of the side effects above are very rare. If you have concerns and/or questions, please discuss them with your care team.

How to Take Your Medicine

- Swallow the medicine whole, with or without food, at approximately the same time each day. Do not chew, crush, split, or dissolve it.
- **Missed dose:** If you miss a dose by less than 12 hours, take it as soon as you think about it. If you miss a dose by 12 hours or more, then skip the missed dose and take your next dose at the regular time. Do not replace a vomited dose.
- **Overdosage:** If you think you have taken too much of this medicine contact a poison control center or emergency room at once.
- **Handling:** Wash your hands with soap and water, before and after handling your medicine. Your caretakers should not handle your medicine with bare hands and should wear latex gloves.
- This medicine may be present in the urine, stool and other body fluids such as blood, vomit, semen, and vaginal fluids. Take precautions to prevent others from coming in contact with your medicine or your body fluids. Follow safety precautions during your treatment and for as long as directed by your care team after your treatment. If you take a pill each day, follow these precautions every day.
- **Storage:** Store this medicine in the original container at room temperature. Keep out of the reach of children and pets.
- **Disposal of unused medicine:** Do not flush any expired and/or unused medicine down the toilet or drain unless you are specifically instructed to do so on the medicine label. Some facilities have take-back programs and/or other options. If you do not have a take-back program in your area, then please discuss with your care team how to dispose of unused medicine.

Treating Side Effects

- Manage tiredness by pacing your activities for the day.



- Be sure to include periods of rest between energy-draining activities.
- Get regular exercise, with your care team's approval. If you feel too tired to exercise vigorously, try taking a short walk.
- To decrease the risk of infection, wash your hands regularly.
- Avoid close contact with people who have a cold, the flu, or other infections.
- Take your temperature as your care team tells you, and whenever you feel like you may have a fever.
- To help decrease the risk of bleeding, use a soft toothbrush. Check with your care team before using dental floss.
- Be very careful when using knives or tools.
- Use an electric shaver instead of a razor.
- Drink enough fluids to keep your urine pale yellow.
- If you throw up or have diarrhea, you should drink more fluids so that you do not become dehydrated (lack of water in the body from losing too much fluid).
- To help with nausea and vomiting, eat small, frequent meals instead of three large meals a day. Choose foods and drinks that are at room temperature. Ask your care team about other helpful tips and medicine that is available to help stop or lessen these symptoms.
- Mouth care is very important. Your mouth care should consist of routine, gentle cleaning of your teeth or dentures and rinsing your mouth with a mixture of 1/2 teaspoon of salt in 8 ounces of water or 1/2 teaspoon of baking soda in 8 ounces of water. This should be done at least after each meal and at bedtime.
- If you have mouth sores, avoid mouthwash that has alcohol. Also avoid alcohol and smoking because they can bother your mouth and throat.
- Taking good care of your mouth may help food taste better and improve your appetite.
- Sugar-free hard candies and chewing gum can keep your mouth moist.
- If you have diarrhea, eat low-fiber foods that are high in protein and calories and avoid foods that can irritate your digestive tracts or lead to cramping.
- If you are not able to move your bowels, check with your care team before you use enemas, laxatives, or suppositories.
- Ask your care team about medicine that can lessen or stop diarrhea and/or constipation.
- To help with decreased appetite, eat small, frequent meals. Eat foods high in calories and protein, such as meat, poultry, fish, dry beans, tofu, eggs, nuts, milk, yogurt, cheese, ice cream, pudding, and nutritional supplements.
- Consider using sauces and spices to increase taste. Daily exercise, with your care team's approval, may increase your appetite.
- If you have diabetes, keep good control of your blood sugar level. Tell your care team if your glucose levels are higher or lower than normal.
- To help with hair loss, wash with a mild shampoo and avoid washing your hair every day. Avoid coloring your hair.
- Avoid rubbing your scalp, pat your hair or scalp dry.
- Limit your use of hair spray, electric curlers, blow dryers, and curling irons.
- If you are interested in getting a wig, talk to your care team and they can help you get in touch with programs in your local area.
- Moisturize your skin several times a day. Keeping your nails moisturized may help with brittleness.
- Avoid sun exposure and apply sunscreen routinely when outdoors.



- If you get a rash do not put anything on it unless your care team says you may. Keep the area around the rash clean and dry. Ask your care team for medicine if your rash bothers you.
- If you have dry eyes, you should use artificial tears, hydrating or lubricating eye gels to help prevent or treat dry eyes. Ask your care team for more information about which product they recommend for you.
- Keeping your pain under control is important to your well-being. Please tell your care team if you are experiencing pain.

Food and Medicine Interactions

- Avoid grapefruit and grapefruit juice while taking this medicine as it may raise the levels of futibatinib in your body which could make side effects worse.
- Check with your care team about all other prescription medicines and over-the-counter medicines and dietary supplements (vitamins, minerals, herbs, and others) you are taking before starting this medicine as there are known medicine interactions with futibatinib. Also, check with your care team before starting any new prescription or over-the-counter medicines, or dietary supplements to make sure that there are no interactions.
- This medicine may interact with St. John's Wort and may lower the levels of the medicine in your body, which can make it less effective.

When to Call Your Care Team

Call your care team if you have any of these symptoms and/or any new or unusual symptoms:

- Fever of 100.4° F (38° C) or higher
- Chills
- Feeling dizzy or lightheaded
- Easy bleeding or bruising
- Tiredness and/or weakness that interferes with your daily activities
- Dry and/or itchy eye
- Blurred vision or other changes in eyesight
- Flashes of light and/or dark areas (black spots) in your field of vision
- Pain in your abdomen that does not go away
- Nausea that stops you from eating or drinking and/or is not relieved by prescribed medicines
- Throwing up more than 3 times a day
- Pain in your mouth or throat that makes it hard to eat or drink
- Trouble eating/swallowing
- Diarrhea, 4 times in one day or diarrhea with lack of strength or a feeling of being dizzy
- No bowel movement in 3 days or when you feel uncomfortable
- Lasting loss of appetite or rapid weight loss of five pounds in a week
- Changes in the way food and drink taste that is causing a loss of appetite
- Signs of a urinary tract infection such as burning or pain when you pass urine, trouble urinating, smelly and/or cloudy urine, pain in your lower abdomen or lower/side of your back.



- Signs of high phosphate: muscle cramps and/or numbness or tingling around your mouth
- Abnormal blood sugar
- Signs of high blood sugar: unusual thirst, passing urine often, headache, sweating, shakiness, irritability
- Signs of low blood sugar: feeling sleepy, increased hunger, sweating, shakiness, irritability
- Pain that does not go away, or is not relieved by prescribed medicines
- Decreased or very dark urine
- Signs of possible liver problems: dark urine, pale bowel movements, pain in your abdomen, feeling very tired and weak, unusual itching, or yellowing of the eyes or skin
- Swelling of the hands, feet, or any other part of the body
- Signs of inflammation/infection (redness, swelling, pain) of the tissue around your nails
- Painful, red, or swollen areas on your hands or feet.
- Numbness and/or tingling of your hands and/or feet
- Dry skin that is bothersome

Reproduction Warnings

- **Pregnancy warning:** This medicine can cause serious birth defects. If you can become pregnant, use birth control while taking this medicine and for 1 week after the last dose. If you can get your partner pregnant, use birth control while taking this medicine and for 1 week after the last dose. Tell your care team right away if you think you might be pregnant or think your partner might be pregnant.
- **Breastfeeding warning:** Do not breastfeed while taking this medicine and for 1 week after the last dose.
- **Fertility warning:** This medicine may affect your ability to have children in the future. If you plan to have children, talk with your care team.

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