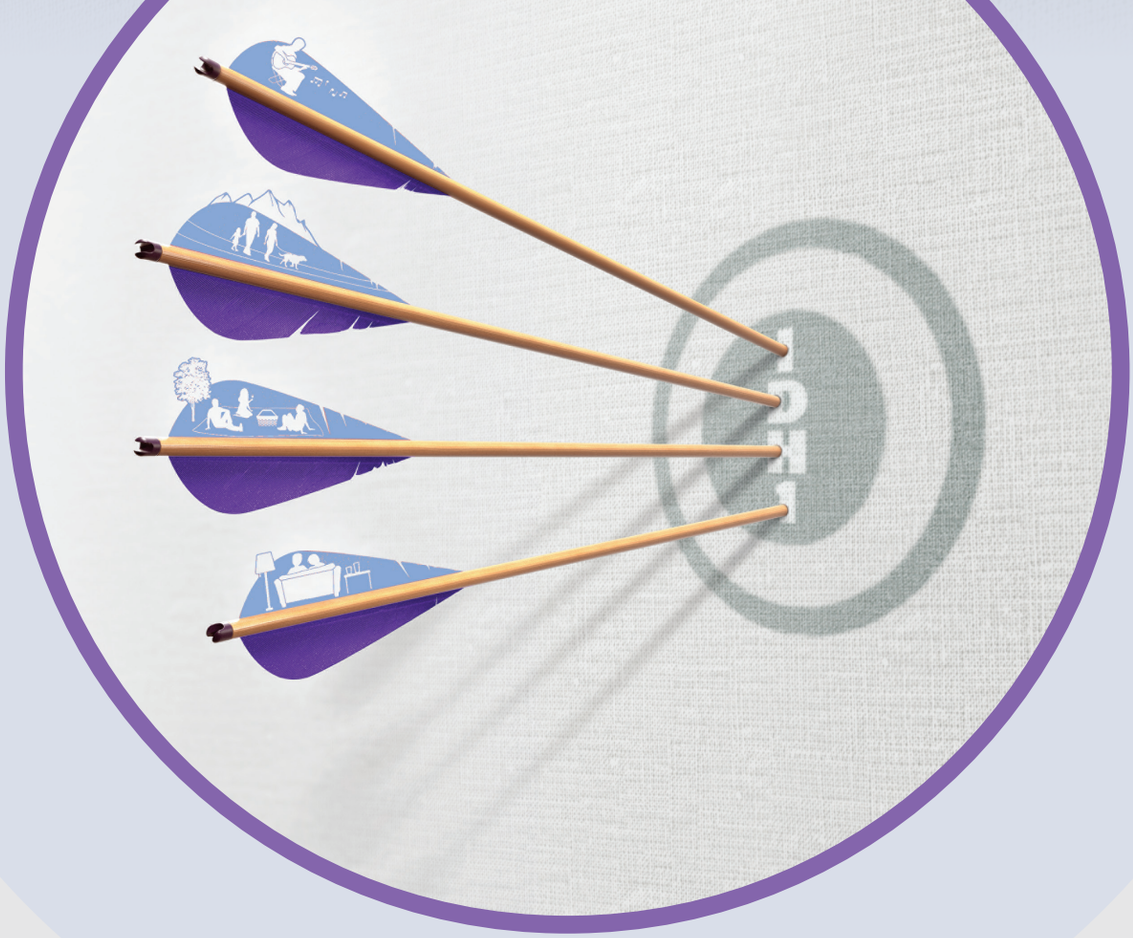

AIM FOR MORE POSSIBILITIES

Understanding treatment with TIBSOVO® for cholangiocarcinoma (bile duct cancer)

What is TIBSOVO?

TIBSOVO is a prescription medicine used to treat adults with an isocitrate dehydrogenase-1 (IDH1) mutation with bile duct cancer (cholangiocarcinoma) that has spread and who have already received previous treatment(s).

Your healthcare provider will perform a test to make sure that TIBSOVO is right for you. It is not known if TIBSOVO is safe and effective in children.

IMPORTANT SAFETY INFORMATION

TIBSOVO may cause serious side effects, including:

- **Changes in the electrical activity of your heart called QTc prolongation. QTc prolongation can cause irregular heartbeats that can be life-threatening**. Your healthcare provider will check the electrical activity of your heart with a test called an electrocardiogram (ECG) before and during treatment with TIBSOVO. Tell your healthcare provider right away if you feel dizzy, lightheaded, or faint

Please see additional Important Safety Information on pages 18-19 and accompanying Full Prescribing Information, including Medication Guide.

TIBSOVO®
ivosidenib tablets 250mg

About this brochure

TIBSOVO: A TARGETED TREATMENT OPTION

It's very difficult to hear your doctor say the words, "You have cancer." Once the shock wears off, the questions and fears can be overwhelming.

Here you will learn how TIBSOVO works, what can be expected during treatment, and how to find support. Please talk to your doctors, nurses, and medical team about your cancer and its treatment. Use the spaces on these pages to organize your notes and questions.

TIBSOVO is a personalized treatment option because it works to target a specific type of genetic mutation known as IDH1. TIBSOVO is a pill you can take at home.

TIBSOVO may slow down the progression of advanced cholangiocarcinoma, **so you can aim for more possibilities.**

TIBSOVO is the first treatment of its kind that inhibits mutated IDH1.

TIBSOVO is a prescription medicine used to treat adults with bile duct cancer (cholangiocarcinoma) that has spread:

- Who have already received previous treatment(s) and
- Whose tumor has a certain type of abnormal isocitrate dehydrogenase-1 (IDH1) mutation

Your healthcare provider will perform a test to make sure that TIBSOVO is right for you. It is not known if TIBSOVO is safe and effective in children.

IMPORTANT SAFETY INFORMATION (cont'd)

TIBSOVO may cause serious side effects, including (cont'd):

- **Guillain-Barré syndrome** has happened in people treated with TIBSOVO. Your healthcare provider will monitor you for nervous system problems and will permanently stop your treatment with TIBSOVO if you develop Guillain-Barré syndrome. Tell your healthcare provider right away if you develop any signs or symptoms of Guillain-Barré syndrome, including:
  - weakness or tingling feeling in your legs, arms, or upper body
  - numbness and pain on one side or both sides of your body
  - any changes in your ability to see, touch, hear, or taste
  - burning or prickling sensation
  - difficulty breathing

Please see additional Important Safety Information on pages 18-19 and accompanying Full Prescribing Information, including Medication Guide.

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To find more information about TIBSOVO and for additional resources, visit TIBSOVO.com/CCA.

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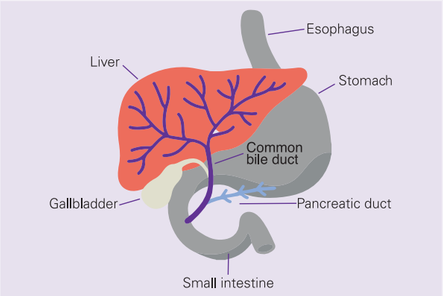
ABOUT CHOLANGIOCARCINOMA

What is cholangiocarcinoma?

- Cholangiocarcinoma, also called bile duct cancer, is a rare and aggressive cancer that forms in the bile ducts inside and around the liver. It accounts for about 3% of cancers in the gastrointestinal system
- Approximately 8000 people in the United States are diagnosed with cholangiocarcinoma each year, but the actual number of cases may be higher
- Signs and symptoms of cholangiocarcinoma are not specific, and many cases are not diagnosed until the disease has progressed when surgery may no longer be an option. The recommended treatment will depend on whether the tumor is localized or metastatic

What is a bile duct?
Bile ducts play an essential role in the digestion of food, and their proper function is essential for your health. The liver excretes a chemical called bile that is carried in tubes known as bile ducts to the gallbladder and then into the intestines. The top half of the common bile duct is located within the liver. Bile ducts can be affected by certain ailments and diseases, including cholangiocarcinoma.



Digestive system diagram showing the bile duct

Types of cholangiocarcinoma

According to the site of origin:

- **Intrahepatic cholangiocarcinoma** means the tumor originates in the bile ducts *inside* of your liver

- **Extrahepatic cholangiocarcinoma** means the tumor originates in the bile ducts *outside* of your liver

According to tumor location:

- If the tumor stays in the place it first formed, it is called **localized disease**
- If the cancer has spread to other parts of your body, it is called **metastatic disease**. If it has spread to other places in the body, such as a lung, it is still considered to be cholangiocarcinoma

Genetic mutations in cholangiocarcinoma

Cholangiocarcinoma can develop because of certain genetic abnormalities, or mutations, in the cells in the bile duct. Genetic mutations are changes in the DNA of a cell. They can result in cancer cells growing and dividing without the usual controls. Over time, a mass of uncontrolled cells can grow and become a tumor.

Biomarker testing

- Your doctor may recommend biomarker testing to look for specific changes in the DNA of the cancer cells
- Biomarker testing involves a piece of your tumor (obtained from biopsy or surgery) being sent to the laboratory for analysis
- It may take a few weeks to get results, but the results will enable your doctor to personalize the best approach to treating your type of cancer

What are biomarkers?
Each cell in your body produces a unique set of molecules that help to identify the function and activities of the cell. A biomarker can be one of these molecules, which can be measured in tumor tissue, blood, or other bodily fluids. Routine blood tests include a variety of standard biomarkers, but your doctor may order special biomarker tests related to certain cancers.

Please see additional Important Safety Information on pages 18-19 and accompanying Full Prescribing Information, including Medication Guide.

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HOW TREATMENT WITH TIBSOVO WORKS

Targeting the IDH1 mutation

The first treatment of its kind, TIBSOVO is a targeted therapy that works against a mutation called the IDH1 mutation. Up to 20% of intrahepatic cholangiocarcinoma cases have an IDH1 mutation. That's why biomarker testing for mutations can help your healthcare team understand if TIBSOVO is right for you.

What is IDH1?
IDH1 stands for isocitrate dehydrogenase-1. In healthy cells, the IDH1 gene makes the IDH1 protein, which plays a role in normal chemical reactions within cells. When the IDH1 gene is altered due to a genetic mutation, cells make an abnormal (mutated) version of the IDH1 protein. This mutated IDH1 protein may promote the development of certain types of cancers, including cholangiocarcinoma.

How TIBSOVO works against your cholangiocarcinoma

Targeted therapy
TIBSOVO can slow down the progression of advanced cholangiocarcinoma by specifically targeting the mutated IDH1 protein.

TIBSOVO works differently from traditional chemotherapy. Chemotherapy kills cells that divide quickly, including both tumor cells and cells in healthy tissue. Chemotherapy is also typically given by infusion, which usually takes place in the hospital.

Proven results
For patients with advanced cholangiocarcinoma who have been previously treated, targeted therapy with TIBSOVO has been shown to increase the length of time a person can live with cholangiocarcinoma without it getting worse.

Convenient once-daily pill
TIBSOVO is a pill that's typically prescribed for patients to take 2 tablets once a day. You can take TIBSOVO at home with or without food and without the infusion time requirements of chemotherapy.

Traditional chemotherapy is cytotoxic, which means it kills both abnormal and healthy cells. Unlike chemotherapy, TIBSOVO only targets tumor cells with mutated IDH1.

Please see additional Important Safety Information on pages 18-19 and accompanying Full Prescribing Information, including Medication Guide.

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HOW TREATMENT WITH TIBSOVO WORKS

The TIBSOVO clinical study

The TIBSOVO clinical study was designed to determine if once-daily TIBSOVO could reduce the risk of disease progression or death in patients with advanced cholangiocarcinoma with an IDH1 mutation whose disease had progressed after previous treatments.

TIBSOVO was studied in a clinical trial involving 185 adult patients with cholangiocarcinoma who:

- Had their cancer become worse after receiving at least 1 but not more than 2 previous treatment regimens
- Had disease that had spread
- Had a certain type of abnormal IDH1 mutation

The purpose of the clinical study was to determine how long patients lived without their cholangiocarcinoma getting worse.

Benefits seen with TIBSOVO in the clinical study

- Patients treated with TIBSOVO achieved longer progression-free survival and better disease control compared with patients who received placebo
- Patients taking TIBSOVO had a lower risk of disease progression over 6 to 12 months
- More than half of the patients who took TIBSOVO achieved stable disease vs 28% among patients who received placebo

TIBSOVO has been shown to increase the length of time a person can live with cholangiocarcinoma without it getting worse.

What is a placebo?
A placebo is an inactive substance, such as a sugar pill, that looks the same as, and is given the same way as, the active drug being tested. The effects of the active drug or other intervention are compared to the effects of the placebo.

What is disease control?
Disease control refers to the percentage of patients whose tumor shrinks or remains stable over the study period.

What is progression-free survival?
Progression-free survival is the length of time during and after cancer treatment that a patient lives with the disease without it getting worse. In a clinical trial, measuring progression-free survival (also called PFS) is one way to see how well treatment works.

What is stable disease?
Stable disease is when there is neither an increase nor decrease in disease severity or tumor size.

Please see additional Important Safety Information on pages 18-19 and accompanying Full Prescribing Information, including Medication Guide.

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TAKING TIBSOVO

Before you take TIBSOVO

Tell your healthcare provider about all of your medical conditions, including if you:

- Have any heart problems, including a condition called long QT syndrome
- Have problems with abnormal electrolytes, such as sodium, potassium, calcium, or magnesium levels
- Have nervous system problems
- Have problems with your kidneys or are on dialysis
- Have any liver disorders, including cirrhosis
- Are pregnant or plan to become pregnant. TIBSOVO may cause harm to your unborn baby. You should avoid becoming pregnant during treatment with TIBSOVO. Tell your healthcare provider right away if you become pregnant or think you might be pregnant during treatment with TIBSOVO
- Are breastfeeding or plan to breastfeed. It is not known if TIBSOVO passes into your breast milk. Do not breastfeed during your treatment with TIBSOVO and for 1 month after your last dose of TIBSOVO

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

Especially tell your healthcare provider if you take hormonal contraceptives. TIBSOVO may affect how hormonal contraceptives work and may cause them to not work as well.

How you should store TIBSOVO

- Store TIBSOVO at room temperature between 68 to 77 °F (20-25 °C)
- Keep TIBSOVO in the original container
- Keep the container tightly closed with the desiccant canister (drying agent) inside to protect the tablets from moisture
- Keep TIBSOVO and all medicines out of reach of children

How to take TIBSOVO

TIBSOVO is an oral medication you can take at home. Take TIBSOVO exactly as your healthcare provider tells you to.

Tablets not shown at actual size.

Take 2 tablets orally, once a day. Taking TIBSOVO at the same time as another daily activity, like when you brush your teeth, can help you remember.

Take TIBSOVO with or without food.
Do not take TIBSOVO with a high-fat meal (about 1000 calories and 58 grams of fat).

An example of a high-fat meal includes 2 eggs fried in butter, 2 strips of bacon, 2 slices of white bread with butter, 1 croissant with 1 slice of cheese, and 8 ounces of whole milk.

Swallow TIBSOVO tablets whole.
Do not split, crush, or chew the tablets.

If you miss a dose of TIBSOVO or did not take it at the usual time, take your dose as soon as possible and at least 12 hours before your next dose. Return to your normal schedule the following day. **Do not** take 2 doses of TIBSOVO within 12 hours. **Do not** change your dose or stop taking TIBSOVO without talking to your healthcare provider.

If you vomit after taking a dose of TIBSOVO, do not take an additional dose. Take your next dose at your usual time.

It's important to keep talking with your healthcare provider about your treatment plan and follow his or her instructions about treatment schedule and dose.

Information about the safe use of TIBSOVO

Medicines are sometimes prescribed for purposes other than those listed in a medication guide. Do not take TIBSOVO for conditions for which it was not prescribed. Do not give TIBSOVO to other people, even if they have the same symptoms you have. It may harm them. You can ask your pharmacist or healthcare provider for information about TIBSOVO that is written for healthcare professionals.

Please see additional Important Safety Information on pages 18-19 and accompanying Full Prescribing Information, including Medication Guide.

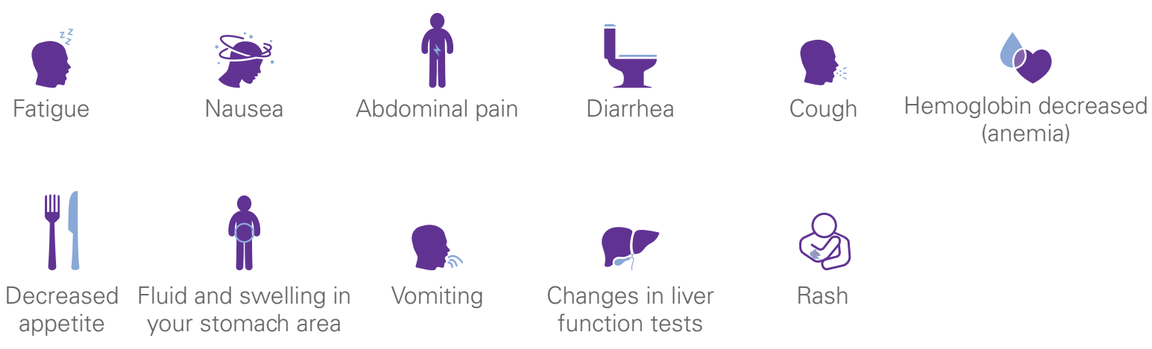
TIBSOVO® ivosidenib tablets 250mg

Possible side effects of TIBSOVO

TIBSOVO may cause serious side effects, including:

- **Changes in the electrical activity of your heart called QTc prolongation. QTc prolongation can cause irregular heartbeats that can be life-threatening.** Your healthcare provider will check the electrical activity of your heart with a test called an electrocardiogram (ECG) before and during treatment with TIBSOVO. Tell your healthcare provider right away if you feel dizzy, lightheaded, or faint
- **Guillain-Barré syndrome** has happened in people treated with TIBSOVO. Your healthcare provider will monitor you for nervous system problems and will permanently stop your treatment with TIBSOVO if you develop Guillain-Barré syndrome. Tell your healthcare provider right away if you develop any signs or symptoms of Guillain-Barré syndrome, including:
  - Weakness or tingling feeling in your legs, arms, or upper body
  - Numbness and pain on one side or both sides of your body
  - Any changes in your ability to see, touch, hear, or taste
  - Burning or prickling sensation
  - Difficulty breathing

The most common side effects of TIBSOVO in adults with cholangiocarcinoma include:



Your healthcare provider will do blood tests before you start and during treatment with TIBSOVO. Your healthcare provider may decrease, temporarily hold, or permanently stop your treatment with TIBSOVO if you develop certain side effects. TIBSOVO may cause fertility problems in females and males, which may affect your ability to have children. Talk to your healthcare provider if you have concerns about fertility. These are not all the possible side effects of TIBSOVO. Call your doctor for medical advice about side effects. You may report side effects to the FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Please see additional Important Safety Information on pages 18-19 and accompanying Full Prescribing Information, including Medication Guide.

What to do if you experience side effects

Always tell your healthcare provider about any side effects you experience. They may be able to prescribe medicines to help you manage them. However, there are some things you can do on your own that may help as well.

If you experience nausea

- If nausea only happens between meals, eat frequent small meals and have a snack at bedtime
- Drink clear liquids served cold and sipped slowly
- Eat bland foods (dry toast and crackers)
- Eat food cold or at room temperature
- Avoid fatty, fried, spicy, or very sweet foods
- Rest quietly while sitting upright for at least an hour after each meal
- Distract yourself with music, TV, or company

If you experience diarrhea

- Eat small meals often
- Avoid acidic drinks (tomato or citrus juices, fizzy soft drinks); hot, spicy, or greasy foods; bran; raw fruits and vegetables; pastries; candies; rich desserts; jellies; preserves; and nuts
- Avoid caffeine, alcohol, and tobacco
- Avoid milk and milk products if they make diarrhea worse
- Try a clear liquid diet as soon as diarrhea starts or when you feel it's going to start
- When diarrhea starts to improve, try eating small amounts of foods that are easy to digest (rice, bananas, applesauce, yogurt, mashed potatoes, low-fat cottage cheese, dry toast). If diarrhea continues to improve after a day or 2, start to eat small, regular meals

If you experience a rash

- Avoid the sun (especially between 10 AM and 4 PM), wear a broad-brimmed hat, and use sunscreen with an SPF of 15 or higher
  - If the sunscreen stings or burns, try one with zinc oxide or titanium dioxide
- Shower with lukewarm (not hot) water and use a mild soap
- Apply a cream-based moisturizer to all skin within 5 minutes of showering or bathing
  - Use a hypoallergenic moisturizer that does not have perfumes or preservatives
- Avoid skin products containing alcohol or retinoids, which can dry out your skin
- Avoid laundry detergent with strong perfumes

ADDITIONAL RESOURCES

SERVIER ONE™

ServierONE Patient Support Services

ServierONE Patient Support Services will work with you, your caregiver, and your healthcare provider(s) to help you get treatment after you've been prescribed TIBSOVO.
Financial assistance may be available, no matter your insurance type or status.[a]
Your healthcare provider or ServierONE Patient Support Services can help figure out which financial assistance program is right for you.

COMMERCIAL/PRIVATE INSURANCE	
What does it mean?	You get your health insurance through your work or your spouse's work, or you purchase it yourself.
The program(s) for you	**Commercial Co-Pay Program** This program can help lower out-of-pocket costs. There are no income restrictions, and it is available to eligible patients with commercial/private insurance. For more information on the co-pay program, go to ServierONE-copay.com. **Note:** If you have government insurance, you are not eligible for this program.
GOVERNMENT INSURANCE	
What does it mean?	You get your health insurance through a government healthcare insurance program such as Medicare, Medicaid, Medigap, Tricare, Veterans Affairs (VA), Department of Defense (DOD), or any state-funded programs.
The program(s) for you	**Independent foundations**[b] Independent foundations may be available to help you pay for TIBSOVO. One of our specialty pharmacies or ServierONE can provide a referral to these foundations.
UNINSURED OR UNDERINSURED	
What does it mean?	You have no insurance coverage or lack coverage for your prescribed therapy.
The program(s) for you	**Patient Assistance Program (PAP)** The PAP may help you get access to TIBSOVO. Income requirements apply. You and your healthcare provider can reach out to ServierONE to learn more.

Please see ServierONE.com for full Terms and Conditions for each program.
[a] If you are waiting for coverage, you may be eligible for a free product program. Contact ServierONE for more information.
[b] Eligibility is determined by the individual foundation. Servier Pharmaceuticals is not affiliated with these organizations.

If you have any questions, please visit **ServierONE.com** or call **1-800-813-5905**, Monday through Friday, 8 AM to 8 PM ET.

Please see additional Important Safety Information on pages 18-19 and accompanying Full Prescribing Information, including Medication Guide.

More information about TIBSOVO and Servier Pharmaceuticals

TIBSOVO
Tibsovo.com/CCA

Servier Pharmaceuticals
Servier.us

Patient advocacy, support, and assistance[a]

There are many patient organizations and online support groups for people living with CCA. To learn more about CCA, to find clinical trials, or to connect with other patients, the list of groups below and other organizations may be useful resources.

Cholangiocarcinoma Foundation®
1-888-936-6731
cholangiocarcinoma.org

American Cancer Society®
1-800-227-2345
cancer.org

American Liver Foundation
1-800-465-4837
liverfoundation.org

CancerCare
1-800-813-4673
cancercare.org

Target Cancer Foundation
1-617-765-4881
targetcancer.org

Triage Cancer
1-424-258-4628
triagecancer.org

[a] These are independent resources. Servier Pharmaceuticals is not affiliated with these organizations.

Servier provides charitable funding to many patient organizations providing support and education to patients and families. The above list may not include all patient organizations available to patients and families.

Independent foundations may also provide support to patients.
Your ServierONE care manager team can provide more information.

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ADDITIONAL RESOURCES

TIBSOVO dosing calendar

Use this dosing calendar to help remind you to take your medication.

Date of first TIBSOVO dose: **Month:**

Time of dose
(2 tablets orally, once a day):

SUNDAY	MONDAY	TUESDAY	WEDNESDAY	THURSDAY	FRIDAY	SATURDAY

Notes

Important questions to ask your healthcare provider

It is important to take an active role in your treatment. One of the best ways you can do this is to talk with your healthcare providers. That can help you feel more confident about your treatment with TIBSOVO.
Some important questions to ask are:

- *What makes TIBSOVO right for me?*
- *What should I expect while taking TIBSOVO?*
- *Is there anything I should avoid while taking TIBSOVO?*
- *How do I take TIBSOVO, and what if I miss a dose?*
- *Is it safe for me to take TIBSOVO while on other medications?*
- *How should I store TIBSOVO?*

Ask every question. Talk with your healthcare provider so you can get answers to any questions regarding your diagnosis and treatment.

Notes

Please see additional Important Safety Information on pages 18-19 and accompanying Full Prescribing Information, including Medication Guide.

TIBSOVO® ivosidenib tablets 250mg

IMPORTANT SAFETY INFORMATION

What is TIBSOVO?

TIBSOVO is a prescription medicine used to treat adults with an isocitrate dehydrogenase-1 (IDH1) mutation with bile duct cancer (cholangiocarcinoma) that has spread and who have already received previous treatment(s).

Your healthcare provider will perform a test to make sure that TIBSOVO is right for you. It is not known if TIBSOVO is safe and effective in children.

IMPORTANT SAFETY INFORMATION

TIBSOVO may cause serious side effects, including:

- **Changes in the electrical activity of your heart called QTc prolongation. QTc prolongation can cause irregular heartbeats that can be life-threatening.** Your healthcare provider will check the electrical activity of your heart with a test called an electrocardiogram (ECG) before and during treatment with TIBSOVO. Tell your healthcare provider right away if you feel dizzy, lightheaded, or faint.
- **Guillain-Barré syndrome.** Guillain-Barré syndrome has happened in people treated with TIBSOVO. Your healthcare provider will monitor you for nervous system problems and will permanently stop your treatment with TIBSOVO if you develop Guillain-Barré syndrome. Tell your healthcare provider right away if you develop any signs or symptoms of Guillain-Barré syndrome, including:
  - weakness or tingling feeling in your legs, arms, or upper body
  - numbness and pain on one side or both sides of your body
  - any changes in your ability to see, touch, hear, or taste
  - burning or prickling sensation
  - difficulty breathing

The most common side effects of TIBSOVO in adults with Cholangiocarcinoma include:

- fatigue
- nausea
- abdominal pain
- diarrhea
- cough
- decreased appetite
- fluid and swelling in your stomach area
- vomiting
- hemoglobin decreased (anemia)
- rash
- changes in liver function tests

Your healthcare provider will do blood tests before you start and during treatment with TIBSOVO. Your healthcare provider may decrease, temporarily hold, or permanently stop your treatment with TIBSOVO if you develop certain side effects.

TIBSOVO may cause fertility problems in females and males, which may affect your ability to have children. Talk to your healthcare provider if you have concerns about fertility.

These are not all the possible side effects of TIBSOVO. Call your doctor for medical advice about side effects. You may report side effects to the FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Before taking TIBSOVO, tell your healthcare provider about all of your medical conditions, including if you:

- have any heart problems, including a condition called long QT syndrome
- have problems with abnormal electrolytes, such as sodium, potassium, calcium, or magnesium levels
- have nervous system problems
- have problems with your kidneys or are on dialysis
- have any liver disorders, including cirrhosis
- are pregnant or plan to become pregnant. TIBSOVO can cause harm to your unborn baby. You should avoid becoming pregnant during treatment with TIBSOVO. Tell your healthcare provider right away if you become pregnant or think you might be pregnant during treatment with TIBSOVO
- are breastfeeding or plan to breastfeed. It is not known if TIBSOVO passes into your breast milk. Do not breastfeed during your treatment with TIBSOVO and for 1 month after your last dose of TIBSOVO

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. **Especially tell your healthcare provider if you take hormonal contraceptives.** TIBSOVO may affect how hormonal contraceptives work and may cause them to not work as well.

TIBSOVO can slow down the progression of advanced cholangiocarcinoma (bile duct cancer) in patients with an IDH1 mutation who have already received previous treatment(s).

WHY TIBSOVO?

Targeted therapy

TIBSOVO works differently from traditional chemotherapy, which kills cells that divide quickly, including cells in healthy tissue. Personalized targeted therapies can only be used for specific mutations, so your doctor will order a biomarker test to determine if TIBSOVO is right for you.

Proven results

TIBSOVO has been shown to increase the length of time a person can live with cholangiocarcinoma without it getting worse.

Convenient once-daily pill

TIBSOVO is a pill that's typically prescribed for patients to take 2 tablets once a day. You can take TIBSOVO at home without the infusion time requirements of chemotherapy.

TIBSOVO may cause serious side effects, including QTc prolongation and Guillain-Barré syndrome. Please see additional Important Safety Information on pages 18-19 and Full Prescribing Information, including Medication Guide.

To find more information about TIBSOVO and for additional resources, visit Tibsovo.com/CCA.

ServierONE Patient Support Services is here for you. Visit ServierONE.com to find assistance for you and your caregiver.

SERVIER

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TIBSOVO is a registered trademark of SERVIER PHARMACEUTICALS LLC, a wholly owned, indirect subsidiary of LES LABORATOIRES SERVIER.
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