



Dabrafenib (Tafinlar®)

Pronounced: da braf e nib

Classification: BRAF Kinase Inhibitor

About Dabrafenib (Tafinlar®)

BRAF is a protein kinase that plays a role in regulating genes that are responsible for cell replication and survival. This mutated form of BRAF appears to promote overgrowth of these cancer cells. Dabrafenib works by blocking the actions of the abnormal BRAF, inhibiting cell replication and potentially causing cell death.

How to Take Dabrafenib

Dabrafenib is taken by mouth in capsule form. Dabrafenib capsules should be taken on an empty stomach (1 hour before or 2 hours after eating) and should not be opened, crushed, broken, or chewed. A missed dose can be taken up to 6 hours before the next scheduled dose. Do not take two doses at once to make up for a missed dose.

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.

The blood levels of this medication can be affected by certain foods and medications, so they should be avoided. These include: grapefruit, grapefruit juice, verapamil, ketoconazole, rifampin, phenytoin, St. John's wort, and modafinil. Dabrafenib can also impact Coumadin (blood thinner) levels.

If possible, you should not take this medication at the same time as "heartburn" medications (including proton pump inhibitors such as prilosec, nexium, protonix; H2 blockers, such as tagamet, zantac; and antacids, such as Tums, Rolaids) as these may affect how dabrafenib is absorbed. If you are taking Coumadin, you may require more frequent blood testing while taking dabrafenib. Be sure to tell your healthcare provider about all medications and supplements you take.

BRAF Testing

This medication only works in cancer that has certain BRAF mutations, and this abnormality must be tested for prior to starting the medication to identify patients appropriate for therapy. In order to test for mutated BRAF, a sample of the tumor is sent to a special laboratory that performs this test.

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 it in the trash.

Where do I get this medication?

Depending on your prescription coverage, this medication may be available at your local retail pharmacy or through a specialty pharmacy. Your oncology team will work with your prescription drug plan to identify the appropriate supplier for 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 dabrafenib. Talk to your care team about these recommendations. They can help you decide what will work best for you. Some of the most common or important side effects of dabrafenib when used alone include:

Fever

Fever can be a serious side effect of this medication. If you develop a fever of 100.4°F or 38°C or greater, call your oncology care team right away and before taking the next dose of medication.

Rash

Some patients may develop a rash, with or without itching, that can become severe or become infected if left untreated. Use an alcohol free moisturizer on your skin and lips; avoid moisturizers with perfumes or scents. If your skin does crack or bleed, be sure to keep the area clean to avoid infection. Be sure to notify your oncology care team of any rash that develops, as this can be a serious reaction. They can give you more tips on [caring for your skin](#) and prescribe topical or oral therapy to help with the itching and rash.

This medication can also cause a reaction on the palms of the hands and soles of the feet that causes the skin to darken, become thickened, red, swollen or tender. Report these symptoms to your oncology care team. This can also be treated with topical medications that your oncology care team can recommend or prescribe.

Loss or Thinning of Scalp and Body Hair (Alopecia)

Your hair may become [thin, brittle, or may fall out](#). This typically begins two to three weeks after treatment starts. This hair loss can be all body hair, including pubic, underarm, legs/arms, eyelashes, and nose hairs. The use of scarves, wigs, hats, and hairpieces may help. Hair generally starts to regrow soon after treatment is completed. Remember your hair helps keep you warm in cold weather, so a hat is particularly important in cold weather or to protect you from the sun.

Hand Foot Syndrome

[Hand foot syndrome](#) (HFS) is a skin reaction that appears on the palms of the hands and/or the soles of the feet, as a result of certain chemotherapy agents being absorbed by the skin cells. HFS can begin as a mild tingling, numbness, pins-and-needles feeling, redness or pain, or swelling of the hands and/or feet. This can then progress to painful swelling, blistering, or peeling skin that can interfere with your ability to do normal activities. Be sure to let your oncology care team know right away if you notice these symptoms, as they may need to adjust the chemotherapy dose or take a break to allow the skin to heal. Some tips to help prevent HFS include:

- Keep hands and feet clean and dry.
- Avoid tight shoes or socks.
- Avoid activities that put pressure on the palms or soles for 1 week after treatment.
- Apply an alcohol-free moisturizer liberally and often. Avoid moisturizers with perfumes or scents.
- Avoid very hot water for baths and showers.

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.

This medication is often given with another medication called trametinib. The following side effects were seen in studies of this combination, but not when dabrafenib was given alone. You should be aware of these side effects regardless if you are taking both medications or not.

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.

Diarrhea

Your oncology 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.

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 antacids, (e.g. milk of magnesia, calcium tablets such as Tums), 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.

Peripheral Edema

Peripheral edema is swelling of the extremities caused by retention of fluid. It can cause swelling of the hands, arms, legs, ankles, and feet. The swelling can become uncomfortable. Notify your oncology care team if you are experiencing any new or worsening swelling.

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.

Muscle or Joint Pain/Aches and Headache

Your oncology care team can recommend medications and other strategies to help relieve pain.

Less common, but important side effects can include:

- **Secondary Skin Cancer:** This medication has been associated with the development of new skin cancers (basal cell or squamous cell cancer). Because of this, it is important to practice sun safety. Avoid the sun between 10-2pm, when it is strongest. Wear sunscreen (at least SPF 15) everyday; wear sunglasses, a hat and long sleeves/pants to protect your skin and seek out shade whenever possible. You should have skin examinations prior to starting treatment, and then every 2 months while on therapy, and for 6 months after the medication has been stopped. Check your own skin regularly and report any new growths, sores or bumps that bleed or do not heal, or notice any changes in moles to your oncology care team.
- **Eye Issues:** In clinical trials, several patients developed conditions called uveitis and iritis, which is a swelling or irritation of the middle layer and the colored part of the eye, respectively. Symptoms of this condition include blurry vision, loss of vision, seeing colored dots or "floaters" (dark spots in the field of vision), seeing a halo (blurred outline around objects), eye redness, swelling, or pain and sensitivity to light. In addition, a disorder called retinal pigment epithelial detachment (RPED) is associated with trametinib, which is often taken with dabrafenib. If you develop any of these symptoms or changes in your vision, notify your oncology care team immediately.
- **Blood Clots:** When used in combination with trametinib, dabrafenib can increase the risk of blood clots in your arms, legs or lungs (DVT, pulmonary embolism or PE). Symptoms can include: swelling, redness, or pain in a leg or arm, chest pain or pressure, or shortness of breath. If you experience symptoms of these problems, you should contact your oncology care team immediately or go to an emergency room.
- **Bleeding:** This medication, when used in combination with trametinib, may increase the risk of bleeding. If you experience headaches, dizziness, cough up blood or blood clots, vomit blood or have red or black tar like looking stools, contact your oncology care team immediately.
- **Heart Problems:** Dabrafenib can cause or worsen pre-existing heart problems including cardiomyopathy, decreased heart function and heart attack. Notify your oncology care team 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.
- **Hemolytic Anemia:** Dabrafenib can cause the breakdown of red blood cells (hemolytic anemia) in people who have a G6PD deficiency, which is an inherited condition in which the body does not have enough of the enzyme glucose-6-phosphate dehydrogenase. You may not even be aware that you have this condition, therefore all patients taking this medication should report the following symptoms of red blood cell breakdown to their oncology care team: jaundice (yellowing of the skin or whites of the eyes), weakness, dizziness, or shortness of breath.

Reproductive Concerns

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 2 weeks after stopping treatment with dabrafenib alone or 4 months when dabrafenib is taken in combination with trametinib. Even if your menstrual cycle stops or you believe you are not producing sperm, you could still be fertile and conceive.

Birth control using hormones (such as birth control pills, injections, or patches) may not work as well while you are taking dabrafenib. You should use another effective method of birth control while taking this medication.

This medication can affect a woman's fertility and future ability to become pregnant. It can also cause lower sperm counts in men and may affect the ability to father a child. Talk with your healthcare provider about [fertility preservation](#) options. You should not breastfeed while receiving this medication or for at least 2 weeks after your last dose.

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