

Ivosidenib (Tibsovo)

About This Drug

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

Possible Side Effects

- A rapid increase in your white blood cells
- Abnormal heartbeats/EKG
- Nausea
- 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)
- Decreased appetite (decreased hunger)
- Swelling of your legs, ankles and/or feet
- Tiredness
- Fever
- Changes in your liver function
- Muscle and joint pain
- Electrolyte changes
- Changes in your kidney function
- Cough
- Trouble breathing
- Rash

Note: Each of the side effects above was reported in 20% or greater of patients treated with ivosidenib. Not all possible side effects are included above.

Warnings and Precautions

- A serious syndrome may happen with the use of this drug known as differentiation syndrome. You may have a fever, weight gain, rash, swelling in your arms, legs or feet, cough, low blood pressure or trouble breathing. This syndrome can be life-threatening if not treated promptly.
- 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.

- Abnormal EKG

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 Medication

- Swallow the medicine whole with or without food daily. Avoid eating 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 and contact your physician.
- Do not replace a vomited dose. If you vomit a dose or miss a dose, contact your physician.
- **Handling:** Wash your hands after handling your medicine, your caretakers should not handle your medicine with bare hands and should wear latex gloves.
- This drug may be present in the saliva, tears, sweat, urine, stool, vomit, semen, and vaginal secretions. Talk to your doctor and/or your nurse about the necessary precautions to take during this time.
- **Storage:** Store this medicine in the original container at room temperature.
- **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 medication label. Some facilities have unused medication 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 plenty of fluids (a minimum of eight glasses per day is recommended).
- 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 loose bowel movements, you should drink more fluids so that you do not become dehydrated (lack of water in the body from losing too much fluid).
- If you have diarrhea, 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.
- Manage tiredness by pacing your activities for the day.
- Be sure to include periods of rest between energy-draining activities.
- 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.
- Keeping your pain under control is important to your well-being. Please tell your doctor or nurse if you are experiencing pain.
- Get regular exercise. If you feel too tired to exercise vigorously, try taking a short walk.

Food and Drug Interactions

- This drug 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 drug 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.
- Avoid the use of St. John's Wort while taking ivosidenib as this may lower the levels of the drug in your body, which can make it less effective.
- Birth control pills (oral contraceptives) may not be effective with this medication, please discuss other methods of contraception with your nurse and/or doctor.

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
- Feeling dizzy or lightheaded
- Blurred vision or other changes in eyesight
- Loss of hearing
- Feeling that your heart is beating fast or in a not normal way (palpitations)
- Coughing up yellow, green, or bloody mucus.
- Wheezing 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 your legs, ankles and/or feet
- Tiredness or weakness that interferes with your daily activities
- Signs of possible liver problems: dark urine, pale bowel movements, bad stomach pain, feeling very tired and weak, unusual itching, or yellowing of the eyes or skin
- Signs of differentiation syndrome such as fever, weight gain, rash, swelling in your arms, legs or feet, cough, low blood pressure or trouble breathing
- New rash and/or itching
- Rash that is not relieved by prescribed medicines
- Decreased urine, or very dark urine
- Pain that does not go away, or is not relieved by prescribed medicines
- 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 drug 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) may not be effective with this medication.**
- **Breastfeeding warning:** Women should not breastfeed during treatment and for at least one month after treatment because this drug could enter the breast milk and cause harm to a breastfeeding baby.
- **Fertility warning:** Human fertility studies have not been done with this drug. Talk with your doctor or nurse if you plan to have children. Ask for information on sperm or egg banking.

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