

MEDICATION GUIDE
TIBSOVO® (tib-SOH-voh)
(ivosidenib tablets)

What is the most important information I should know about TIBSOVO?

TIBSOVO may cause serious side effects, including:

Differentiation Syndrome. Differentiation syndrome is a common condition that affects your blood cells and may be life-threatening or lead to death. Differentiation syndrome in adults with acute myeloid leukemia (AML) and myelodysplastic syndromes (MDS) has happened as early as 1 day and up to 3 months after starting TIBSOVO. Call your healthcare provider or go to the nearest hospital emergency room right away if you develop any of the following symptoms of differentiation syndrome during treatment with TIBSOVO:

- fever
- cough
- trouble breathing
- rash
- decreased urination
- dizziness or lightheadedness
- rapid weight gain
- swelling of your arms or legs

If you develop signs and symptoms of differentiation syndrome, your healthcare provider may treat you with a corticosteroid medicine or a medicine called hydroxyurea and may monitor you in the hospital.

See “**What are the possible side effects of TIBSOVO?**” for more information about side effects.

What is TIBSOVO?

TIBSOVO is a prescription medicine used to treat adults with an isocitrate dehydrogenase-1 (IDH1) mutation with:

- acute myeloid leukemia (AML):
 - with newly diagnosed AML treated in combination with azacitidine, or alone, who are 75 years or older or who have health problems that prevent the use of certain chemotherapy treatments.
 - when the disease has come back or has not improved after previous treatment(s).
- myelodysplastic syndrome (MDS):
 - when the disease has come back or has not improved after previous treatment(s).
- bile duct cancer (cholangiocarcinoma):
 - with bile duct cancer 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.

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 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 should I take TIBSOVO?

- Take TIBSOVO exactly as your healthcare provider tells you to.
- Do not change your dose or stop taking TIBSOVO without talking to your healthcare provider.
- Take TIBSOVO 1 time a day about the same time each day.
- Swallow TIBSOVO tablets whole. Do not split, crush, or chew the tablet.
- TIBSOVO can be taken with or without food.
- Do not take TIBSOVO with a high-fat meal. 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 (approximately 1,000 calories and 58 grams of fat).
- If you vomit after taking a dose of TIBSOVO, do not take an additional dose. Take your next dose at your usual time.
- 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.

What are the possible side effects of TIBSOVO?

TIBSOVO may cause serious side effects, including:

- See “**What is the most important information I should know about TIBSOVO?**”
- 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 when used in combination with azacitidine or alone in adults with AML include:

- changes in certain blood cell counts
- diarrhea
- increased blood sugar
- fatigue
- changes in certain liver function tests
- swelling of arms or legs
- decreased levels of electrolytes in the blood
- nausea
- vomiting
- decreased appetite
- joint pain
- shortness of breath
- uric acid increased
- stomach (abdominal) pain
- changes in certain kidney function tests
- pain or sores in your mouth or throat
- rash
- irregular heart rhythm or heartbeat (QTc prolongation)
- differentiation syndrome
- muscle pain

The most common side effects of TIBSOVO when used in adults with Myelodysplastic Syndromes (MDS) include:

- changes in certain kidney function tests
- changes in certain blood cell counts
- joint pain, back pain, or neck pain
- decreased levels of albumin in the blood
- changes in liver function tests
- fatigue
- diarrhea
- cough
- decreased levels of sodium in the blood
- pain or sores in your mouth or throat
- decreased appetite
- muscle pain
- decreased levels of phosphorus in the blood
- itchy skin
- rash

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

- fatigue
- fluid and swelling in your stomach area

- nausea
- abdominal pain
- diarrhea
- cough
- decreased appetite
- 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 of the possible side effects of TIBSOVO.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store TIBSOVO?

- Store TIBSOVO at room temperature between 68°F to 77°F (20°C to 25°C).
- Do not remove the desiccant canister from the bottle.

Keep TIBSOVO and all medicines out of the reach of children.

General information about the safe and effective 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.

What are the ingredients in TIBSOVO?

Active ingredient: ivosidenib

Inactive ingredients: colloidal silicon dioxide, croscarmellose sodium, hypromellose acetate succinate, magnesium stearate, microcrystalline cellulose, and sodium lauryl sulfate. The tablet coating includes FD&C blue #2, hypromellose, lactose monohydrate, titanium dioxide, and triacetin.

Manufactured for Servier Pharmaceuticals LLC, Boston, MA 02210

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For more information go to www.TIBSOVO.com or call 1-800-807-6124.

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