

ORAL CANCER TREATMENT EDUCATION



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IVOSIDENIB

Name of your medication

Generic name — ivosidenib (I-voh-SIH-deh-nib)
Brand name — Tibsovo® (tib-SOH-voh)

Common uses

Ivosidenib is used to treat patients with relapsed or refractory acute myeloid leukemia (AML) with an isocitrate dehydrogenase-1 (*IDH1*) variant.

Ivosidenib is also used by itself or in combination with another agent to treat patients with newly diagnosed AML with a susceptible *IDH1* variant who are aged 75 years or older or who have comorbidities that preclude use of intensive induction chemotherapy.

Ivosidenib is also used to treat patients with cholangiocarcinoma with an *IDH1* variant after prior treatment.

Ivosidenib can also be used to treat patients with relapsed or refractory myelodysplastic syndromes with an *IDH1* variant.

Ivosidenib may also be used for other treatments.

Dose and schedule

Taking ivosidenib as instructed is important to allow your treatment to be as effective as possible, so here are some key points to remember.

- Your dose may vary, but the usual dose of ivosidenib is 500 milligrams (500 mg) to be taken by mouth at a scheduled time once a day.
- Ivosidenib can be taken with or without food but at the same time each day. Avoid consuming a high-fat meal while taking a dose of ivosidenib.
- Ivosidenib should be swallowed whole. Do not crush, cut, or dissolve the tablet. If you are unable to swallow ivosidenib, talk to your care provider or pharmacist for possible options.
- If you vomit immediately after taking ivosidenib, do not take a replacement dose. Wait until the next scheduled dose.
- If a dose of ivosidenib is missed, take a dose as soon as possible, as long as it is at least 12 hours prior to the next scheduled dose.
- Be sure to write down if you miss a dose and let your care provider know about any missed doses.

Storage and handling

Handle ivosidenib with care. Just like when chemotherapy is given into the vein, this drug can be toxic, and exposure of the drug to others should be limited.

- Store ivosidenib at room temperature (68°F–77°F) in a dry location away from light.
- Keep ivosidenib out of reach of children and pets.

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- Whenever possible, you should give ivosidenib to yourself and follow the steps below. If a family member, friend, or caregiver needs to give the ivosidenib to you, they also need to follow these steps.
 1. Wash hands with soap and water.
 2. Put on gloves to avoid touching the medication. (Gloves are not necessary if you give the drug to yourself.)
 3. Gently transfer the ivosidenib from its package to a small medicine or other disposable cup.
 4. Administer the medicine immediately by mouth with water.
 5. Remove gloves and do not use them for anything else.
 6. Throw gloves and medicine cup in household trash.
 7. Wash hands with soap and water.
- If a daily pill box or pill reminder is used, a separate one should be used for ivosidenib. Do not mix other medications into the box with ivosidenib. The person filling the box or reminder should wear gloves (gloves are not necessary if you are filling the box or reminder). When empty, the box or reminder should be washed with soap and water before refilling. Be sure to wash hands with soap and water after the task is complete, whether or not gloves are worn.
- If you have any unused ivosidenib, **do not** throw it in the trash and **do not** flush it down the sink or toilet. Talk to your care provider or pharmacist about proper disposal of ivosidenib.
- If you are traveling, put your ivosidenib in a sealed plastic bag. Ask your pharmacist if any additional travel precautions are needed.

Handling body fluids and waste

Ivosidenib remains in your body for several days after it is taken, and some of the drug may be present in urine, stool, sweat, or vomit. Once you have started to take ivosidenib, it is important to know the following instructions every day for as long as your treatment lasts. This is to keep yourself, loved ones, and the environment as safe as possible.

- Pregnant women should avoid touching anything that may be soiled with body fluids from the patient.
- Toilet and septic systems
 - You may use the same toilet, septic tank, and/or sewer that you usually use. If you have a low-flow toilet, close the lid and flush twice to ensure that all waste has been discarded.
 - If the toilet or toilet seat becomes soiled with urine, stool, or vomit, clean the surfaces before other people use the toilet.
 - Wash hands with soap and water after using the toilet.
- If you need a bedpan, be sure your caregiver knows to wear gloves to assist with cleanup and to wash the bedpan with soap and water every day.
- If you do not have good control of bladder or bowels, use a disposable pad with a plastic back, a diaper, or a sheet to absorb body waste.
- Wash any skin that has been exposed to body waste or ivosidenib with soap and water.
- Linens or clothing that are soiled with body fluids or body waste should be washed separately from other linens and clothing. If you do not have a washer, place the soiled linens in a plastic bag until they can be washed.
- Wash hands with soap and water after touching linens or clothing that may be soiled with body fluids.

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Drug and food interactions

- ❑ Ivosidenib has many drug interactions. Please inform your care providers of all prescription medications, over-the-counter medications, vitamins, and herbal products.
- ❑ Grapefruit or grapefruit juice may interact with ivosidenib; avoid eating or drinking these during treatment with ivosidenib.
- ❑ Talk with your care provider or pharmacist before taking new medications or supplements, or receiving any vaccines.

Side Effects of Ivosidenib

The common side effects that have been known to happen in more than 30% of patients taking ivosidenib are listed in the left side of this table. You **MAY NOT** experience these side effects. Options to help manage any side effects that do occur are included on the right side of this table. These should be discussed with your care provider. If you experience any side effect you cannot manage or that is not listed here, contact your care provider.

Possible Side Effect	Management
<p>Changes in electrolytes and other laboratory values</p> <ul style="list-style-type: none"> • Increased white blood cell count (leukocytosis) • Increased uric acid levels • Low magnesium levels • Low potassium levels • Low sodium levels 	<p>Changes in some lab values may occur and will be monitored by a simple blood test.</p> <ul style="list-style-type: none"> • You may not feel any symptoms if the changes are mild, and they usually are not a sign of a serious problem. • More severe changes may occur, which can be a sign of a serious problem. <p>Notify your care provider if you have any of the following:</p> <ul style="list-style-type: none"> • Shortness of breath • Chest discomfort • Weakness or fatigue • New aches and pains • Headaches • Dizziness • Swelling of your legs or feet • Red- or brown-colored urine
<p>Decreased hemoglobin, part of the red blood cells that carry iron and oxygen</p>	<p>Your hemoglobin should be monitored by a simple blood test. When your hemoglobin is low, you may notice that you get tired or fatigued more easily.</p> <ul style="list-style-type: none"> • Try to get 7–8 hours of sleep per night. • Avoid operating heavy machinery if you feel too tired. • Find a balance between work and rest. • Stay as active as possible, but know that it is okay to rest as needed. • You might notice that you are more pale than usual. <p>Let your care provider know right away if you experience any of the following:</p> <ul style="list-style-type: none"> • Shortness of breath • Dizziness • Palpitations

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Possible Side Effect	Management
<p>Diarrhea (loose and/or urgent bowel movements)</p>	<p>Monitor how many bowel movements you have each day.</p> <ul style="list-style-type: none"> • Drink 8–10 glasses of water/fluid each day unless your care provider has instructed you to limit your fluid intake. • Eat small, frequent meals throughout the day rather than a few large meals. • Eat bland, low-fiber foods (such as bananas, applesauce, potatoes, chicken, rice, and toast). • Avoid high-fiber foods, such as raw vegetables, raw fruits, and whole grains. • Avoid foods that cause gas, such as broccoli and beans. • Avoid lactose-containing foods, such as yogurt and milk. • Avoid spicy, fried, and greasy foods. <p>Contact your provider if any of the following occur:</p> <ul style="list-style-type: none"> • The number of bowel movements you have in a day increases by four or more. • You feel dizzy or lightheaded. <p>Your care provider may recommend an over-the-counter medication called loperamide (Imodium®) to help with your diarrhea, but talk to your care provider before starting this medication.</p>
<p>Fatigue</p>	<ul style="list-style-type: none"> • You may be more tired than usual or have less energy. • Stay as active as possible, but know it is okay to rest as needed. • Try to do some activity every day. • Plan your activities, and do them at a time of day when you feel a bit more energetic. • Avoid operating heavy machinery if you feel too tired.
<p>Nausea or vomiting</p>	<ul style="list-style-type: none"> • Eat and drink slowly. • Drink 8-10 glasses of water or fluid each day unless your care provider has instructed you to limit your fluid intake. • Eat small, frequent meals throughout the day rather than a few large meals. • Eat bland foods; avoid spicy, fried, and greasy foods. • Avoid vigorous exercise immediately after eating. • Don't lie down immediately after eating. • Avoid strong odors. <p>Let your provider know if you experience nausea or vomiting.</p> <p>Your provider may prescribe medication to help with the nausea or vomiting.</p>

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Possible Side Effect	Management
Fluid retention or swelling	<ul style="list-style-type: none"> Do not stand for long periods of time. Keep your legs elevated when sitting or lying down. Try not to eat salty foods, which can increase swelling. Avoid tight-fitting clothing and shoes. Weigh yourself daily. <p>Contact your provider if you notice any of the following:</p> <ul style="list-style-type: none"> Swelling in the hands, feet, or legs Shortness of breath Weight gain of five pounds or more in one week
Muscle or joint pain or weakness	<ul style="list-style-type: none"> Keep a diary of your pain, including a description of when and where the pain is occurring, what it feels like, and how long it lasts. Stay as active as possible, but know it is okay to rest as needed. Tell your care provider if pain interferes with your activity. <p>If the pain or weakness bothers you, ask your provider what you may use to help with this discomfort. Take only pain medication that has been prescribed or recommended by your care provider.</p>
Decreased appetite or weight loss	<p>Talk to your care team if you notice a weight loss while taking this medication. When you do not feel like eating, try:</p> <ul style="list-style-type: none"> Small frequent meals instead of 3 large meals each day Keep snacks nearby so you can eat when you feel hungry. Liquid nutritional supplements Drink 8–10 glasses of water or fluid each day, especially if you are not eating, unless your care team has instructed you to limit your fluid intake.

Serious side effects

- Ivosidenib can cause differentiation syndrome, which is a condition that affects your blood cells and may be life-threatening. Differentiation syndrome has happened as early as one day and up to three months after starting ivosidenib. Call your healthcare provider or go to the nearest emergency room right away if you develop any of the following symptoms of differentiation syndrome while taking ivosidenib: fever, cough, trouble breathing, rash, decreased urination, dizziness or lightheadness, rapid weight gain, and swelling of your arms or legs.
- Ivosidenib may cause a condition called QT or QTc prolongation which is a heart rhythm that can cause fast, irregular heartbeats. These fast heartbeats may cause you to faint or have a seizure. In rare cases, this could be life-threatening. Tell your care team right away if you feel faint, lightheaded, dizzy, or if you feel your heart beating irregularly or fast, while taking Ivosidenib.
- Guillain-Barré Syndrome has been seen in patients treated with ivosidenib. Contact your Care Team if you experience weakness or tingling sensation in the legs, arms, or upper body, numbness and pain on one side or both sides of the body, changes to any sensory function, or burning or prickling sensation, or difficulty breathing.

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If you experience ANY uncontrolled side effect, call your physician or healthcare center immediately:

_____ (INSTITUTIONAL CONTACT INFO)

Pregnancy, sexual activity, and contraception

- Women should not become pregnant and men should not get a partner pregnant while taking ivosidenib. Women of childbearing age and potential should use effective contraception during therapy and for a minimum of 1 month after the last dose of ivosidenib. Men of reproductive age and potential should use effective contraception during therapy and for a minimum of 1 month after the last dose of ivosidenib.
- Do not breastfeed while taking ivosidenib and for 1 month after the last dose of ivosidenib.
- Please inform your care provider if you become pregnant.
- It is safe to hug and kiss. Special precautions may be needed for sexual activity while on oral chemotherapy, and you are encouraged to ask your care provider.

Obtaining medication

- Talk with your care provider about the process for obtaining your ivosidenib.

_____ (PHARMACY OR SPECIALTY PHARMACY CONTACT INFO)

Additional resources

Product website: www.tibsovo.com

Product prescribing information: www.tibsovo.com/pdf/prescribinginformation.pdf

Product resources: 1-844-409-1141

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Additional instructions

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Important notice: The Association of Community Cancer Centers (ACCC), Hematology/Oncology Pharmacy Association (HOPA), National Community Oncology Dispensing Association, Inc. (NCODA), and Oncology Nursing Society (ONS) have collaborated in gathering information for and developing this patient education guide. This guide represents a brief summary of the medication derived from information provided by the drug manufacturer and other resources. This guide does not cover all existing information related to the possible uses, directions, doses, precautions, warnings, interactions, adverse effects, or risks associated with this medication and should not substitute for the advice of a qualified healthcare professional. Provision of this guide is for informational purposes only and does not constitute or imply endorsement, recommendation, or favoring of this medication by ACCC, HOPA, NCODA, or ONS, who assume no liability for and cannot ensure the accuracy of the information presented. The collaborators are not making any representations with respect to the medications whatsoever, and any and all decisions, with respect to such medications, are at the sole risk of the individual consuming the medication. All decisions related to taking this medication should be made with the guidance and under the direction of a qualified healthcare professional.

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