AMMF
THE CHOLANGIOCARCINOMA CHARITY

Information for Patients

FUTIBATINIB
For biliary tract cancers

Precision BTC Network

European Network for the Study of Cholangiocarcinoma (ENS-CCA)

EUROPEAN COOPERATION IN SCIENCE & TECHNOLOGY

Funded by the European Union

Generated by Dr V Zanuso and Prof C Braconi (oncologists) and Ms H Morement (patient representative and CEO of AMMF – The Cholangiocarcinoma Charity). This material is based upon work from the European Network for the Study of Cholangiocarcinoma and the COST Action CA22125 Precision medicine in biliary tract cancer (Precision-BTC-Network) supported by COST (European Cooperation in Science and Technology: www.cost.eu.

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FUTIBATINIB for biliary tract cancers

If your doctor recommended the administration of FUTIBATINIB to treat your cancer, here is some important information about this medication and some aspects related to it.

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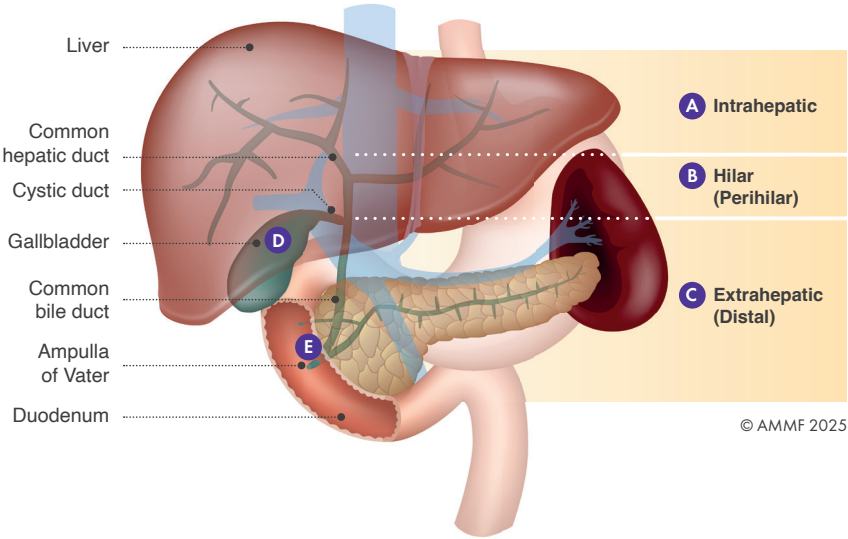
Biliary tract cancer

Biliary tract cancers develop from cells (called cholangiocytes) that normally make up the lining of the biliary system (depicted in green in the picture below). The biliary ducts are small tubes that connect the liver and gallbladder to the small bowel and normally carry the bile, which is a fluid that helps to digest food.



- **A** Intrahepatic cholangiocarcinoma
- **B** Hilar (Perihilar) cholangiocarcinoma
- **C** Extrahepatic (Distal) cholangiocarcinoma
- **D** Gallbladder cancer
- **E** Ampullary cancer

Biliary tract cancers include cholangiocarcinoma, gallbladder cancer and ampullary cancer:

- **Cholangiocarcinoma** – arises from the bile ducts. This cancer is further classified into three different types, depending on which part of the bile duct the cancer develops:
  - intrahepatic cholangiocarcinoma – the cancer develops in the ducts inside the liver
  - perihilar cholangiocarcinoma – it develops in the ducts just outside the liver
  - distal/extrahepatic cholangiocarcinoma – it develops in the ducts further away from the liver
- **Gallbladder cancer** – arises from the cells of the gallbladder
- **Ampullary cancer** – arises from the join between the bile ducts and the small bowel, called ampulla of Vater

You have been given this leaflet because you have been diagnosed with a biliary tract cancer. Your oncologist can discuss with you which biliary tract cancer you have and how extended it is.

What is FUTIBATINIB?

FUTIBATINIB is a targeted drug treatment for biliary tract cancers, and it is used when the cancer has a change in the gene producing the Fibroblast Growth Factor Receptor 2 (FGFR2). FUTIBATINIB is a tyrosine kinase inhibitor (TKI) that blocks tyrosine kinases, which are enzymes (chemical messengers) that favour cell growth. Blocking tyrosine kinases stops cell growth and proliferation.

How is FUTIBATINIB administered?

You will take FUTIBATINIB orally as tablets. The recommended starting dose is 20mg FUTIBATINIB (5 tablets of 4mg each) taken orally once daily. Treatment should be continued until disease progression or unacceptable toxicity. Tablets need to be swallowed with a glass of water and can be taken with or without food. Do not crush, chew, split or dissolve the tablets.

You should take the tablets at the same time, every day. If you miss a dose by more than 12 hours or vomiting occurs after taking a dose, an additional dose should not be taken, and treatment should be resumed with the next scheduled dose.

Do not take a double dose to make up for a missed dose.

Tell your doctor if you have taken more FUTIBATINIB than you should have.

Your doctor will tell you the exact dosage of FUTIBATINIB you will receive. Before you start this treatment, your doctor will collect information on your general health and underlying conditions. You will see an ophthalmologist before you start FUTIBATINIB, in order to assess the functional status of your eyes.

This drug contains lactose. If you are lactose intolerant, you should tell your doctor. Usually, this will not prevent you from receiving FUTIBATINIB, but those patients with rare hereditary problems of galactose intolerance, total lactase deficiency or glucose-galactose malabsorption should not take FUTIBATINIB.

Duration of FUTIBATINIB treatment

Your doctor will discuss the duration of your treatment with you. Take FUTIBATINIB for as long as it is prescribed by your doctor.

Side effects of the FUTIBATINIB treatment

There are known side effects with this treatment, but you may not experience any of them. This does not mean that the treatment is not working. There is no relationship between the presence or severity of side effects and the efficacy of the treatment.

You may get some of the side effects, but you are unlikely to get them all. Importantly, side effects are often predictable in terms of their onset, duration, and severity; they are almost always reversible and should completely go away after treatment. However, their frequency and severity may vary from person to person.

Fortunately, there are many medications available that can be taken during treatment to control and minimise the impact of any side effects you may have.

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 booklet.

Some of the most common side effects related to treatment (FUTIBATINIB)

Low sodium levels: Sodium is a mineral found in many foods. It is important for muscle and nerve functions, and it also keeps body fluids in balance. When the levels of sodium are low you may have headaches, feel sick, confused or restless. Your sodium will be regularly checked with blood tests during treatment. Sodium levels will go back to normal when you finish your treatment.

High or low phosphate levels: Phosphate is a mineral that is normally found in many foods (meat, fish, eggs, and cheese). An alteration of blood levels of phosphate can cause muscle cramps, bone weakness and confusion. Your phosphate levels will be regularly checked with blood tests during treatment. Your doctor might ask you to follow either a low or a high phosphate diet depending on your blood levels.

High levels of liver enzymes: High levels of liver enzymes may occur during treatment, therefore you will have blood tests regularly to check for this.

Taste changes: You may find that some foods taste different or you may not want certain foods and drinks because of their altered taste. Your taste will return to normal after the end of treatment.

Dry eyes: You may use eye drops to cope with this problem.

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Constipation or diarrhoea: In case of constipation, eating high-fibre foods (vegetables, fruit, wholemeal bread) and drinking at least 2 litres of water can help you. You may need laxatives if it lasts for longer than two/three days. In case of diarrhoea, you need to get in touch with your team if you have 4 or more loose stools (poos) in 24 hours. Your doctor will give you anti-diarrhoea medicines. Remember to drink plenty of water to replace fluids lost. You should eat low-fibre food and avoid raw fruits, fruit juice, cereals and vegetables. It can help to also avoid alcohol, caffeine, dairy products and high-fat-foods.

Sore mouth, sore throat, ulcers: Brushing your teeth every time after eating will help to avoid germs growing. Use a soft toothbrush and rinse three times a day with half to one teaspoon of baking soda mixed in water. Tell your doctor or nurse if you have ulcers, as they can help to prevent or to treat these mouth sores.

Dry mouth: If you have a dry mouth, talk to your healthcare team. They can give you artificial saliva to help, and it can also help to drink plenty of fluids.

Hand-foot syndrome: This is a condition in which the skin of your hands and feet may become sore and red or may peel. You may also have numbness, pain, and dryness. You may moisturise your skin regularly in order to reduce dryness. This usually gets back to normal after the end of the treatment.

Nail changes: Your nails may become darker or lighter during treatment. They might also be painful, separate from the nail bed and come off. The nails can also become infected. Tell your health care team if this happens.

Fatigue: A very common side effect, which may increase during the treatment course.

Hair loss: Your hair may get thinner, but it is unlikely that you will lose your hair.

Joint or muscle pain: If this happens, speak to your healthcare team for advice on the appropriate painkillers to take to help you.

Nausea: It is rarely accompanied by vomiting and it is usually well controlled by anti-sickness medications. Contact your doctor or nurse if they are not effective and you've been feeling sick more than once in a day.

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). Tell your healthcare team if you experience any of these symptoms.

Your eye functional status will be checked regularly by an ophthalmologist.

Abdominal pain: If you experience abdominal (tummy) pain, tell your doctor or nurse. They can check for the cause of the pain and give you medicine to help.

Occasionally abdominal pain can be due to a blockage in your bowel (bowel obstruction). This causes abdominal pain that comes and goes. Other symptoms include a swollen abdomen, feeling or being sick and difficulty having a poo.

A less common side effect related to treatment (FUTIBATINIB)

Migraine: this side effect can happen in between 1 and 10 out of every 100 people (between 1 and 10%).

Medication to help control side effects

Make sure to let your doctor know of any side effects, including any possible side effects you experience that are not listed above. There are useful medications to control the symptoms.

Should I continue to take my usual medications?

Tell your healthcare team about all medicines you are taking and they will advise you. This includes vitamins, herbal supplements and over the counter remedies. Also let them know about any other medical conditions or allergies you may have.

Other medicines, food and drink

Cancer drugs can interact with some other medicines, herbal products and food and drink. For example, patients should avoid grapefruit and grapefruit juice during FUTIBATINIB treatment, as they can increase drug levels and increase side effects. Speak to your healthcare team for further advice.

Treatment for other conditions

If you are having tests or treatment for anything else, always mention your cancer treatment. For example, if you are visiting your dentist.

Can I have the flu and COVID vaccination?

Yes, it is advised you have the flu and COVID vaccination before you start your treatment. If you have already started your treatment, please ask your doctor who can advise on the best timing to have the vaccination.

When to contact the hospital?

If your symptoms are severe or do not improve after 24 hours, do not hesitate to contact the hospital.

Hospital emergency contact:

Reporting side effects

If you get any side effects, talk to your healthcare team. This includes any possible side effects not listed in this booklet.

You can also report side effects directly via the Yellow Card Scheme, on the 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.

Tips during treatment

- Drink plenty of fluids (at least 2 litres per day).
- Maintain good nutrition. Eating small frequent meals may help to reduce nausea. You should avoid fatty or fried foods. You can take anti-sickness drugs if you need.
- Avoid sun exposure. Wear SPF 15 (or higher) sunblock and protective clothing.
- Get plenty of rest.
- Keep at home the medications you may need to help control the symptoms.
- Before starting treatment, tell your doctor about any medication you are taking. Sometimes side effects may be related to your medicines.
- If your symptoms are severe or do not improve after 24 hours, do not hesitate to contact the hospital.
- Do not receive any kind of vaccination without your doctor's approval while taking treatment.
- If you are a woman of childbearing age:
  - inform your doctor if you are pregnant or may be pregnant prior to starting this treatment
  - avoid getting pregnant during treatment
  - do not breastfeed during treatment

Notes

Where can I get more information?

Visit the ESMO website, for the booklet,
"Biliary tract cancer: Guide for Patients":

www.esmo.org/for-patients/patient-guides/biliary-tract-cancer-a-guide-for-patients

There is also information on biliary tract cancers on the website of AMMF – The Cholangiocarcinoma Charity:
www.ammf.org.uk/cholangiocarcinoma

You can also visit the Precision-BTC-Network COST action website:
www.precision-btc.eu/info/patientbrochures

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