



Tivozanib (Fotivda®)

Pronounced: tye-VOE-za-nib

Classification: Kinase Inhibitor

About Tivozanib (Fotivda®)

A kinase is an enzyme that promotes cell growth. There are many types of kinases, which control different phases of cell growth. By blocking a particular enzyme from working, this medication can slow the growth of cancer cells.

How to take Tivozanib

This medication comes as a capsule to be taken by mouth. You should swallow the capsule whole. Do not open or break the capsule. The medication should be taken with a whole glass of water with or without food. If you miss a dose take your next dose at its scheduled time. Do not take two doses in the same day.

It is important to make sure you are taking the correct amount of medication every time. Before every dose, check that what you are taking matches what you have been prescribed. If you take too much of your medication call your provider right away. Because of the way this medication is scheduled, you should also make sure you are supposed to take the medication that day.

Talk to your provider before taking this medication if you have an allergy to tartrazine, also known as yellow dye #5. The 0.89 mg strength capsules contain tartrazine and you could have an allergic reaction. The following medications can interact with this medication, please consult with your medical team if you are also on any of the following medications before taking tivozanib: apalutamide, carbamazepine, enzalutamide, fosphenytoin, lumacaftor and ivacaftor, mitotane, phenobarbital, phenytoin, primidone or rifampin.

Storage and Handling

Store your medication in the original, labeled container at room temperature and in a dry location (unless otherwise directed by your healthcare provider or pharmacist). This medication should not be stored in a pillbox. Keep containers out of reach of children and pets. If a caregiver prepares your dose for you, they should consider wearing gloves or pour the pills directly from their container into the cap, a small cup, or directly into your hand. They should avoid touching the pills. They should always wash their hands before and after giving you the medication. Pregnant or nursing women should not prepare the dose for you. Ask your oncology team where to return any unused medication for disposal. Do not flush down the toilet or throw in the trash.

Where do I get this medication?

Certain cancer medications are only available through specialty pharmacies. If you need to get this medication through a specialty pharmacy, your provider will help you start this process. Where you can fill your prescriptions may also be influenced by your prescription drug coverage. Ask your health care provider or pharmacist for assistance in identifying where you can get this medication.

Insurance Information

This medication may be covered under your prescription drug plan. Patient assistance may be available to qualifying individuals depending upon prescription drug coverage. Co-pay cards, which reduce the patient co-pay responsibility for eligible commercially (non-government sponsored) insured patients, may also be available. Your care team can help you find these resources if they are available.

Possible Side Effects

There are a number of things you can do to manage the side effects of tivozanib. Talk to your care team about these recommendations. They can help you decide what will work best for you. These are some of the most common or important side effects:

Fatigue

Fatigue is very common during cancer treatment and is an overwhelming feeling of exhaustion that is not usually relieved by rest. While on cancer treatment, and for a period after, you may need to adjust your schedule to manage fatigue. Plan times to rest during the day and conserve energy for more important activities. Exercise can help combat fatigue; a simple daily walk with a friend can help. Talk to your healthcare team for helpful tips on dealing with this side effect.

High Blood Sugar

This medication can cause elevated blood sugar levels in patients with and without diabetes. Your oncology care team will monitor your blood sugar. If you develop increased thirst, urination or hunger, blurry vision, headaches or your breath smells like fruit, notify your healthcare team. Diabetics should monitor their blood sugar closely and report elevations to the healthcare team.

High Blood Pressure

This medication can cause high blood pressure (hypertension). Patients should have their blood pressure checked regularly during therapy. Any hypertension should be treated appropriately. If hypertension cannot be controlled, the medication may be stopped. Report any headaches, vision changes or dizziness to your oncology care team.

Diarrhea

Your oncology care team can recommend medications to relieve **diarrhea**. Also, try eating **low-fiber**, bland foods, such as white rice and boiled or baked chicken. Avoid raw fruits, vegetables, whole grain breads, cereals, and seeds. Soluble fiber is found in some foods and absorbs fluid, which can help relieve diarrhea. Foods high in soluble fiber include: applesauce, bananas (ripe), canned fruit, orange sections, boiled potatoes, white rice, products made with white flour, oatmeal, cream of rice, cream of wheat, and farina. Drink 8-10 glasses of non-alcoholic, un-caffeinated fluid a day to prevent dehydration.

Decrease in Appetite or Taste Changes

Nutrition is an important part of your care. Cancer treatment can affect your appetite and, in some cases, the side effects of treatment can make eating difficult. Ask your oncology care team about nutritional counseling services at your treatment center to help with food choices.

- Try to eat five or six small meals or snacks throughout the day, instead of 3 larger meals.
- If you are not eating enough, nutritional supplements may help.
- You may experience a metallic taste or find that food has no taste at all. You may dislike foods or beverages that you liked before receiving cancer treatment. These symptoms can last for several months or longer after treatment ends.
- Avoid any food that you think smells or tastes bad. If red meat is a problem, eat chicken, turkey, eggs, dairy products, and fish without a strong smell. Sometimes cold food has less of an odor.
- Add extra flavor to meat or fish by marinating it in sweet juices, sweet and sour sauce, or dressings. Use seasonings like basil, oregano, or rosemary to add flavor. Bacon, ham, and onion can add flavor to vegetables.

Nausea and/or Vomiting

Talk to your oncology care team so they can prescribe medications to help you manage **nausea and vomiting**. In addition, dietary changes may help. Avoid things that may worsen the symptoms, such as heavy or greasy /fatty, spicy or acidic foods (lemons, tomatoes, oranges). Try saltines or ginger ale to lessen symptoms. Call your oncology care team if you are unable to keep fluids down for more than 12 hours or if you feel lightheaded or dizzy at any time.

Liver Toxicity

This medication can cause liver toxicity, which your oncology care team may monitor for using blood tests called liver function tests. Notify your healthcare provider if you notice yellowing of the skin or eyes, your urine appears dark or brown, or you have

pain in your abdomen, as these can be signs of liver toxicity.

Electrolyte Abnormalities

This medication can affect the normal levels of electrolytes (sodium, potassium, magnesium, phosphate, etc.) in your body. Your levels will be monitored using blood tests. If your levels become too low, your care team may prescribe specific electrolytes to be given by IV or taken by mouth. Do not take any supplements without first consulting with your care team.

Dysphonia

This medication can cause dysphonia, which is a hoarse voice. Speak to your provider if you have any changes to your voice or trouble speaking.

Low White Blood Cell Count

White blood cells (WBC) are important for fighting infection. While receiving treatment, your [WBC count can drop](#), putting you at a higher risk of getting an infection. You should let your doctor or nurse know right away if you have a fever (temperature greater than 100.4°F or 38°C), sore throat or cold, shortness of breath, cough, burning with urination, or a sore that doesn't heal. Tips to preventing infection:

- [Washing hands](#), both yours and your visitors, is the best way to prevent the spread of infection.
- Avoid large crowds and people who are sick (i.e.: those who have a cold, fever, or cough or live with someone with these symptoms).
- When working in your yard, wear protective clothing including long pants and gloves.
- Do not handle pet waste.
- Keep all cuts or scratches clean.
- Shower or bath daily and perform frequent [mouth care](#).
- Do not cut cuticles or ingrown nails. You may wear nail polish, but not fake nails.
- Ask your oncology care team before scheduling dental appointments or procedures.
- Ask your oncology care team before you, or someone you live with, has any vaccinations.

Mucositis

Certain cancer treatments can cause [sores or soreness in your mouth and/or throat](#). Notify your oncology care team if your mouth, tongue, inside of your cheek or throat becomes white, ulcerated or painful. Performing [regular mouth care](#) can help prevent or manage mouth sores. If mouth sores become painful, your doctor or nurse can recommend a pain reliever.

- Brush with a soft-bristle toothbrush or cotton swab twice a day.
- Avoid mouthwashes that contain alcohol. A baking soda and/or salt with warm water mouth rinse (2 level teaspoons of baking soda or 1 level teaspoon of salt in an eight ounce glass of warm water) is recommended 4 times daily.
- If your mouth becomes dry, eat moist foods, drink plenty of fluids (6-8 glasses), and suck on sugarless hard candy.
- Avoid smoking and chewing tobacco, drinking alcoholic beverages and citrus juices.

Kidney Problems

This medication can cause kidney problems, including an increased creatinine level, which your oncology care team may monitor for using blood tests. Notify your healthcare provider if you notice decreased urine output, blood in the urine, swelling in the ankles, or loss of appetite.

Less common, but important side effects can include:

- **Hemorrhage (Bleeding):** Serious bleeding has also occurred in patients treated with this medication. If you take aspirin, non-steroidal anti-inflammatory medications (i.e. Motrin, ibuprofen, naproxen) or other medication that interferes with blood clotting, let your healthcare provider know. Signs of bleeding can include: nose bleeds, blood in the stool or dark, tarry stools, coughing up or vomiting blood or vomit that looks like coffee grounds. While some bleeding, such as a nosebleed, may not seem like much of a concern, you should notify your healthcare team right away if you develop bleeding of any sort.
- **Proteinuria:** This medication may cause proteinuria, the presence of protein in the urine. This can be a sign of kidney

damage. Your oncology team will periodically check your urine for protein. Your kidney function will also be monitored throughout treatment.

- **Thyroid Problems:** This medication can cause hypothyroidism (under active thyroid) and hyperthyroidism (over active thyroid). Your healthcare provider will perform blood tests to check the function of your thyroid and treat this side effect if it develops. Symptoms of thyroid problems include: tiredness, feeling hot or cold, change in your voice, weight gain or loss, hair loss and muscle cramps. Report any of these symptoms to your oncology care team.
- **Heart Problems:** Tivozanib can cause or worsen pre-existing heart problems including congestive heart failure, restrictive cardiomyopathy, decreased heart function, and heart attack. Notify your healthcare provider if you have sudden weight gain or swelling in the ankles or legs. If you develop chest pain or pressure, pain in the left arm, back, or jaw, sweating, shortness of breath, clammy skin, nausea, dizziness or lightheadedness, call 911 or go to the nearest emergency room.
- **Blood Clots:** Tivozanib can increase the risk of blood clots (DVT or PE). Symptoms can include: swelling, redness or pain in an extremity, or shortness of breath. If you experience symptoms of these problems, you should contact your healthcare provider immediately or go to an emergency room.
- **Posterior Reversible Encephalopathy Syndrome (PRES):** In rare cases, this medication has caused a neurological disorder called posterior reversible encephalopathy syndrome (PRES), also called reversible posterior leukoencephalopathy (RPLS). Symptoms of PRES/RPLS include headache, seizure, lethargy, confusion, blindness and other visual and neurological disturbances. Report any of these symptoms to your healthcare team immediately.
- **Wound Healing:** This medication can lead to slower or incomplete wound healing, such as a surgical wound not healing or staying closed. Be sure to inform the team performing the surgical procedure that you are taking x drug. You should also inform your oncology team that a surgical procedure is planned. It is recommended that this medication be discontinued 24 days prior to any surgery. In addition, any surgical incision should be fully healed prior to starting or restarting the medication. If you have a surgical wound that has not healed or begins to have signs of infection (redness, swelling, warmth), report this to your healthcare team.

Sexual & Reproductive Concerns

This medication may affect your reproductive system, resulting in the menstrual cycle or sperm production becoming irregular or stopping permanently. Women may experience menopausal effects including hot flashes and vaginal dryness. In addition, the desire for sex may decrease during treatment. You may want to consider sperm banking or egg harvesting if you may wish to have a child in the future. Discuss these options with your oncology team.

Exposure of an unborn child to this medication could cause birth defects, so you should not become pregnant or father a child while on this medication. Effective birth control is necessary during treatment and for at least 1 month after treatment, even if your menstrual cycle stops or you believe you are not producing sperm. You should not breastfeed while taking this medication or for 1 month after your last dose.

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