

Tivozanib (Fotivda)

About This Medicine

TIVOZANIB (tye VOE za nib) treats kidney cancer. It works by blocking a protein that causes cancer cells to grow and multiply. This helps to slow or stop the spread of cancer cells. It is given orally (by mouth).

This medicine may be used for other purposes; ask your care team if you have questions.

Possible Side Effects

- Decrease in the number of white blood cells. This may raise your risk of infection.
- Longer blood clotting times. This means your blood is taking longer than usual to form clots.
- Nausea
- Soreness of the mouth and throat. You may have red areas, white patches, or sores that hurt.
- Diarrhea (loose bowel movements)
- Decreased appetite (decreased hunger)
- Tiredness
- Changes in your thyroid and pancreas function
- Changes in your liver and kidney function
- Electrolyte changes
- Blood sugar levels may change
- Voice changes/hoarseness
- Cough
- High blood pressure

Note: Each of the side effects above was reported in 20% or greater of people treated with tivozanib. 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 care team.

Warnings and Precautions

- High blood pressure which can be severe and life-threatening.



- Abnormal bleeding which can be life-threatening. Symptoms may be coughing up blood, throwing up blood (may look like coffee grounds), red or black tarry bowel movements, abnormally heavy menstrual flow, nosebleeds, or any other unusual bleeding.
- Changes in your heart function which can be life-threatening. This medicine may cause congestive heart failure – your heart is not pumping blood as well as it should be, and fluid can build up in your body.
- Blood clots and events such as stroke and heart attack which can be severe and life-threatening. A blood clot in your leg may cause your leg to swell, appear red and warm, and/or cause pain. A blood clot in your lungs may cause trouble breathing, pain when breathing, and/or chest pain.
- Increased protein in your urine, which can affect how your kidneys work.
- Slow wound healing
- Perforation or fistula- an abnormal hole in your stomach, intestine, esophagus, or other organ, which can be life-threatening.
- Changes in your thyroid function
- Swelling in the brain that is usually reversible. Symptoms can be sudden (acute) and may include a headache, confusion, changes in eyesight, extreme tiredness/coma, and/or seizures. **If you start to have any of these symptoms let your care team know right away.**

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

Important Information

- Tivozanib may cause slow wound healing. It should not be given within at least 24 days of planned surgery, including dental surgeries, and for at least 2 weeks and until adequate wound healing following major surgery. If you must have emergency surgery or have an accident that results in a wound, tell the care team that you are on tivozanib.
- Tell your care team before taking this medicine if you have an allergy to FDandC Yellow No.5 (tartrazine) or aspirin. Tivozanib capsules contain FDandC Yellow No.5 which may cause allergic-type reactions in certain people, especially people who also have an allergy to aspirin.

How to Take Your Medicine

- Swallow this medicine whole with a glass of water, with or without food. Do not open capsules.
- **Missed dose:** If you miss a dose, take your next dose at the regular time. Do not take 2 doses at the same time and do not double up on the next dose.
- **Overdosage:** If you think you have taken too much of this medicine contact a poison control center or emergency room at once.
- **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.
- This medicine may be present in the urine, stool and 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 care team after your treatment. If you take a pill each day, follow these precautions every day.



- **Storage:** Store this medicine in the original container at room temperature. Keep out of the reach of children and pets.
- **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 take-back programs and/or other options. If you do not have a take-back program in your area, then please discuss with your care team how to dispose of unused medicine.

Treating Side Effects

- 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 care team tells you, and whenever you feel like you may have a fever.
- Manage tiredness by pacing your activities for the day.
- Be sure to include periods of rest between energy-draining activities.
- Drink enough fluids to keep your urine pale yellow.
- 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 care team about other helpful tips and medicine that is available to help stop or lessen these symptoms.
- 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.
- 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 care team about medicine that can lessen or stop your diarrhea.
- 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 care team's approval, may increase your appetite.
- If you have diabetes, keep good control of your blood sugar level. Tell your care team if your glucose levels are higher or lower than normal.

Food and Medicine Interactions

- There are no known interactions of tivozanib with food.
- Check with your care team 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 tivozanib. Also, check with your care team 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.

When to Call Your Care Team

Call your care team if you have any of these symptoms and/or any new or unusual symptoms:

- Fever of 100.4° F (38° C) or higher
- Chills
- Blurry vision or other changes in eyesight
- A headache that does not go away
- Tiredness that interferes with your daily activities
- Extreme tiredness and/or coma
- Confusion
- Symptoms of a seizure such as confusion, blacking out, passing out, loss of hearing or vision, blurred vision, unusual smells or tastes (such as burning rubber), trouble talking, tremors or shaking in parts or all of the body, repeated body movements, tense muscles that do not relax, and loss of control of urine and bowels. **If you or your family member suspects you are having a seizure, call 911 right away.**
- Cough that is bothersome
- Wheezing and/or trouble breathing
- Feeling your heart is beating fast or in a not normal way (palpitations)
- Chest pain or symptoms of a heart attack. Most heart attacks involve pain in the center of the chest that lasts more than a few minutes. The pain may go away and come back, or it can be constant. It can feel like pressure, squeezing, fullness, or pain. Sometimes pain is felt in one or both arms, the back, neck, jaw, or stomach. **If any of these symptoms last 2 minutes, call 911.**
- Symptoms of a stroke such as sudden numbness or weakness of your face, arm, or leg, mostly on one side of your body; sudden confusion, trouble speaking or understanding; sudden trouble seeing in one or both eyes; sudden trouble walking, feeling dizzy, loss of balance or coordination; or sudden, bad headache with no known cause. **If you have any of these symptoms for 2 minutes, call 911.**
- Your leg is swollen, red, warm and/or painful
- Swelling of the legs, feet, or ankles
- Pain in your mouth or throat that makes it hard to eat or drink
- Trouble swallowing
- Nausea that stops you from eating or drinking and/or is not relieved by prescribed medicines
- Throwing up more than 3 times a day
- Diarrhea, 4 times in one day or diarrhea with lack of strength or a feeling of being dizzy
- Severe pain in your abdomen that does not go away
- Lasting loss of appetite or rapid weight loss of five pounds in a week
- Weight gain of 5 pounds in one week (fluid retention)
- 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 high blood sugar: unusual thirst, passing urine often, headache, sweating, shakiness, irritability
- Signs of abnormal bleeding such as coughing up blood, throwing up blood (may look like coffee grounds), easy bleeding or bruising, red or black tarry bowel movements, abnormally heavy menstrual flow, nosebleeds, or any other unusual bleeding
- Foamy or bubbly-looking urine
- Decreased or very dark urine
- Signs of high phosphate: muscle cramps and/or numbness or tingling around your mouth
- Signs of severe low sodium levels: confusion, agitation, feeling that your heart is beating fast, passing out, seizure and/or coma
- Signs of low thyroid function: unexplained weight gain, hair loss, dry skin, constipation, increased sensitivity to cold
- Signs of increased thyroid function: unexplained weight loss, sweating, irritability, feeling that your heart is beating fast or in a not normal way (palpitations)

Reproduction Warnings

- **Pregnancy:** This medicine can cause serious birth defects. If you can become pregnant, use birth control while taking this medicine and for 1 month after the last dose. If you can get your partner pregnant, use birth control while taking this medicine and for 1 month after the last dose. Tell your care team right away if you think you might be pregnant or think your partner might be pregnant.
- **Breastfeeding:** Do not breastfeed while taking this medicine and for 1 month after the last dose.
- **Fertility Warning:** This medicine can affect your ability to have children in the future. If you plan to have children, talk with your care team.

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