

## Dabrafenib (Tafinlar)

---

### About This Medicine

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. 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 medical team.

### Warnings and Precautions

- Serious reaction causing swelling in the eye which can cause eye pain, swelling, or redness, blurred vision or other changes in eyesight. Very rarely, this can 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, such as changes in your heart's ability to pump blood properly.
- Serious fever reactions. This may be accompanied by dehydration (lack of water in the body from losing too much fluid), low blood pressure, dizziness, and changes in your kidney function which can cause kidney failure.
- Blood sugar levels may change
- This medicine may raise your risk of getting a second cancer and the development of skin lesions that may or may not be cancer.

- A genetic disorder which breaks down your red blood cells and cause anemia (decreased red blood cells)
- Serious abnormal bleeding which can be life-threatening can occur when taken in combination with trametinib. 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.
- Hemophagocytic lymphohistiocytosis when taken in combination with trametinib - an immune reaction that can cause damage to blood cells in your bone marrow and any organs in your body, which can be life-threatening.

**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 Medicine

- **Capsules:** Take this medicine 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.
- **Tablets for suspension:** Refer to the medication guide that comes with your medicine for instructions on how to prepare and dose the medicine correctly.
- **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.
- If you vomit 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.
- **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.
- Cytotoxic medicines leave the body through urine and stool, but they can also be present in 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 health care provider after your treatment. If you take a cytotoxic pill each day, follow these precautions every day.
- **Storage: Capsules:** Store this medicine in the original container at room temperature. Do not remove the desiccant cannister.
- **Tablets for suspension:** Store this medicine, along with the two plastic dessicant cannisters in the original container at room temperature. Keep the lid tightly closed. Do not remove the desiccant cannisters. Throw away any mixed oral suspension after 30 minutes of preparation.
- **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 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 enough fluids to keep your urine pale yellow.
- 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 coloring your hair.
- Avoid rubbing your scalp, pat your hair or scalp dry.
- 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 and they can help you get in touch with programs in your local area.
- Examine your skin often for new skin lesions/growths or changes to existing lesions.

## Food and Medicine Interactions

- This medicine 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 medicine 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.
- This medicine interacts with hormonal birth control (i.e., birth control pills, skin patches, vaginal rings, injections) and affects how they work. Discuss with your doctor and/or nurse what method of birth control may be right for you during your treatment.

## 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
- Blurred vision or other changes in eyesight, see color dots or halo
- Red, painful, or swollen eyes
- Headache that does not go away
- Feeling dizzy or lightheaded
- Tiredness and/or weakness that interferes with your daily activities
- Yellowing of the eyes or skin
- Trouble breathing
- Feeling that your heart is beating fast or in a not normal way (palpitations)
- Abnormal blood sugar
- Unusual thirst, passing urine often, headache, sweating, shakiness, irritability

- Decreased or very dark urine
- 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
- Signs of hemophagocytic lymphohistiocytosis: fever, chills, swollen lymph nodes, yellowing of the eyes or skin, nausea, vomiting (throwing up), headache, confusion, trouble breathing, and/or rash
- Pain that does not go away or is not relieved by prescribed medicines
- Painful, red, or swollen areas on your hands or feet
- Numbness and/or tingling of your hands and/or feet
- Swelling of the legs, feet, or ankles
- Weight gain of 5 pounds in one week (fluid retention)
- 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 or changes to existing lesions
- New wart
- Skin sore or reddish bump that bleed or does not heal
- Change in size or color of a mole
- If you think you may be pregnant or may have impregnated your partner

## Reproduction Warnings

- **Pregnancy warning:** This medicine 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 stopping 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 stopping treatment. Men should use condoms even after a vasectomy. Let your doctor know right away if you think you may be pregnant or may have impregnated your partner.
- **Breastfeeding warning:** Women should not breastfeed during treatment and for 2 weeks after stopping treatment because this medicine could enter the breast milk and cause harm to a breastfeeding baby.
- **Fertility warning:** In men and women both, this medicine 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.

Revised August 2023

