

## Ivosidenib (Tibsovo)

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### About This Medicine

Ivosidenib is used to treat cancer. It is given orally (by mouth).

### Possible Side Effects

- A rapid increase in your white blood cells
- Bone marrow suppression. This is a decrease in the number of white blood cells, red blood cells, and platelets. This may raise your risk of infection, make you tired and weak, and raise your risk of bleeding.
- Decreased in a blood protein called albumin
- Abnormal electrocardiogram (EKG/ECG)
- Nausea and vomiting (throwing up)
- Soreness of the mouth and throat. You may have red areas, white patches, or sores in your mouth that hurt.
- Diarrhea (loose bowel movements)
- Constipation (not able to move bowels)
- Pain in your abdomen
- Decreased appetite (decreased hunger)
- Blood sugar levels may change
- Swelling of the hands, feet, or any other part of the body
- Collection of fluid in your abdomen
- Tiredness
- A serious syndrome may happen with the use of this medicine in acute myeloid leukemia and myelodysplastic syndrome patients known as differentiation syndrome, which can be life-threatening. It can cause fever, weight gain, swelling, and breathing problems. **Immediately report any of these symptoms to your healthcare provider.**
- Changes in your liver function
- Muscle and joint pain
- Headache
- Electrolyte changes
- Changes in your kidney function
- Increased uric acid in the blood
- Cough
- Trouble breathing

- Rash
- Itching
- High blood pressure

**Note:** Each of the side effects above was reported in 15% or greater of patients treated with ivosidenib. All possible side effects are not included. Your side effects may be different depending on your cancer diagnosis, condition, or if you are receiving other medicines in combination. Please discuss any concerns or questions with your medical team.

## Warnings and Precautions

- Guillain-Barre syndrome - a serious condition that can attack your nerves. You may get numbness, tingling or a sensation of pins and needles on one side or both sides of your body and/or in your arms, hands, legs or feet. You may have trouble breathing, changes in your eyesight and/or loss of hearing.

**Note:** Some of the side effects above are very rare. If you have concerns and/or questions, please discuss them with your medical team.

## How to Take Your Medicine

- Swallow the medicine whole with or without food daily. Do not take with a high-fat meal (1,000 calories and 58 grams of fat). Do not split, crush, or chew tablets.
- Take this medicine at the same time each day.
- **Missed dose:** If you miss a dose, take it as soon as you think about it **ONLY** if your next dose is due in more than 12 hours. If your next dose is due in **LESS** than 12 hours, then skip the missed dose and take your next dose at the regular time. Do not take 2 doses within 12 hours. Do not replace a vomited dose.
- **Handling:** Wash your hands with soap and water, before and after handling your medicine, your caretakers should not handle your medicine with bare hands and should wear latex gloves.
- Cytotoxic medicines leave the body through urine and stool, but they can also be present in other body fluids such as blood, vomit, semen, and vaginal fluids. Take precautions to prevent others from coming in contact with your medicine or your body fluids. Follow safety precautions during your treatment and for as long as directed by your health care provider after your treatment. If you take a cytotoxic pill each day, follow these precautions every day.
- **Storage:** Store this medicine in the original container at room temperature. Do not remove the desiccant canister from the bottle.
- **Disposal of unused medicine:** Do not flush any expired and/or unused medicine down the toilet or drain unless you are specifically instructed to do so on the medicine label. Some facilities have unused medicine take-back programs and/or other options. If you do not have a take-back program in your area, then please discuss with your nurse or your doctor how to dispose of unused medicine.



## Treating Side Effects

- Drink enough fluids to keep your urine pale yellow.
- Mouth care is very important. Your mouth care should consist of routine, gentle cleaning of your teeth or dentures and rinsing your mouth with a mixture of 1/2 teaspoon of salt in 8 ounces of water or 1/2 teaspoon of baking soda in 8 ounces of water. This should be done at least after each meal and at bedtime.
- If you have mouth sores, avoid mouthwash that has alcohol. Also avoid alcohol and smoking because they can bother your mouth and throat.
- To help with nausea and vomiting, eat small, frequent meals instead of three large meals a day. Choose foods and drinks that are at room temperature. Ask your nurse or doctor about other helpful tips and medicine that is available to help stop or lessen these symptoms.
- If you throw up or have diarrhea, you should drink more fluids so that you do not become dehydrated (lack of water in the body from losing too much fluid). Eat low-fiber foods that are high in protein and calories and avoid foods that can irritate your digestive tracts or lead to cramping.
- Ask your nurse or doctor about medicine that can lessen or stop your diarrhea and/or constipation.
- To help with decreased appetite, eat small, frequent meals. Eat foods high in calories and protein, such as meat, poultry, fish, dry beans, tofu, eggs, nuts, milk, yogurt, cheese, ice cream, pudding, and nutritional supplements.
- Consider using sauces and spices to increase taste. Daily exercise, with your doctor's approval, may increase your appetite.
- If you are not able to move your bowels, check with your doctor or nurse before you use enemas, laxatives, or suppositories.
- If you have diabetes, keep good control of your blood sugar level. Tell your nurse or your doctor if your glucose levels are higher or lower than normal.
- Manage tiredness by pacing your activities for the day.
- Be sure to include periods of rest between energy-draining activities.
- Get regular exercise, with your doctor's approval. If you feel too tired to exercise vigorously, try taking a short walk.
- To decrease the risk of infection, wash your hands regularly.
- Avoid close contact with people who have a cold, the flu, or other infections.
- Take your temperature as your doctor or nurse tells you, and whenever you feel like you may have a fever.
- To help decrease the risk of bleeding, use a soft toothbrush. Check with your nurse before using dental floss.
- Be very careful when using knives or tools.
- Use an electric shaver instead of a razor.
- If you get a rash do not put anything on it unless your doctor or nurse says you may. Keep the area around the rash clean and dry. Ask your doctor for medicine if your rash bothers you.
- To help with itching, moisturize your skin several times a day.
- Avoid sun exposure and apply sunscreen routinely when outdoors.
- Keeping your pain under control is important to your well-being. Please tell your doctor or nurse if you are experiencing pain.



## Food and Medicine Interactions

- This medicine may interact with grapefruit and grapefruit juice. Talk to your doctor as this could make side effects worse.
- Check with your doctor or pharmacist about all other prescription medicines and over-the-counter medicines and dietary supplements (vitamins, minerals, herbs, and others) you are taking before starting this medicine as there are known medicine interactions with ivosidenib. Also, check with your doctor or pharmacist before starting any new prescription or over-the-counter medicines, or dietary supplements to make sure that there are no interactions.
- This medicine may interact with St. John's Wort and may lower the levels of the medicine in your body, which can make it less effective.
- This medicine may interact with hormonal birth control (i.e., birth control pills, skin patches, vaginal rings, injections) and affect how they work. Discuss with your doctor and/or nurse what method of birth control may be right for you during your treatment.

## When to Call the Doctor

Call your doctor or nurse if you have any of these symptoms and/or any new or unusual symptoms:

- Fever of 100.4° F (38° C) or higher
- Chills
- Headache that does not go away
- Feeling dizzy or lightheaded
- Blurred vision or other changes in eyesight
- Tiredness and/or weakness that interferes with your daily activities
- Easy bleeding or bruising
- Loss of hearing
- Feeling that your heart is beating fast or in a not normal way (palpitations)
- Cough that is bothersome
- Wheezing and/or trouble breathing
- Lasting loss of appetite or rapid weight loss of five pounds in a week
- Nausea that stops you from eating or drinking and/or is not relieved by prescribed medicines
- Throwing up more than 3 times a day
- Pain in your mouth or throat that makes it hard to eat or drink
- Diarrhea, 4 times in one day or diarrhea with lack of strength or a feeling of being dizzy
- No bowel movement in 3 days or when you feel uncomfortable
- Weight gain of 5 pounds in one week (fluid retention)
- Swelling of the hands, feet, or any other part of the body
- Swelling of your abdomen
- Pain in your abdomen that does not go away
- Signs of possible liver problems: dark urine, pale bowel movements, pain in your abdomen, feeling very tired and weak, unusual itching, or yellowing of the eyes or skin



- Signs of differentiation syndrome such as fever, weight gain, swelling and/or trouble breathing. **Immediately report any of these symptoms to your healthcare provider.**
- Signs of tumor lysis: confusion or agitation, decreased urine, nausea/vomiting, diarrhea, muscle cramping, numbness and/or tingling, seizures.
- New rash and/or itching that is bothersome
- Rash that is not relieved by prescribed medicines
- Decreased or very dark urine
- Pain that does not go away, or is not relieved by prescribed medicines
- Abnormal blood sugar
- Unusual thirst, passing urine often, headache, sweating, shakiness, irritability
- Numbness, tingling, pins and needles, or pain on one side of your body or both sides, your arms, hands, legs or feet
- If you think you may be pregnant

## Reproduction Warnings

- **Pregnancy warning:** This medicine may have harmful effects on the unborn baby. Women of child-bearing potential should use effective methods of birth control during your cancer treatment. Let your doctor know right away if you think you may be pregnant. Birth control pills (oral contraceptives) and other hormonal forms of birth control may not be effective with this medicine.
- **Breastfeeding warning:** Women should not breastfeed during treatment and for one month after stopping treatment because this medicine could enter the breast milk and cause harm to a breastfeeding baby.
- **Fertility warning:** Fertility studies have not been done with this medicine. Talk with your doctor or nurse if you plan to have children. Ask for information on sperm or egg banking.

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