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## Dabrafenib

pronounced as (da braf' e nib)

### Why is this medication prescribed?

Dabrafenib is used alone or in combination with trametinib (Mekinist) to treat a certain types of melanoma (a type of skin cancer) that cannot be treated with surgery or that has spread to other parts of the body. It is also used along with trametinib to treat and prevent the return of a certain type of melanoma after surgery to remove it and any affected lymph nodes. Dabrafenib is also used in combination with trametinib to treat a certain type of non-small cell lung cancer (NSCLC) that has spread to nearby tissues or to other parts of the body. It is also used to treat a certain type of thyroid cancer that has spread to nearby tissues or to other parts of the body that has not responded to previous treatment(s). Dabrafenib is in a class of medications called kinase inhibitors. It works by blocking the action of an abnormal protein that signals cancer cells to multiply. This helps stop the spread of cancer cells.

### How should this medicine be used?

Dabrafenib comes as a capsule to take by mouth. It is usually taken twice a day on an empty stomach, 1 hour before or 2 hours after a meal. Take dabrafenib about 12 hours apart at around the same times every day. Follow the directions on your prescription label carefully, and ask your doctor or pharmacist to explain any part you do not understand. Take dabrafenib exactly as directed. Do not take more or less of it or take it more often than prescribed by your doctor. Do not stop taking dabrafenib without talking to your doctor.

Swallow the capsules whole; do not open, break, or crush them.

Your doctor may adjust your dose or temporarily or permanently stop your treatment depending on your response to treatment and any side effects that you experience. Talk to your doctor about how you are feeling during your treatment.

Your doctor or pharmacist will give you the manufacturer's patient information sheet (Medication Guide) when you begin treatment with dabrafenib and each time you refill your prescription. Read the information carefully and ask your doctor or pharmacist if you have any questions. You can also visit the Food and Drug Administration (FDA) website (<http://www.fda.gov/Drugs/DrugSafety/ucm085729.htm> [<http://www.fda.gov/Drugs/DrugSafety/ucm085729.htm>] ) or the manufacturer's website to obtain the Medication Guide.

## Other uses for this medicine

This medication may be prescribed for other uses; ask your doctor or pharmacist for more information.

## What special precautions should I follow?

### Before taking dabrafenib,

- tell your doctor and pharmacist if you are allergic to dabrafenib, any other medications, or any of the ingredients in dabrafenib capsules. Ask your pharmacist or check the Medication Guide for a list of the ingredients.
- tell your doctor and pharmacist what other prescription and nonprescription medications, vitamins, nutritional supplements, and herbal products you are taking or plan to take. Be sure to mention any of the following: clarithromycin (Biaxin, in PrevPac); dexamethasone; gemfibrozil (Lopid); ketoconazole; midazolam; nefazodone; rifampin (Rifadin, in Rifamate, in Rifater, Rimactane); and warfarin (Coumadin, Jantoven). Your doctor may need to change the doses of your medications or monitor you carefully for side effects. Many other medications may also interact with dabrafenib, so be sure to tell your doctor about all the medications you are taking, even those that do not appear on this list.
- tell your doctor if you have or have ever had diabetes; glucose-6-phosphate dehydrogenase (G6PD) deficiency (a genetic condition); bleeding problems; eye problems; heart failure or other heart problems; liver or kidney disease; or any other medical condition.
- tell your doctor if you are pregnant or plan to become pregnant, or if you plan to father a child. If you are female, you will need to have a pregnancy test before you start treatment, and you should use effective birth control to prevent pregnancy during your treatment and for 2 weeks after your final dose. If you are a male and your partner can become pregnant, you should use a condom while taking this medication, and for 2 weeks after your treatment, even if you have had a vasectomy (surgery to prevent sperm from leaving your body and causing pregnancy). You should know that this medication may decrease fertility in men and women; however, you should not assume that you cannot get pregnant or that you cannot get someone else pregnant. If you or your partner becomes pregnant while taking dabrafenib, call your doctor. Dabrafenib may harm the fetus.
- you should know that dabrafenib may decrease the effectiveness of hormonal contraceptives (birth control pills, patches, rings, implants, and injections). You should use another method of birth control to prevent pregnancy in yourself or your partner during your treatment with dabrafenib and for 2 weeks after your final dose. Talk to your doctor about birth control methods that will work for you.
- tell your doctor if you are breastfeeding or plan to breastfeed. You should not breastfeed while taking dabrafenib and for 2 weeks after your final dose.
- if you are having surgery, including dental surgery, tell the doctor or dentist that you are taking dabrafenib.

## What special dietary instructions should I follow?

Unless your doctor tells you otherwise, continue your normal diet.

## What should I do if I forget a dose?

Take the missed dose as soon as you remember it. However, if it is less than 6 hours until your next scheduled dose, skip the missed dose and continue your regular dosing schedule. Do not take a double dose to make up for a missed one.

## What side effects can this medication cause?

**Dabrafenib may cause side effects. Tell your doctor if any of these symptoms are severe or do not go away:**

- headache
- joint, muscle, or back pain
- nausea
- diarrhea
- constipation
- loss of appetite
- cough, runny nose, or sore throat
- hair loss
- tiredness

**Some side effects can be serious. If you experience any of these symptoms call your doctor immediately:**

- changes in skin (new wart, skin sore, or red bump that bleeds or does not heal)
- change in size or color of a mole
- rash, red skin, or pimples
- fever
- fainting
- dizziness, lightheadedness, or weakness
- chills
- decreased urination
- swelling of hands, feet, ankles, or lower legs
- frequent urination
- increased thirst
- eye pain
- red or swollen eyelids
- sensitivity to light
- blurred vision or vision changes, including seeing halos (blurred outline around objects) or colored dots
- swelling, pain, redness, or peeling of skin on the palms and soles of the feet
- ongoing pain that begins in the stomach area but may spread to the back
- unusual bleeding or bruising

- bloody or black, tarry stools
- coughing up or vomiting blood or material that looks like coffee grounds
- chest pain
- shortness of breath
- swelling of the hands, feet, ankles or lower legs
- fast, irregular, or pounding heartbeat
- yellowing of the skin and eyes

Dabrafenib may increase the risk that you will develop new skin cancers or other cancers. Talk to your doctor about the risks of taking this medication.

Dabrafenib may cause other side effects. Call your doctor if you have any unusual problems while taking this medication.

If you experience a serious side effect, you or your doctor may send a report to the Food and Drug Administration's (FDA) MedWatch Adverse Event Reporting program online (<http://www.fda.gov/Safety/MedWatch> [<http://www.fda.gov/Safety/MedWatch>] ) or by phone (1-800-332-1088).

## What should I know about storage and disposal of this medication?

Keep this medication in the container it came in, tightly closed, and out of reach of children. Store it at room temperature and away from excess heat and moisture (not in the bathroom).

It is important to keep all medication out of sight and reach of children as many containers (such as weekly pill minders and those for eye drops, creams, patches, and inhalers) are not child-resistant and young children can open them easily. To protect young children from poisoning, always lock safety caps and immediately place the medication in a safe location – one that is up and away and out of their sight and reach. <http://www.upandaway.org> [<http://www.upandaway.org>]

Unneeded medications should be disposed of in special ways to ensure that pets, children, and other people cannot consume them. However, you should not flush this medication down the toilet. Instead, the best way to dispose of your medication is through a medicine take-back program. Talk to your pharmacist or contact your local garbage/recycling department to learn about take-back programs in your community. See the FDA's Safe Disposal of Medicines website (<http://goo.gl/c4Rm4p> [<http://goo.gl/c4Rm4p>] ) for more information if you do not have access to a take-back program.

## In case of emergency/overdose

In case of overdose, call the poison control helpline at 1-800-222-1222. Information is also available online at <https://www.poisonhelp.org/help> [<https://www.poisonhelp.org/help>] . If the victim has collapsed, had a seizure, has trouble breathing, or can't be awakened, immediately call emergency services at 911.

## What other information should I know?

Keep all appointments with your doctor and the laboratory. Your doctor will order a lab test before you begin your treatment to see whether your cancer can be treated with dabrafenib. Your doctor will order certain lab tests before and during your treatment to check your body's response to dabrafenib. Your doctor will check your skin for any changes before, every 2 months during your treatment, and for up to 6 months after treatment.

Do not let anyone else take your medication. Ask your pharmacist any questions you have about refilling your prescription.

It is important for you to keep a written list of all of the prescription and nonprescription (over-the-counter) medicines you are taking, as well as any products such as vitamins, minerals, or other dietary supplements. You should bring this list with you each time you visit a doctor or if you are admitted to a hospital. It is also important information to carry with you in case of emergencies.

## Brand names

- Tafinlar<sup>®</sup>

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