

ORAL CHEMOTHERAPY EDUCATION



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ENCORAFENIB AND BINIMETINIB

Name of your medication

Generic names — encorafenib (EN-kor-A-feh-nib) and binimetinib (BIH-nee-MEH-tih-nib)

Brand names — Braftovi® (braf-TOH-vee) and Mektovi® (mek-TOH-vee)

Please make sure to follow the instructions on the side of the table that your provider has checked.

Common uses

The combination of encorafenib and binimetinib is used to treat patients with melanoma that have a genetic mutation called BRAF V600E or V600K.

Encorafenib and binimetinib may also be used for other treatments.

Dose and schedule

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

<input type="checkbox"/> Encorafenib	<input type="checkbox"/> Binimetinib
Usual dose: 450 mg (six 75 mg capsules) by mouth once daily	Usual dose: 45 mg (three 15 mg tablets) by mouth twice daily
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.	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.

For both encorafenib and binimetinib, **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 encorafenib and binimetinib can be taken with or without food, but at the same time each day.
- Encorafenib and binimetinib should be taken whole and not crushed, cut, or dissolved. If you are unable to swallow encorafenib and binimetinib, talk to your care provider or pharmacist for possible options.

Drug and food interactions

- Encorafenib and binimetinib have 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 encorafenib; avoid eating or drinking these during treatment with encorafenib.

ORAL CHEMOTHERAPY EDUCATION



PASSION FOR PATIENTS
NCODA.ORG



ENCORAFENIB AND BINIMETINIB

- Talk with your care team or pharmacist before taking new medications or supplements, or receiving any vaccines.

Storage and handling

Handle encorafenib and binimetinib with care. Just like when chemotherapy is given into the vein, these drugs can be toxic, and exposure of the drugs to others should be limited.

- Store encorafenib and binimetinib at room temperature (68°F–77°F) in a dry location away from light.
- Keep out of reach of children and pets.
- Leave encorafenib and binimetinib in the provided packaging until it is ready to be taken.
- Whenever possible, you should give these medications to yourself and follow the steps below. If a family member, friend, or caregiver needs to give them 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 medication 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 reminder may be used for binimetinib (but not for encorafenib, as it should be kept in the original packaging). Contact your care team before using a daily pill box.
 - The person filling the box or reminder should wear gloves (gloves are not necessary if you as the patient 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 encorafenib and binimetinib, **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 these medications.
- If you are traveling, put your medications in a sealed plastic bag. Ask your pharmacist if any additional travel precautions are needed.

ORAL CHEMOTHERAPY EDUCATION



PASSION FOR PATIENTS
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ENCORAFENIB AND BINIMETINIB

Side Effects of Encorafenib and Binimetinib

The common side effects that have been known to happen in more than 30% of patients taking encorafenib and binimetinib 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 kidney function	Your kidney (renal) function will be checked periodically by a simple blood test. Contact your care provider if you notice either of the following: <ul style="list-style-type: none"> • Decreased amount of urination • Unusual swelling in your legs and feet
Changes in electrolytes and other laboratory values <ul style="list-style-type: none"> • High creatine phosphokinase • High gamma glutamyl transferase 	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
Fatigue	You may be more tired than usual or have less energy. <ul style="list-style-type: none"> • Stay as active as possible, but know it is okay to rest as needed, too. • 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.

Continued on the next page

ORAL CHEMOTHERAPY EDUCATION



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ENCORAFENIB AND BINIMETINIB

Possible Side Effect	Management
<p>Nausea or vomiting</p>	<ul style="list-style-type: none"> • Eat and drink slowly. • Drink 8–10 glasses of water or 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 lie down immediately after eating. • Avoid strong odors. <p>Let your provider know if you experience nausea or vomiting. Your provider may prescribe medication to help with the nausea or vomiting.</p>
<p>Diarrhea (loose and/or urgent bowel movements)</p>	<p>Monitor how many bowel movements you have each day.</p> <ul style="list-style-type: none"> • Drink 8–10 glasses of water or 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 (e.g., bananas, applesauce, potatoes, chicken, rice, toast). • Avoid high-fiber foods (e.g., raw vegetables, raw fruits, whole grains). • Avoid foods that cause gas (e.g., broccoli, beans). • Avoid lactose-containing foods (e.g., yogurt, milk). • Avoid spicy, fried, and greasy foods. <p>Contact your provider if either of the following occurs:</p> <ul style="list-style-type: none"> • The number of bowel movements you have in a day increases by 4 or more. • You feel dizzy or lightheaded. <p>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.</p>
<p>Decreased hemoglobin, part of the red blood cells that carry iron and oxygen</p>	<p>Your hemoglobin should be monitored by a simple blood test. When your hemoglobin is low, you may notice that you get tired or fatigued more easily.</p> <ul style="list-style-type: none"> • 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 know that it is OK to rest as needed. • You might notice that you are more pale than usual. <p>Let your care provider know right away if you experience any of the following:</p> <ul style="list-style-type: none"> • Shortness of breath • Dizziness • Palpitations

ORAL CHEMOTHERAPY EDUCATION



PASSION FOR PATIENTS
NCODA.ORG



ENCORAFENIB AND BINIMETINIB

Serious side effects

- You may be at a higher risk of bleeding while taking these medications. Be sure to seek medical attention right away if you have any major bleeding. Also be sure to check for any signs of bleeding in your stool.
- These medications may be harmful to your eyes. Be sure to inform your care provider of any issues you have with your vision or pain in your eyes. Your provider may stop treatment with either of these medications if your eyes are affected.
- The development of skin and non-skin cancers have been observed in patients who have taken encorafenib. It is recommended that you perform a skin self-examination prior to starting encorafenib and then every 2 months during treatment, and for up to 6 months following stopping encorafenib.
- Encorafenib may cause a condition called QT or QTc prolongation, which is a heart rhythm that can cause fast, irregular heartbeats. These fast heartbeats may cause you to faint or have a seizure. In rare cases, this could be life-threatening. Tell your care team right away if you feel faint, lightheaded, or dizzy or if you feel your heart beating irregularly or fast while taking encorafenib.
- Binimetinib can increase your risk of a blood clot. Notify your healthcare provider right away if you notice any swelling or pain (especially with movement) in your arms or legs, as well as shortness of breath or chest pain.
- Binimetinib can make your heart work harder to pump blood to the rest of your body. Notify your healthcare provider if you experience shortness of breath or chest pain.
- Binimetinib may be harmful to your lungs. Inform your care provider of any new difficulty breathing, cough, or fever. Your provider may stop treatment with binimetinib if your lungs are affected.
- Binimetinib may be harmful to your liver. Seek medical attention if you notice yellowing of the skin or whites of your eyes, dark or brown urine, bleeding, or bruising.

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

(INSTITUTIONAL CONTACT INFO)

Handling body fluids and waste

Since encorafenib and binimetinib remain in your body for several days after they are taken, some of these drugs may be present in urine, stool, sweat, or vomit. Once you have started to take these medications, it is important to follow these instructions every day for as long as your treatment lasts. This is to 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.

ORAL CHEMOTHERAPY EDUCATION



PASSION FOR PATIENTS
NCODA.ORG



ENCORAFENIB AND BINIMETINIB

- 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 these medications 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 encorafenib and binimetinib. Men and women of childbearing age and potential should use effective contraception during therapy and for a minimum of 30 days after the last dose of these medications.
- Effective contraception could include one or more of the following: oral contraceptive, barrier methods, etc.
- These medications can interfere with hormonal contraception. Talk to your care team for more information.
- Do not breastfeed while taking these medications and for 2 weeks after the last dose.
- 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 provider.

Obtaining medication

Talk with your care provider about the process for obtaining encorafenib and binimetinib.

_____ (PHARMACY OR SPECIALTY PHARMACY CONTACT INFO)

Additional resources

Product website: <https://www.braftovimektovi.com/>

Product prescribing information: <http://labeling.pfizer.com/ShowLabeling.aspx?id=12990> (encorafenib),
<http://labeling.pfizer.com/ShowLabeling.aspx?id=12988> (binimetinib)

Product resources: <https://www.braftovimektovi.com/patient-support>

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Additional instructions

ORAL CHEMOTHERAPY EDUCATION



PASSION FOR PATIENTS
NCODA.ORG



ENCORAFENIB AND BINIMETINIB

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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