

PATIENT INFORMATION
MEKTOVI® (mek-TOE-vee)
(binimetinib)
tablets

Important Information: If your healthcare provider prescribes MEKTOVI with encorafenib, please read the Medication Guide that comes with encorafenib.

What is MEKTOVI?

MEKTOVI is a prescription medicine used in combination with a medicine called encorafenib to treat people with a type of skin cancer called melanoma:

- that has spread to other parts of the body or cannot be removed by surgery, **and**
- that has a certain type of abnormal “BRAF” gene

Your healthcare provider will perform a test to make sure that MEKTOVI is right for you.

It is not known if MEKTOVI is safe and effective in children.

Before taking MEKTOVI, tell your healthcare provider about all of your medical conditions, including if you:

- have heart problems
- have had blood clots
- have eye problems
- have lung or breathing problems
- have liver or kidney problems
- have any muscle problems
- have bleeding problems
- have high blood pressure (hypertension)
- are pregnant or plan to become pregnant. MEKTOVI can harm your unborn baby.
 - Females who are able to become pregnant should use effective birth control (contraception) during treatment with MEKTOVI and for at least 30 days after the final dose of MEKTOVI.
 - Talk to your healthcare provider about birth control methods that may be right for you during this time.
 - Your healthcare provider will do a pregnancy test before you start taking MEKTOVI. Tell your healthcare provider right away if you become pregnant or think you might be pregnant during treatment with MEKTOVI.
- are breastfeeding or plan to breastfeed. It is not known if MEKTOVI passes into your breast milk. Do not breastfeed during treatment with MEKTOVI and for 3 days after the final dose of MEKTOVI. Talk to your healthcare provider about the best way to feed your baby during this time.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

Know the medicines you take. Keep a list of them to show your healthcare provider and pharmacist when you get a new medicine.

How should I take MEKTOVI?

- Take MEKTOVI exactly as your healthcare provider tells you to take it. Do not change your dose or stop taking MEKTOVI unless your healthcare provider tells you to.
- Your healthcare provider may change your dose of MEKTOVI, temporarily stop, or completely stop your treatment with MEKTOVI if you develop certain side effects.
- Take MEKTOVI in combination with encorafenib by mouth 2 times a day, about 12 hours apart.
- MEKTOVI may be taken with or without food.
- If you miss a dose of MEKTOVI, take it as soon as you remember. If it is within 6 hours of your next scheduled dose, take your next dose at your regular time. Do not make up for the missed dose.
- Do not take an extra dose if you vomit after taking your scheduled dose. Take your next dose at your regular time.
- If you stop treatment with encorafenib, talk to your healthcare provider about whether your MEKTOVI treatment may need to be stopped.

What are the possible side effects of MEKTOVI?

MEKTOVI may cause serious side effects, including:

- **Heart problems, including heart failure.** Your healthcare provider should check your heart function before and during treatment with MEKTOVI. Call your healthcare provider right away if you have any of the following signs and symptoms of a heart problem:
 - feeling like your heart is pounding or racing
 - shortness of breath
 - swelling of your ankles and feet
 - feeling lightheaded
- **Blood clots.** MEKTOVI can cause blood clots in your arms or legs, which can travel to your lungs and can lead to death. Get medical help right away if you have the following symptoms:
 - chest pain
 - sudden shortness of breath or trouble breathing
 - pain in your legs with or without swelling
 - swelling in your arms and legs
 - a cool pale arm or leg
- **Eye problems.** MEKTOVI can cause serious eye problems that might lead to blindness. Call your healthcare provider right away if you develop any of these symptoms of eye problems:
 - blurred vision, loss of vision, or other vision changes
 - see colored dots
 - see halos (blurred outline around objects)
 - eye pain, swelling, or redness
- **Lung or breathing problems.** MEKTOVI can cause lung or breathing problems. Tell your healthcare provider if you have any new or worsening symptoms of lung or breathing problems, including:
 - shortness of breath
 - cough
- **Liver problems.** Your healthcare provider should perform blood tests to check your liver function before and during treatment with MEKTOVI. Tell your healthcare provider if you have any of the following signs and symptoms of a liver problem:
 - yellowing of your skin or the white part of your eyes (jaundice)
 - dark or brown (tea-colored) urine
 - nausea or vomiting
 - loss of appetite
- **Muscle problems (rhabdomyolysis).** MEKTOVI can cause muscle problems that can be severe. Treatment with MEKTOVI may increase the level of an enzyme in your blood called creatine phosphokinase (CPK) and can be a sign of muscle damage. Your healthcare provider should perform a blood test to check your levels of CPK before and during treatment. Tell your healthcare provider right away if you develop any of these symptoms:
 - weakness
 - muscle aches or pain
 - dark, reddish urine
- **Bleeding problems.** MEKTOVI, when taken with encorafenib, can cause serious bleeding problems, including in your brain or stomach, that can lead to death. Call your healthcare provider and get medical help right away if you have any signs of bleeding, including:
 - headaches, dizziness, or feeling weak
 - cough up blood or blood clots
 - vomit blood or your vomit looks like “coffee grounds”
 - red or black stool that look like tar

The most common side effects of MEKTOVI when taken with encorafenib, include:

- fatigue
- nausea
- diarrhea
- vomiting
- abdominal pain

These are not all the possible side effects of MEKTOVI.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

You may also report side effects to Array BioPharma Inc. at 1-844-792-7729.

How should I store MEKTOVI?

- Store MEKTOVI at room temperature between 68°F to 77°F (20°C to 25°C).

Keep MEKTOVI and all medicines out of the reach of children.

General information about the safe and effective use of MEKTOVI.

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use MEKTOVI for a condition for which it was not prescribed. Do not give MEKTOVI to other people, even if they have the same symptoms that you have. It may harm them. You can ask your healthcare provider or pharmacist for information about MEKTOVI that is written for health professionals.

What are the ingredients in MEKTOVI?

Active ingredient: binimetinib

Inactive ingredients: lactose monohydrate, microcrystalline cellulose, croscarmellose sodium, magnesium stearate (vegetable source), and colloidal silicon dioxide

Tablet coating: polyvinyl alcohol, polyethylene glycol, titanium dioxide, talc, ferric oxide yellow, ferrousferrous oxide

Distributed by: Array BioPharma Inc. Boulder, Colorado 80301.

MEKTOVI® is a registered trademark of Array BioPharma Inc. in the United States and various other countries.

For more information, go to www.BRAFTOVIMEKTOVI.com or call 1-844-792-7729.

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This Patient Information has been approved by the U.S. Food and Drug Administration.

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