



Information for Patients

IVOSIDENIB

For biliary tract cancers



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

IVOSIDENIB for biliary tract cancers

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

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.



Generated by Dr V Zanuso and Dr C Braconi (oncologists) based on information developed by Macmillan Cancer Support and used with permission. Revised by Ms J Milne (nurse), Ms H Morement (patient representative). 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).



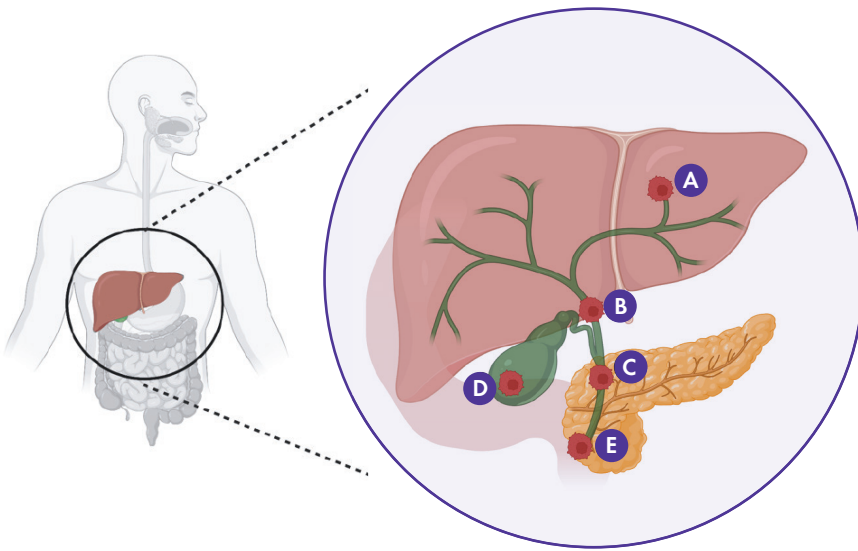
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Biliary tract cancer

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** Perihilar cholangiocarcinoma
- C** Extrahepatic 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

What is IVOSIDENIB?

IVOSIDENIB is a targeted drug treatment for cholangiocarcinoma (bile duct cancer), and it is used when the cancer has a change in a gene called isocitrate dehydrogenase-1 (IDH-1), which leads to the differentiation of normal cells into malignant cells. As an inhibitor of IDH-1, IVOSIDENIB blocks cancer cells from growing and proliferating.

How is IVOSIDENIB administered?

You will take IVOSIDENIB orally as tablets. The tablets are taken once daily at about the same time each day. Patients should not eat anything for 2 hours before and through 1 hour after taking the tablets. The tablets should be swallowed whole with water. 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 IVOSIDENIB you will receive. Before you start this treatment, your doctor will collect information on your general health and underlying conditions.

You will see a cardiologist before starting with the treatment, in order to assess your cardiovascular function. An electrocardiography (ECG) will be performed to evaluate the electrical activity of your heart.

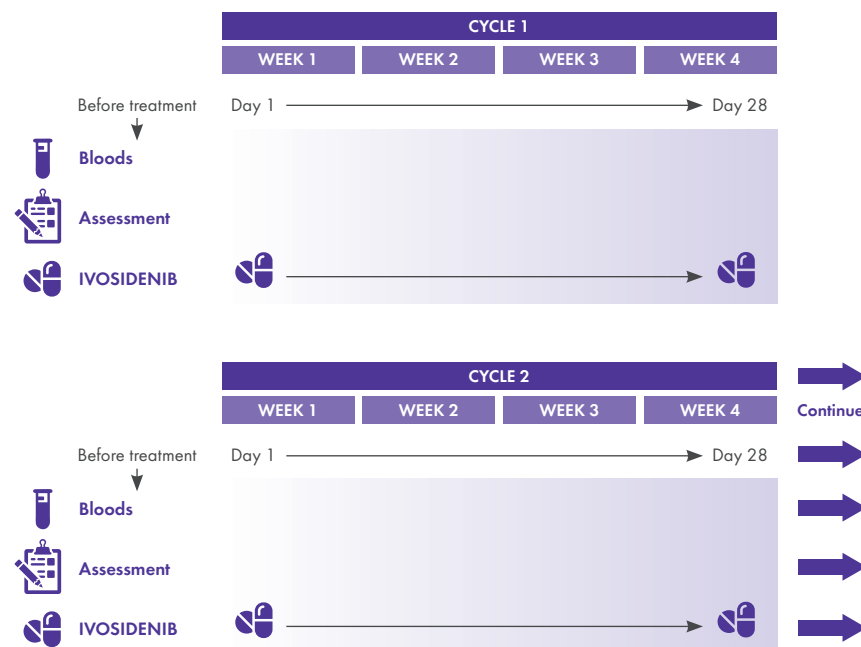
Schedule of IVOSIDENIB treatment

You will receive IVOSIDENIB in cycles of treatment. The standard schedule of IVOSIDENIB treatment follows a four-week cycle. You should take IVOSIDENIB once a day for 28 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.

Duration of IVOSIDENIB treatment

The doctor will discuss the duration of your treatment with you. Each IVOSIDENIB cycle will last for 4 weeks. If you are tolerating the treatment well, you will receive IVOSIDENIB for at least 3 months before you will have a 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 have a repeat scan every 3 months. You should keep taking IVOSIDENIB until your doctor tells you to stop. Do not stop taking the tablets before discussing it with your doctor first.

IVOSIDENIB once daily in continuous 28-day cycles



Side effects of the IVOSIDENIB 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 serious side effects related to treatment (IVOSIDENIB)


QTc prolongation: This is a change in the electrical activity of your heart. QTc prolongation can cause irregular heartbeats. Your doctor and nurse will check the electrical activity of your heart before and during treatment with IVOSIDENIB. **If you feel dizzy, lightheaded or faint, you should contact your hospital immediately.**


Guillain-Barré Syndrome: This syndrome has been reported in people treated with IVOSIDENIB. Your doctor will monitor your nervous system functions and will permanently stop the treatment if you develop this syndrome. Tell your doctor or nurse if you have any of these symptoms:


- Weakness or tingling feeling in your legs, arms, or upper body
- Any changes in the ability to see, touch, hear, taste
- Numbness and pain on one side or both sides of your body
- Burning or prickling sensation
- Difficult breathing


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


 **Low number of red blood cells:** Red blood cells normally carry oxygen to every part of your body. If the number of red blood cells is too low (this is called anaemia) you can feel tired and breathless. If the anaemia is severe, you will need a blood transfusion.


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


 **Nausea:** Sometimes accompanied by vomiting but is usually well controlled by anti-sickness drugs (injections and tablets). It is important to take anti-sickness medicines even if you don't feel sick, because it is easier to prevent sickness rather than treat it once it has started. Contact your doctor or nurse straight away if you've been feeling sick more than once in a day.

 **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.

 **Poor appetite:** Don't worry if you don't eat much for a day or two. Also, your taste can change.

 **Build-up of fluid:** You may put on weight and stomach may swell. The swelling will get better after the end of treatment.

 **Skin changes:** Your skin may be drier or develop a rash.

 **Changes in liver function test:** You will have blood tests before each cycle in order to check your liver function.

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 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.

When to contact the hospital?

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

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

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

There is also information on biliary tract cancers on the
website of AMMF – The Cholangiocarcinoma Charity:

www.ammf.org.uk

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

www.precision-btc.eu/info/patientbrochures



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