PATIENT & CAREGIVER EDUCATION

Dabrafenib

This information from UpToDate® Lexidrug™ explains what you need to know about this medication, including what it's used for, how to take it, its side effects, and when to call your healthcare provider.

Brand Names: US

Tafinlar

Brand Names: Canada

Tafinlar

What is this drug used for?

- It is used to treat cancer.

What do I need to tell my doctor BEFORE I take this drug?

- If you are allergic to this drug; any part of this drug; or any other drugs, foods, or substances. Tell your doctor about the allergy and what signs you had.
- If you are breast-feeding. Do not breast-feed while you take this drug and for 2 weeks after your last dose.

This drug may interact with other drugs or health problems.

Tell your doctor and pharmacist about all of your drugs (prescription or OTC, natural products, vitamins) and health problems. You must check to make sure that it is safe for you to take this drug with all of your drugs and health problems. Do not start, stop, or change the dose of any drug without checking with your doctor.

What are some things I need to know or do while I take this drug?

For all patients taking this drug:

- Tell all of your health care providers that you take this drug. This includes your doctors, nurses, pharmacists, and dentists.
- Sometimes, dabrafenib is taken with trametinib. If you are taking dabrafenib with trametinib, be sure you know the side effects that can happen with each drug. When these drugs are taken together, the chance of certain side effects may be raised. These side effects can be very bad and sometimes deadly. This includes bleeding, bleeding in the brain, blood clots, eye problems, fever, heart problems (like heart failure), high blood sugar, other cancers, and severe skin reactions like Stevens-Johnson syndrome. Talk with your doctor about the chance of side effects with your drugs.
- Have your blood work and heart function checked as you have been told by your doctor. You will also need to

have eye exams.

- Be careful if you have low levels of an enzyme called G6PD. Anemia may happen. Low levels of G6PD may be more likely in patients of African, South Asian, Middle Eastern, and Mediterranean descent.
- This drug may make you sunburn more easily. Use care if you will be in the sun. Tell your doctor if you sunburn easily while taking this drug.
- This drug may add to the chance of getting some types of cancer. Talk with the doctor.
- Have your skin checked. Tell your doctor if you have any skin changes like a new wart, skin sore or reddish bump that bleeds or does not heal, or a change in the color or size of a mole.
- If you have high blood sugar (diabetes), talk with your doctor. This drug may raise blood sugar.
- Check your blood sugar as you have been told by your doctor.
- If you are 65 or older, use this drug with care. You could have more side effects.
- This drug may affect fertility. Fertility problems may lead to not being able to get pregnant or father a child. If you plan to get pregnant or father a child, talk with your doctor before taking this drug.

- This drug may cause harm to an unborn baby. A pregnancy test will be done before you start this drug to show that you are NOT pregnant.
- Use a non-hormone type of birth control like condoms to prevent pregnancy while taking this drug and for at least 2 weeks after stopping this drug. Birth control pills and other hormone-based birth control may not work as well to prevent pregnancy.
- If you get pregnant or think you may be pregnant, call your doctor right away.
- If your sex partner is pregnant or may become pregnant, you must use condoms while taking this drug and for 2 weeks after your last dose. Use a condom even if you have had a vasectomy. If your partner is pregnant or gets pregnant, call the doctor right away.

Children:

- If your child's weight changes, talk with the doctor. The dose of this drug may need to be changed.

What are some side effects that I need to call my doctor about right away?

WARNING/CAUTION: Even though it may be rare, some people may have very bad and sometimes deadly side effects when taking a drug. Tell your doctor or get medical

help right away if you have any of the following signs or symptoms that may be related to a very bad side effect:

- Signs of an allergic reaction, like rash; hives; itching; red, swollen, blistered, or peeling skin with or without fever; wheezing; tightness in the chest or throat; trouble breathing, swallowing, or talking; unusual hoarseness; or swelling of the mouth, face, lips, tongue, or throat.
- Signs of bleeding like throwing up or coughing up blood; vomit that looks like coffee grounds; blood in the urine; black, red, or tarry stools; bleeding from the gums; abnormal vaginal bleeding; bruises without a cause or that get bigger; or bleeding you cannot stop.
- Signs of fluid and electrolyte problems like mood changes, confusion, muscle pain or weakness, fast or abnormal heartbeat, severe dizziness or passing out, increased thirst, seizures, feeling very tired or weak, decreased appetite, unable to pass urine or change in the amount of urine produced, dry mouth, dry eyes, or severe upset stomach or throwing up.
- Signs of kidney problems like unable to pass urine, change in how much urine is passed, blood in the urine, or a big weight gain.
- Signs of high blood sugar like confusion, feeling sleepy, unusual thirst or hunger, passing urine more often,

flushing, fast breathing, or breath that smells like fruit.

- Signs of a pancreas problem (pancreatitis) like very bad stomach pain, very bad back pain, or very bad upset stomach or throwing up.
- Weakness on 1 side of the body, trouble speaking or thinking, change in balance, drooping on one side of the face, or blurred eyesight.
- Fever or chills.
- Dark urine or yellow skin or eyes.
- Eye pain.
- Redness or irritation of the palms of hands or soles of feet.
- Chest pain or pressure.
- A burning, numbness, or tingling feeling that is not normal.
- Very bad eye problems have happened with this drug. Sometimes, this has led to loss of eyesight. Call your doctor right away if you have blurred eyesight, loss of eyesight, or other changes in eyesight. Call your doctor right away if you see color dots or halos or if bright lights bother you.
- This drug may cause heart failure. You will need to have your heart function checked while taking this drug. Call

your doctor right away if you have signs of heart problems like a cough or shortness of breath that is new or worse, swelling of the ankles or legs, a heartbeat that does not feel normal, weight gain of more than 5 pounds in 24 hours, dizziness, or passing out.

- Skin reactions are common with this drug. However, severe skin reactions may also happen. This may include Stevens-Johnson syndrome (SJS). Sometimes, body organs may also be affected. These reactions can be deadly. Get medical help right away if you have signs like red, swollen, blistered, or peeling skin; red or irritated eyes; sores in your mouth, throat, nose, eyes, genitals, or any areas of skin; fever; chills; body aches; shortness of breath; or swollen glands.
- An immune system problem called hemophagocytic lymphohistiocytosis (HLH) has happened with this drug. Call your doctor right away if you have a fever, swollen gland, rash, or swelling in the stomach area or severe stomach pain.

What are some other side effects of this drug?

All drugs may cause side effects. However, many people have no side effects or only have minor side effects. Call your doctor or get medical help if any of these side effects or any other side effects bother you or do not go away:

- Hair loss.
- Change in skin to hard and thick.
- Pimples (acne).
- Dry skin.
- Headache.
- Feeling dizzy, tired, or weak.
- Back, muscle, or joint pain.
- Constipation, diarrhea, stomach pain, upset stomach, throwing up, or decreased appetite.
- Cough.
- Nose or throat irritation.

These are not all of the side effects that may occur. If you have questions about side effects, call your doctor. Call your doctor for medical advice about side effects.

You may report side effects to your national health agency.

You may report side effects to the FDA at 1- 800-332-1088. You may also report side effects at https://www.fda.gov/medwatch.

How is this drug best taken?

Use this drug as ordered by your doctor. Read all information given to you. Follow all instructions closely.

All products:

- Take this drug at the same time of day.
- Take this drug on an empty stomach. Take at least 1 hour before or at least 2 hours after a meal.
- Talk with your doctor about drinking lots of fluids and other ways to prevent fluid loss. If you have a lot of fluid loss, you may have more side effects from this drug.
- If you throw up after taking a dose, do not repeat the dose. Take your next dose at your normal time.
- Keep taking this drug as you have been told by your doctor or other health care provider, even if you feel well.

Capsules:

- Swallow whole. Do not chew, break, open, or crush.

Tablets for suspension:

- If the patient is a small child who cannot go without food, breast milk or formula may be given as needed.
- Do not swallow whole. Do not chew or crush.
- Before using, be sure you know how to mix and measure

the dose of this drug. Talk with the doctor or pharmacist if you are not sure.

- To mix this drug, place the number of tablets needed for a dose into a cup. Add 5 mL of water if the dose is 1 to 4 tablets. Add 10 mL of water if the dose is 5 to 15 tablets. Gently stir with the handle of a teaspoon until the tablets are fully mixed. It may take at least 3 minutes.
- The mixed drug will be cloudy white.
- Take your dose within 30 minutes after mixing. Throw away any part not used within 30 minutes of mixing.
- After taking this drug, add 5 mL water to the empty cup and stir with the handle of a spoon to loosen any of this drug left in the cup. Drink to be sure you take the whole dose.
- Those who have feeding tubes may use this drug. Use as you have been told. Flush the feeding tube after this drug is given.

What do I do if I miss a dose?

- Take a missed dose as soon as you think about it.
- If it is less than 6 hours until the next dose, skip the missed dose and go back to the normal time.
- Do not take 2 doses at the same time or extra doses.

How do I store and/or throw out this drug?

All products:

- Store at room temperature in a dry place. Do not store in a bathroom.
- Keep all drugs in a safe place. Keep all drugs out of the reach of children and pets.
- Throw away unused or expired drugs. Do not flush down a toilet or pour down a drain unless you are told to do so. Check with your pharmacist if you have questions about the best way to throw out drugs. There may be drug take-back programs in your area.

Tablets for suspension:

- If this drug comes in a bottle, keep the lid tightly closed. Each bottle has 2 desiccants (protects the drug from moisture). Keep them in the bottle. Do not eat the desiccants.

General drug facts

- If your symptoms or health problems do not get better or if they become worse, call your doctor.
- Do not share your drugs with others and do not take anyone else's drugs.
- Some drugs may have another patient information leaflet. If you have any questions about this drug, please

talk with your doctor, nurse, pharmacist, or other health care provider.

- This drug comes with an extra patient fact sheet called a Medication Guide. Read it with care. Read it again each time this drug is refilled. If you have any questions about this drug, please talk with the doctor, pharmacist, or other health care provider.
- If you think there has been an overdose, call your poison control center or get medical care right away. Be ready to tell or show what was taken, how much, and when it happened.

Consumer Information Use and Disclaimer

This generalized information is a limited summary of diagnosis, treatment, and/or medication information. It is not meant to be comprehensive and should be used as a tool to help the user understand and/or assess potential diagnostic and treatment options. It does NOT include all information about conditions, treatments, medications, side effects, or risks that may apply to a specific patient. It is not intended to be medical advice or a substitute for the medical advice, diagnosis, or treatment of a health care provider based on the health care provider's examination and assessment of a patient's specific and unique circumstances. Patients must speak with a health care provider for complete information about their health,

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If you have questions or concerns, contact your healthcare provider. A member of your care team will answer Monday through Friday from 9 a.m. to 5 p.m. Outside those hours, you can leave a message or talk with another MSK provider. There is always a doctor or nurse on call. If you're not sure how to reach your healthcare provider, call 212-639-2000.

For more resources, visit www.mskcc.org/pe to search our virtual library.

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