

## Dabrafenib (Tafinlar)

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### About This Medicine

DABRAFENIB (da BRAF e nib) treats some types of 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

- 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 people 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 care team.

### Warnings and Precautions

- Serious reactions 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, along with problems with your organs, swollen lymph nodes, fever and higher than normal white blood cells.
- Changes in your heart function can occur when taken in combination with trametinib, 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 another cancer and the development of skin lesions that may or may not be cancer.
- 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 care team.

## Important Information

- Tell your care team if you have a glucose-6-phosphate dehydrogenase (G6PD) deficiency. This can put you at risk of anemia (decreased red blood cell) due to the breakdown of your red blood cells.

## How to Take Your Medicine

- **Capsules:** Take this medicine at the same time each day, approximately 12 hours apart. Take by mouth without food. Take 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 medicine guide that comes with your medicine for instructions on how to prepare and dose the medicine correctly. Do not chew, crush or swallow whole tablets for oral suspension.
- **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 after taking 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: Capsules:** Store this medicine in the original container at room temperature. Do not remove the desiccant cannister. Keep out of the reach of children and pets.



- **Tablets for suspension:** Store this medicine, along with the two plastic desiccant 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 care team how to dispose of unused medicine.

## Treating Side Effects

- 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.
- Keeping your pain under control is important to your well-being. Please tell your care team 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 care team says you may. Keep the area around the rash clean and dry. Ask your care team 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 care team 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 care team as this could make side effects worse.
- 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 dabrafenib. Also, check with your care team 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 care team what method of birth control may be right for you during your treatment.

## 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
- Swollen lymph nodes in your neck and/or armpits
- 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

## Reproduction Warnings

- **Pregnancy warning:** This medicine can cause serious birth defects. If you can become pregnant, use a non-hormonal method of birth control while taking this medicine and for 2 weeks after the last dose. If you can get your partner pregnant, use a condom, even if you have had a vasectomy, while taking this medicine and for at least 2 weeks after the last dose. Tell your care team right away if you think you might be pregnant or think your partner might be pregnant.
- Birth control pills (oral contraceptives) and other hormonal forms of birth control may not be effective with this medicine.
- **Breastfeeding warning:** Do not breastfeed while taking this medicine and for 2 weeks after the last dose.



- **Fertility warning:** This medicine may affect your ability to have children in the future. If you plan to have children, talk with your care team.

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