







DABRAFENIB AND TRAMETINIB

Name of your medication

Generic Names – dabrafenib (duh-BRA-feh-nib) and trametinib (truh-MEH-tih-nib) Brand Name – Tafinlar (TA-fin-lar) and Mekinist (MEH-kih-nist)

Common uses

The combination of dabrafenib and trametinib is used to treat a variety of cancers including melanoma, lung cancer, thyroid cancer or other cancers that have a certain mutation in a gene called BRAF.

Dabrafenib and trametinib may also be used for other treatments.

Dose and schedule		

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

Dabrafenib	Trametinib
Usual dose: 150 mg twice a day	Usual dose: 2 mg once daily
If you miss a dose: Only take if it has been less than 6 hours since you were supposed to take it. Then take the next dose at the regularly scheduled time.	If you miss a dose: Only take if it has been less than 12 hours since you were supposed to take it. Then take the next dose at the regularly scheduled time.

- For both dabrafenib and trametinib, **do not** take two doses at one time, and be sure to write down if you miss a dose and to let your care provider know about any missed doses.
- □ Do not take an additional dose of either medication if vomiting occurs after administration. Continue with the next scheduled dose.
- Both dabrafenib and trametinib should be taken on an empty stomach. Take dabrafenib and trametinib 1 hour before or at least 2 hours after a meal.
- Dabrafenib and trametinib should be taken whole and not crushed, cut, or dissolved. If you are unable to swallow dabrafenib and trametinib, talk to your care provider or pharmacist for possible options.

Drug and food interactions

- Dabrafenib and trametinib have many drug interactions. Inform your care providers of all prescription medications, overthe 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.









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Storage and handling

Handle dabrafenib and trametinib 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 to 77 F) in a dry location away from light.
- Store trametinib in the <u>refrigerator</u> (36 to 46 F) in a sealed plastic bag or closed container to prevent exposure to food and spills. **Do not** freeze.
- Keep dabrafenib and trametinib out of reach of children and pets.
- Leave dabrafenib and trametinib in the provided packaging until it is ready to be taken.
- Whenever possible, you should give dabrafenib and trametinib to yourself and follow the steps below. If a family member, friend, or caregiver needs to give the dabrafenib and trametinib 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 and trametinib 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.
- A daily pill box or pill reminder **is not** recommended to be used with dabrafenib or trametinib.
- If you have any unused dabrafenib and trametinib, **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 and trametinib.
- ☐ If you are traveling, put your dabrafenib and trametinib in a sealed plastic bag. Ask your pharmacist if any additional travel precautions are needed.









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Side Effects of Dabrafenib and Trametinib

The common side effects that have been known to happen in about one third or more of patients taking dabrafenib and trametinib are listed in 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
Changes in electrolytes and other laboratory values • High glucose levels • Low sodium levels • Low phosphate levels • Low albumin levels • Low calcium levels • Low magnesium levels	 Changes in some lab values may occur and will be monitored by a simple blood test. 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: 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
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. • 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.
Changes in liver function	Your liver function will be checked periodically by a simple blood test. Contact your care provider if you notice any of the following: • Yellowing of the skin or whites of your eyes • Dark or brown urine • Unusual bleeding or bruising
	Continued on the next page









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Possible Side Effect	Management
Decreased white blood cells (WBCs) and increased risk for infection	Your WBCs should be monitored by a simple blood test. When your WBCs are low, you are at a greater risk of having an infection. Take the following precautions to protect yourself from infection. Wash your hands often, especially before eating and after using the bathroom. Avoid crowds and people with fevers, flu, or other infection. Bathe regularly to keep good personal hygiene. Contact your care provider if you experience any signs or symptoms of an infection such as: Fever (temperature more than 100.4°F or 38°C) Chills Sore throat Burning with urination Unusual tiredness A sore that becomes red, is draining, or does not heal Check with your care provider before taking any medicine for a fever or chills.
Decreased hemoglobin, part of the red blood cells that carry iron and oxygen	Your hemoglobin should be monitored using a blood test. When your hemoglobin is low, you may notice that you get tired or fatigued more easily. Try to get 7-8 hours of sleep per night. Avoid operating heavy machinery if you feel too tired. Find a balance between "work" and "rest." Stay as active as possible, but known that it is okay to rest as needed, too. You might notice that you are more pale than usual. Let your healthcare provider know right away if you experience: Shortness of breath Dizziness Palpitations
Nausea or vomiting	 Eat and drink slowly. Drink 8–10 glasses of water/fluid each day unless your care provider has instructed you to limit your fluid intake. Eat small, frequent meals throughout the day rather than a few large meals. Eat bland foods; avoid spicy, fried, and greasy foods. Avoid vigorous exercise immediately after eating. Don't lay down immediately after eating. Avoid strong odors. Let your provider know if you experience nausea or vomiting. Your provider may prescribe medication to help with the nausea or vomiting.
	Your provider may prescribe medication to help with the hausea or vomiting. Continued on the next page









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Possible Side Effect	Management
Diarrhea (loose and/ or urgent bowel movements)	 Monitor how many bowel movements you have each day. Drink 8–10 glasses of water/fluid each day unless your care provider has instructed you to limit your fluid intake. Eat small, frequent meals throughout the day rather than a few large meals. Eat bland, low-fiber foods (such as bananas, applesauce, potatoes, chicken, rice, and toast). Avoid high fiber foods, such as raw vegetables, raw fruits, and whole grains. Avoid foods that cause gas, such as broccoli and beans. Avoid lactose-containing foods, such as yogurt and milk. Avoid spicy, fried, and greasy foods. Contact your provider if any of the following occur: The number of bowel movements you have in a day increases by 4 or more. You feel dizzy or lightheaded.
	Your care provider may recommend an over-the-counter medication called loperamide (Imodium®) to help with your diarrhea, but talk to your care provider before starting this medication.
Rash or thickening of the skin (hyperkeratosis)	 Keep your skin moisturized with creams and moisturizing lotions to decrease the risk of rash or itchiness, and wear loose fitting clothing. Avoid using perfumes and cologne as these products may increase rash symptoms. Avoid being in the heat for long periods of time. Your provider may recommend an over-the-counter antihistamine or a topical cream. Sunlight can make symptoms worse. Avoid sun exposure as much as possible to decrease the risk of sunburn. The highest exposure to UV (ultraviolet) radiation occurs between the hours of 10 am and 4 pm. Wear long-sleeved clothing, with UV protection if possible. Wear broad-brimmed hats. Apply broad-spectrum sunscreen (UVA/UVB) with at least SPF 30 as often as directed on the bottle. Use lip balm with at least SPF 30.
Fatigue	You may be more tired than usual or have less energy. Stay as active as possible, but know it is okay to rest as needed. Try to do some activity every day. Plan your activities, and do them at a time of day when you feel a bit more energetic. Avoid operating heavy machinery if you feel too tired.









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Possible Side Effect Management 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. 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.

Serious side effects of dabrafenib and trametinib

- □ Secondary malignancy is the growth of a cancer months or years after treatment. This is a rare but possible side effect of dabrafenib.
- Dabrafenib and trametinib 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.
- ☐ Trametinib may rarely cause irritation of your bowel or tear or hole in your intestine, called bowel perforation. Speak to your care team right away if you have diarrhea, high fever, nausea, vomiting, or severe stomach pain.
- ☐ Trametinib may cause your lung tissue to scar, which is called interstitial lung disease, or swelling of lung tissue which is called pneumonitis. Call your care team if you are feeling short of breath, chest pain, have a fever, or have a lasting dry cough.
- □ Dabrafenib and trametinib can cause serious birth defects. Do not take dabrafenib and trametinib if you are pregnant or think you might be pregnant.
- Dabrafenib and trametinib may affect your heart's ability to pump blood. Notify your care team right away if you experience new or worsening shortness of breath, chest pain, irregular heartbeat, or swelling of your ankles or legs.
- ☐ Trametinib can increase your risk of having a blood clot.

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

(INSTITUTIONAL CONTACT INFO)

Handling body fluids and waste

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









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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 and trametinib 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	
☐ Women should not become pregnant and men should not get a partner pregnant while taking dabrafenib and trametinib.	
Females of childbearing age and potential should use effective non-hormonal contraception during therapy and for a minimum of 2 weeks after the last dose of dabrafenib and effective contraception (may be hormonal) during therapy and for a minimum of 4 months after the last dose of trametinib.	r
 Males with female partners of reproductive potential should use effective contraception during therapy and for a minimum week after the last dose of dabrafenib and 4 months after trametinib. 	of
□ Do not breastfeed while taking dabrafenib and trametinib and for 2 week after the last dose of dabrafenib and 4 months after the last dose of trametinib.	er
☐ Please 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 oral chemotherapy and you are encouraged to ask your care team for assistance.	
Obtaining medication	
Talk with your care provider about the process for obtaining your dabrafenib and trametinib.	
(PHARMACY OR SPECIALTY PHARMACY CONTACT INFO)	









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Additional resources

Product website: www.us.tafinlarmekinist.com

Product prescribing information: www.novartis.com/us-en/sites/novartis_us/files/tafinlar.pdf,

www.novartis.com/us-en/sites/novartis_us/files/mekinist.pdf

Product website: www.us.tafinlarmekinist.com/advanced-melanoma,

www.us.tafinlarmekinist.com/metastatic-nsclc

	Updated – May 10, 2023
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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