

PEMIGATINIB for biliary tract cancers

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

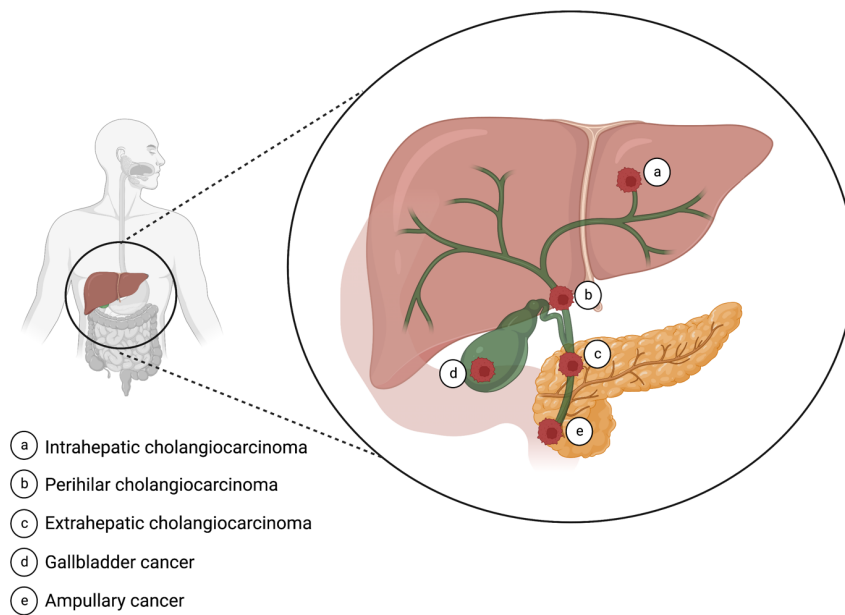
Biliary tract cancer

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.

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 PEMIGATINIB?

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

How is PEMIGATINIB administered?

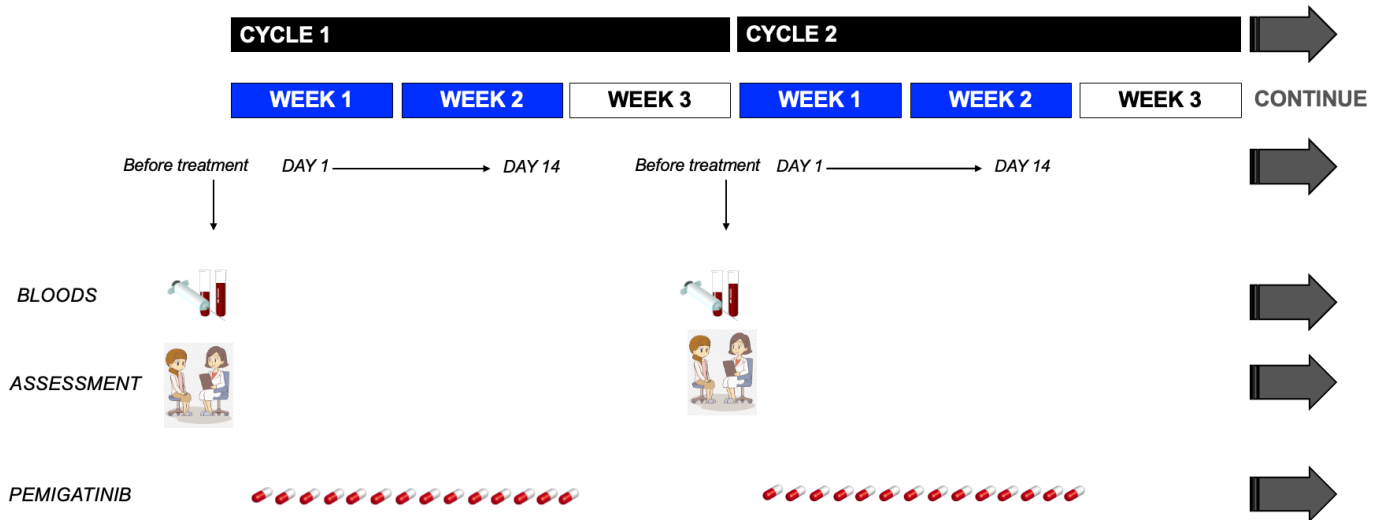
You will take pemigatinib orally as tablets. Tablets need to be swallow with a glass of water and can be taken with or without food. You should take the tablets at the same time, every day. You should not crush or chew the tablets. If you miss a dose, you should talk to your doctor or nurse.

Your doctor will tell you the exact dosage of pemigatinib 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 pemigatinib, in order to assess the functional status of your eye.

Schedule of PEMIGATINIB treatment

You will receive pemigatinib in cycles of treatment. The standard schedule of pemigatinib treatment follows a three-week cycle. You should take pemigatinib once a day for 14 days and then have a rest of 7 days. Before each cycle, you will have a blood test and your oncological team will check whether you are fit enough for the treatment. It is important that you report any symptom(s) and problem(s) since your last session so that the dose can be adjusted for you. The doctor may ask you to have the bloods taken at your GP practice the day before your treatment appointment.

PEMIGATINIB cycle: 2 weeks on, 1 week off



Duration of PEMIGATINIB treatment

The doctor will discuss the duration of your treatment with you. Each pemigatinib cycle will last for 3 weeks. If you are tolerating the treatment well, you will receive pemigatinib for at least 3 months before you will repeat scan to understand if the treatment is working. If the first 3 months scan shows your cancer is stable or shrinking, you may continue the treatment. You will continue taking pemigatinib for as long as the treatment is helping you. You will repeat a scan every 3 months.

What are the side effects of the PEMIGATINIB 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.

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

Low sodium levels: sodium is a mineral found in many foods. 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 restlessness. 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 whether a low or a high phosphate diet depending on your blood levels.

High creatinine levels: creatinine is a protein produced by muscle and removed by the kidneys from blood. Its levels can raise during treatment, therefore you will have blood tests regularly.

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

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.

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 poos (stools) 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.

Mouth sores, ulcers and dry mouth: you need to brush your teeth every time after eating to avoid germs growing. Use a soft toothbrush and rinse three times a day with 1/2 to 1 teaspoon of baking soda mixed in water. It's better to avoid acidic foods such as oranges, lemons, and grapefruits; tell your doctor or nurse if you have ulcers, as they can help to prevent or to treat mouth sores. If you have dry mouth, it can help to drink plenty of fluids.

Hand-foot syndrome: it 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. Your nails may become dry too, and they may change colour or develop ridges. This usually gets back to normal after the end of the treatment.

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 pain: if this happens, you may take painkillers like paracetamol.

Some less common side effects related to treatment (PEMIGATINIB)

Eye toxicity: you may experience blurred or loss vision. You may have a build-up of fluid under the coloured layer of the eye, that is called retina; this can cause a break in your retina. You may have also inflammation in the cornea, which is another part of the eye. You may also notice a change in your eyelashes, that may become long and grow inwards towards the eye. Your eye functional status will be checked regularly by an ophthalmologist.

Medication to help control side effects

Make sure to let your doctor know of any side effects; there are useful medications to control the symptoms.

Should I continue to take all my usual medications?

Yes, you have to keep taking all your usual medications. Please report to your oncology team all the medications you are taking, so that they can advise. Cancer drugs can have interaction with some other medicines and herbal products. You should not eat grapefruit or drink its juice because it can react with the drug.

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.

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

When to contact the hospital?

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

Where can I get more information?

If you want to get more information in this field, you can visit **ESMO** website for *Biliary tract cancer: Guide for Patients* and on the **AMMF** *The Cholangiocarcinoma Charity* website.

You can find the related link below:

<https://www.esmo.org/for-patients/patient-guides/biliary-tract-cancer>

<https://ammf.org.uk/cholangiocarcinoma/>

You can also visit the Precision-BTC-Network COST action website:

<https://precision-btc.eu/info/patientmaterials>