

Dabrafenib (Tafinlar)

About This Drug

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

Possible Side Effects

- Headache
- Fever
- Pain in the joints
- Hair loss. Hair loss is often temporary, although with certain medicine, hair loss can sometimes be permanent. Hair loss may happen suddenly or gradually. If you lose hair, you may lose it from your head, face, armpits, pubic area, chest, and/or legs. You may also notice your hair getting thin.
- Hand-foot syndrome. The palms of your hands or soles of your feet may tingle, become numb, painful, swollen, or red.
- Thickening of the skin
- New skin growths

Note: Each of the side effects above was reported in 20% or greater of patients treated with dabrafenib. Not all possible side effects are included above. You may experience different side effects if you take dabrafenib in combination with trametinib.

Warnings and Precautions

- Blurred vision or other changes in eyesight which can rarely cause blindness
- Severe allergic skin reaction. You may develop blisters on your skin that are filled with fluid or a severe red rash all over your body that may be painful.
- Changes in your heart function
- Serious fever reactions. This may be accompanied by dehydration (lack of water in the body from losing too much fluid), low blood pressure and changes in your kidney function which can cause kidney failure.
- Blood sugar levels may change. If you have diabetes, changes may need to be made to your diabetes medication.
- This drug may raise your risk of getting a second cancer and the development of skin lesions that may or may not be cancer.
- Breakdown of your red blood cells which can cause anemia (decreased red blood cells) in people with a G6PD deficiency.

- Serious 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.

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

How to Take Your Medication

- Take doses of this drug approximately 12 hours apart, by mouth without food, , at least 1 hour before you eat or 2 hours after you eat. Do not open, crush or break the capsules.
- **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 6 hours. If your next dose is due in LESS than 6 hours, then skip the missed dose and take your next dose at your regular time and contact your doctor.
- If you vomit a dose, take your next dose at the regular time, and contact your physician. Do not take 2 doses at the same time and do not double up on the next dose.
- **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 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

- 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.
- Keeping your pain under control is important to your well-being. Please tell your doctor or nurse if you are experiencing pain.
- Drink plenty of fluids (a minimum of eight glasses per day is recommended).
- Avoid sun exposure and apply sunscreen routinely when outdoors.
- 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 hair loss, wash with a mild shampoo and avoid washing your hair every day.
- Avoid rubbing your scalp, pat your hair or scalp dry.
- Avoid coloring your hair.
- Limit your use of hair spray, electric curlers, blow dryers, and curling irons.
- If you are interested in getting a wig, talk to your nurse. You can also call the American Cancer Society at 800-ACS-2345 to find out information about the “Look Good, Feel Better” program close



to where you live. It is a free program where women getting chemotherapy can learn about wigs, turbans and scarves as well as makeup techniques and skin and nail care.

- Examine your skin often for new skin lesions/growth.

Food and Drug Interactions

- Avoid grapefruit or grapefruit juice while taking this medicine. Grapefruit and grapefruit juice may raise the levels of dabrafenib in your body. 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 dabrafenib. Also, check with your doctor or pharmacist before starting any new prescription or over-the-counter medicines, or dietary supplement to make sure that there are no interactions.

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
- Easy bleeding or bruising
- Coughing up blood
- Blurred vision or other changes in eyesight
- Red or painful eyes
- Headache that does not go away
- Feeling dizzy or weak
- Tiredness that interferes with your daily activities
- Feeling that your heart is beating in a fast or not normal way (palpitations)
- Trouble breathing
- Pain that does not go away or is not relieved by prescribed medicines
- Swelling of legs, ankles, or feet
- Weight gain of 5 pounds in one week (fluid retention)
- Abnormal blood sugar
- Unusual thirst, passing urine often, headache, sweating, shakiness, irritability
- Blood in your urine, vomit (bright red or coffee-ground) and/or stools (bright red, or black/tarry)
- Decreased urine
- Painful, red, or swollen areas on your hands or feet
- Numbness and/or tingling of your hands and/or feet
- A new rash or a rash that is not relieved by prescribed medicines
- Flu-like symptoms: fever, headache, muscle and joint aches, and fatigue (low energy, feeling weak)
- New skin lesions



- If you think you may be pregnant or may have impregnated your partner

Reproduction Warnings

- **Pregnancy warning:** This drug can have harmful effects on the unborn baby. Women of childbearing potential should use effective non-hormonal methods of birth control (i.e., condom, sponge, diaphragm, spermicide and/or cervical cap) during your cancer treatment and for 2 weeks after treatment. Men should use condoms with female partners of childbearing potential or partners that may be pregnant during cancer treatment and for at least 2 weeks after cancer treatment. Men should use condoms even after a successful vasectomy. Let your doctor know right away if you think you may be pregnant or may have impregnated your partner. **Birth control pills (oral contraceptives) may not be effective with this medication.**
- **Breastfeeding warning:** Women should not breastfeed during treatment and for 2 weeks after treatment because this drug could enter the breast milk and cause harm to a breastfeeding baby.
- **Fertility warning:** In men and women both, this drug may affect your ability to have children in the future. Talk with your doctor or nurse if you plan to have children. Ask for information on sperm or egg banking.

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