

For the Patient: Ivosidenib **TIBSOVO®** Other names:

- Ivosidenib (eye"voe sid' e nib) is a drug that is used to treat some types of cancer. It is a tablet that you take by mouth. The tablet contains lactose.
- Tell your doctor if you have ever had an unusual or allergic reaction to ivosidenib before taking ivosidenib.
- Blood tests may be taken regularly during treatment. The dose and timing of your treatment may be changed based on the test results and/or other side effects.
- It is important to **take** ivosidenib exactly as directed by your doctor. Make sure you understand the directions.
- **Take** ivosidenib on an empty stomach.
- If you miss a dose of ivosidenib, take it as soon as you can if it is within 12 hours of the missed dose. If it is more than 12 hours since you missed dose, then skip the missed dose and go back to your usual dosing times. Do NOT take more than one dose to make up for the missed dose. Be sure to mention it to your healthcare team at your next visit.
- If you **vomit** the dose of ivosidenib, do not take a second dose. Take your next dose at your usual dosing time. Call your healthcare team during office hours for advice as a medication to prevent nausea may be required for future doses.
- Other drugs such as itraconazole (SPORANOX®) and rifampin (RIFADIN®) may interact with ivosidenib. Tell your doctor if you are taking these or any other drugs as you may need extra blood tests or your dose may need to be changed. Check with your doctor or pharmacist before you start or stop taking any other drugs.
- Avoid grapefruit and grapefruit juice for the duration of your treatment, as these may interact with ivosidenib.
- The **drinking of alcohol** (in small amounts) does not appear to affect the safety or usefulness of ivosidenib.
- Ivosidenib may affect **fertility** in men and women. If you plan to have children, discuss this with your doctor before being treated with ivosidenib.

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- Ivosidenib may damage sperm and may harm the baby if used during pregnancy. It is best to use birth control while being treated with ivosidenib and for 1 month after your treatment has ended. Do NOT use hormonal birth control as it may not work as well while you are taking ivosidenib. Tell your doctor right away if you or your partner becomes pregnant. Do not breastfeed during treatment and for at least 1 month after your last dose.
- **Store** ivosidenib tablets out of the reach of children, at room temperature, away from heat, light, and moisture.
- Tell your doctor, dentist, and other health professionals that you are being treated with ivosidenib before you receive any treatment from them.

Side effects are listed in the following table in the order in which they may occur. Tips to help manage the side effects are included.

SIDE EFFECTS	MANAGEMENT
Differentiation syndrome can sometimes occur with ivosidenib and some drugs used to treat blood cancers. Symptoms can be serious and may include fever, shortness of breath or difficulty in breathing, cough, rash, dizziness, swelling of arms or legs, rapid weight gain, and decreased amount of urine (you pee less often than usual). Symptoms usually occur within a few weeks after you start ivosidenib, but can sometimes occur months later.	Call your healthcare team <i>immediately</i> if you have these symptoms.
Nausea and vomiting may occur. If you are vomiting and it is not controlled, you can quickly become dehydrated. Most people have little or no nausea.	You may be given a prescription for antinausea drug(s) to take at home. It is easier to prevent nausea than treat it once it has occurred, so follow directions closely. • Drink plenty of fluids. • Eat and drink often in small amounts. • Try the ideas in <i>Practical Tips to Manage Nausea</i> .* Tell your healthcare team if nausea or vomiting continues or is not controlled with your antinausea drug(s).

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SIDE EFFECTS	MANAGEMENT
Diarrhea may sometimes occur. If you have diarrhea and it is not controlled, you can quickly become dehydrated.	 If diarrhea is a problem: Drink plenty of fluids. Eat and drink often in small amounts. Avoid high fibre foods as outlined in Food Choices to Help Manage Diarrhea.* Note: If lactose in milk usually gives you diarrhea, the lactose in the tablet may be causing your diarrhea. Take LACTAID® tablets just before your ivosidenib dose Tell your healthcare team if you have diarrhea for more than 24 hours.
Constipation may sometimes occur.	 Exercise if you can. Drink plenty of fluids. Try the ideas in Food Choices to Manage Constipation.*
Sore mouth may sometimes occur. Mouth sores can occur on the tongue, the sides of the mouth, or in the throat. Mouth sores or bleeding gums can lead to an infection.	 Brush your teeth gently after eating and at bedtime with a very soft toothbrush. If your gums bleed, use gauze instead of a brush. Use baking soda instead of toothpaste. Make a mouthwash with ¼ teaspoon baking soda AND ¼ teaspoon salt in 1 cup warm water and rinse several times a day. Try the ideas in Food Ideas to Try with a Sore Mouth.*
Abnormal heart rhythm (QT prolongation) can occur.	Minimize your risk of abnormal heart rhythm by: • always checking with your pharmacist or doctor about drug interactions when starting a new medication, herbal product, or supplement. • always taking ivosidenib on an empty stomach (not with food). • avoiding grapefruit and grapefruit juice. Get emergency help <i>immediately</i> if your heart is beating irregularly or fast OR if you feel faint, lightheaded, or dizzy.

Ivosidenib

SIDE EFFECTS	MANAGEMENT
Headache may sometimes occur.	Take acetaminophen (e.g., TYLENOL®) every 4-6 hours if needed, to a maximum of 4 g (4000 mg) per day.
Muscle or joint pain may sometimes occur.	You may take acetaminophen (e.g., TYLENOL®) every 4-6 hours to a maximum of 4 g (4000 mg) per day day or ibuprofen (e.g., ADVIL®) for mild to moderate pain. Tell your healthcare team if the pain interferes with your activity.
Loss of appetite and weight loss may sometimes occur.	Try the ideas in Food Ideas to Help with Decreased Appetite.*
Tiredness and lack of energy may commonly occur.	Do not drive a car or operate machinery if you are feeling tired.
	 Try the ideas in Fatigue/Tiredness – Patient Handout.*
Numbness or tingling of the fingers or toes may sometimes occur.	Be careful when handling items that are sharp, hot, or cold.
	Be careful when walking on uneven surfaces or doing activities that need you to balance or be steady.
	Tell your healthcare team at your next visit if you have trouble with buttons, writing, picking up small objects, walking, or have fallen.
Hair loss does not occur with ivosidenib.	

^{*}Please ask your nurse or pharmacist for a copy.

STOP TAKING IVOSIDENIB AND CHECK WITH YOUR HEALTHCARE TEAM OR **GET EMERGENCY HELP IMMEDIATELY IF YOU HAVE:**

- Signs of differentiation syndrome such as fever, shortness of breath or difficulty in breathing, cough, rash, dizziness, swelling of arms or legs, rapid weight gain, and decreased amount of urine (you pee less often than usual).
- Signs of **heart problems** such as fast or uneven heartbeat, chest pain, or fainting.

CHECK WITH YOUR HEALTHCARE TEAM AS SOON AS POSSIBLE (DURING **OFFICE HOURS) IF YOU HAVE:**

- Signs of **anemia** such as unusual tiredness or weakness.
- Signs of kidney problems such as lower back or side pain, swelling of feet or lower
- Signs of **liver problems** such as yellow eyes or skin, white or clay-coloured stools.

CHECK WITH YOUR HEALTHCARE TEAM IF ANY OF THE FOLLOWING CONTINUE **OR BOTHER YOU:**

- Abdominal pain.
- Headache not controlled with acetaminophen (e.g., TYLENOL®).

	REPORT ADDITIONAL PROBLEMS TO YOUR HEALTHCARE TEAM
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