

ORAL CHEMOTHERAPY EDUCATION



DABRAFENIB

Name of your medication

Generic name — dabrafenib (duh-BRA-feh-nib)
Brand name — Tafinlar® (TA-fin-lar)

Common uses

Dabrafenib is used to treat patients with the following:

- Melanoma that has a genetic mutation called *BRAF* V600E or V600K and may be used in combination with trametinib
- Non-small cell lung cancer that has a genetic mutation called *BRAF* V600E and may be used in combination with trametinib
- Anaplastic thyroid cancer that has a genetic mutation called *BRAF* V600E and may be used in combination with trametinib
- Unresectable or metastatic solid tumors that have a genetic mutation called *BRAF* V600E and may be used in combination with trametinib
- Low-grade glioma in pediatric patients 1 year of age and older that have a genetic mutation called *BRAF* V600E and may be used in combination with trametinib

Dabrafenib may also be used for other treatments.

Dose and schedule

Taking dabrafenib as instructed is important to allow your treatment to be as effective as possible, so here are some key points to remember.

- Your dose may vary, but the usual dose of dabrafenib is 150 milligrams (mg) to be taken by mouth at a scheduled time twice a day.
- Dabrafenib should be taken on an empty stomach (one hour before or two hours after a meal or snack) and at the same time each day.
- Dabrafenib should be taken whole and not crushed, cut, or dissolved. If you are unable to swallow dabrafenib, talk to your care provider or pharmacist for possible options.
- If you miss a dose of dabrafenib:
 - Take the missed dose only if it has been less than six hours since you were supposed to take it. Then take the next dose at the regularly scheduled time.
 - **Do not** take two doses at one time.
 - Be sure to write down if you miss a dose and let your care provider know about any missed doses.

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Drug and food interactions

- ❑ Dabrafenib has many drug interactions. Inform your care providers of all prescription medications, over-the-counter medications, vitamins, and herbal products that you are taking.
- ❑ Grapefruit or grapefruit juice may interact with dabrafenib. Avoid eating or drinking these during treatment with dabrafenib.
- ❑ Talk with your care provider or pharmacist before taking new medications or supplements, or receiving any vaccines.

Storage and handling

Handle dabrafenib with care. Just like when chemotherapy is given into the vein, this drug can be toxic, and exposure of the drug to others should be limited.

- ❑ Store dabrafenib at room temperature (68°F–77°F) in a dry location away from light.
- ❑ Keep dabrafenib out of reach of children and pets.
- ❑ Leave dabrafenib in the provided packaging until it is ready to be taken.
- ❑ Whenever possible, give dabrafenib to yourself and follow the steps below. If a family member, friend, or caregiver needs to give dabrafenib to you, they also need to follow these steps:
 1. Wash hands with soap and water.
 2. Put on gloves to avoid touching the medication. (Gloves are not necessary if you give the drug to yourself.)
 3. Gently transfer the dabrafenib from its package to a small medicine or other disposable cup.
 4. Administer the medicine immediately by mouth with water.
 5. Remove gloves and do not use them for anything else.
 6. Throw gloves and medicine cup in household trash.
 7. Wash hands with soap and water.
- ❑ If a daily pill box or pill reminder will be used, contact your care team before using:
 - The person filling the box or reminder should wear gloves (gloves are not necessary if you are filling the box or reminder).
 - When empty, the box or reminder should be washed with soap and water before refilling. Be sure to wash hands with soap and water after the task is complete, whether or not gloves are worn
- ❑ If you have any unused dabrafenib, **do not** throw it in the trash and **do not** flush it down the sink or toilet. Talk to your care provider or pharmacist about proper disposal of dabrafenib.
- ❑ If you are traveling, put your dabrafenib's packaging in a sealed plastic bag. Ask your pharmacist if any additional travel precautions are needed.

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Side Effects of Dabrafenib

Below are common side effects that have been known to happen in about one third or more of patients taking dabrafenib are listed on the left side of this table. You **MAY NOT** experience these side effects. Options to help manage any side effects that do occur are included on the right side of this table. These should be discussed with your care provider. If you experience any side effect you cannot manage or that is not listed here, contact your care provider.

Possible Side Effect	Management
Thickening of the skin (hyperkeratosis)	Ask your care provider for management strategies if this bothers you.
Changes in electrolyte and other laboratory values <ul style="list-style-type: none"> • High glucose levels • Low phosphate levels 	Changes in some lab values may occur and will be monitored by a simple blood test. <ul style="list-style-type: none"> • You may not feel any symptoms if the changes are mild, and they usually are not a sign of a serious problem. • More severe changes may occur, which can be a sign of a serious problem. Notify your care provider if you have any of the following: <ul style="list-style-type: none"> • Shortness of breath • Chest discomfort • Weakness or fatigue • New aches and pains • Headaches • Dizziness • Swelling of your legs or feet • Red- or brown-colored urine
Headache	Ask your provider what you may use to ease headaches. Contact your care provider immediately if your headache: <ul style="list-style-type: none"> • Follows a head injury • Is severe, or starts suddenly • Does not go away after three days • Is associated with vomiting, visual disturbance, neck stiffness, drowsiness, confusion, made worse by coughing or lowering the head, rash, weakness in an arm or leg, or numbness
Fever	You may feel hot, cold and shivery, achy, or dizzy. This usually starts during the first month of therapy but could happen at any time. <ul style="list-style-type: none"> • Call your doctor immediately if you have a fever (temperature more than 100.4°F or 38°C). • Ask your doctor if you can take medicine to help with the fever.

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Possible Side Effect	Management
Muscle or joint pain or weakness	<ul style="list-style-type: none">• Keep a diary of your pain, including a description of when and where the pain is occurring, what it feels like, and how long it lasts.• Stay as active as possible, but know that it is okay to rest as needed, too.• Tell your care provider if pain interferes with your activity. <p>If the pain or weakness bothers you, ask your provider how you may ease this discomfort. Take pain medication only that has been prescribed or recommended by your care provider.</p>

Serious side effects of dabrafenib

- Secondary malignancy is the growth of a cancer months or years after treatment. This is a rare but possible side effect of treatment with dabrafenib.
- Dabrafenib may be harmful to your eyes. Be sure to inform your care provider of any issue you have with your vision, or pain in your eyes. Your provider may stop treatment with dabrafenib if your eyes are affected.
- Serious fevers can occur when dabrafenib is used with trametinib.
- If you have a G6PD deficiency, dabrafenib can increase risk for hemolytic anemia. Call your care team if you experience weakness, dizziness, yellowing of the skin or whites of your eyes, or dark or brown urine.
- Dabrafenib can make your heart work harder to pump blood to the rest of your body. Notify your care team if you are having shortness of breath or chest pain.
- You may be at a higher risk of bleeding while taking dabrafenib. Contact your care team if you notice frequent nose bleeds, blood in your stool, bleeding that occurs by itself without injury, or bleeding that will not stop after 5 minutes of pressure.
- Your blood sugar levels may be higher while taking dabrafenib. Your care provider may have you regularly check your blood sugar. Contact your care team if you are urinating more than normal, are very thirsty, more tired than normal, or are having trouble keeping your blood sugar within a desired range.
- Rarely, dabrafenib can cause severe skin reactions, including Stevens-Johnson syndrome, which can be life-threatening. Seek emergency care if you have a severe rash or a rash on your mouth, eyes, or genitals.

If you experience ANY uncontrolled side effect, call your physician or healthcare center immediately:

(INSTITUTIONAL CONTACT INFO)

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Handling body fluids and waste

Dabrafenib remains in your body for several days after it is taken, so some of the drug may be present in urine, stool, sweat, or vomit. Once you have started to take dabrafenib, it is important to follow the instructions below every day for as long as your treatment lasts. This will keep yourself, loved ones, and the environment as safe as possible.

- Pregnant women should avoid touching anything that may be soiled with body fluids from the patient.
- Toilet and septic systems
 - You may use the same toilet, septic tank, and/or sewer that you usually use. If you have a low-flow toilet, close the lid and flush twice to ensure all waste has been discarded.
 - If the toilet or toilet seat becomes soiled with urine, stool, or vomit, clean the surfaces before other people use the toilet.
 - Wash hands with soap and water after using the toilet.
- If you need a bedpan, be sure your caregiver knows to wear gloves to assist with cleanup and to wash the bedpan with soap and water every day.
- If you do not have good control of bladder or bowels, use a disposable pad with a plastic back, a diaper, or a sheet to absorb body waste.
- Wash any skin that has been exposed to body waste or dabrafenib with soap and water.
- Linens or clothing that are soiled with body fluids or body waste should be washed separately from other linens and clothing. If you do not have a washer, place the soiled linens in a plastic bag until they can be washed.
- Wash hands with soap and water after touching linens or clothing that may be soiled with body fluids.

Pregnancy, sexual activity, and contraception

- Men and women of childbearing age and potential should use effective nonhormonal contraception during therapy and for a minimum of **2 weeks** after the last dose of dabrafenib. **Dabrafenib can cause hormonal contraceptive to be ineffective.**
- Do not breastfeed while taking dabrafenib and for 2 weeks after the last dose of dabrafenib.
- Inform your care provider if you become pregnant.
- It is safe to hug and kiss. Special precautions may be needed for sexual activity while on dabrafenib, and you are encouraged to ask your care provider.

Obtaining medication

Talk with your care provider about how to obtain your dabrafenib.

_____ (PHARMACY OR SPECIALTY PHARMACY CONTACT INFO)

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Additional resources

Product website: <https://www.us.tafinlarmekinist.com>

Product prescribing information: <https://www.novartis.us/sites/www.novartis.us/files/tafinlar.pdf>

Product resources:

<https://www.us.tafinlarmekinist.com/advanced-melanoma/patient-support/patient-resources>

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Additional instructions

Important notice: The Association of Community Cancer Centers (ACCC), Hematology/Oncology Pharmacy Association (HOPA), National Community Oncology Dispensing Association, Inc. (NCODA), and Oncology Nursing Society (ONS) have collaborated in gathering information for and developing this patient education guide. This guide represents a brief summary of the medication derived from information provided by the drug manufacturer and other resources. This guide does not cover all existing information related to the possible uses, directions, doses, precautions, warnings, interactions, adverse effects, or risks associated with this medication and should not substitute for the advice of a qualified healthcare professional. Provision of this guide is for informational purposes only and does not constitute or imply endorsement, recommendation, or favoring of this medication by ACCC, HOPA, NCODA, or ONS, who assume no liability for and cannot ensure the accuracy of the information presented. The collaborators are not making any representations with respect to the medications whatsoever, and any and all decisions, with respect to such medications, are at the sole risk of the individual consuming the medication. All decisions related to taking this medication should be made with the guidance and under the direction of a qualified healthcare professional.

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