

Patient Medication Information

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

Pr **MEKTOVI**[®]

Binimetinib tablets

This Patient Medication Information is written for the person who will be taking **MEKTOVI**. This may be you or a person you are caring for. Read this information carefully. Keep it as you may need to read it again.

This Patient Medication Information is a summary. It will not tell you everything about this medication. If you have more questions about this medication or want more information about **MEKTOVI**, talk to a healthcare professional.

Your melanoma will be treated with MEKTOVI in combination with another medicine called encorafenib. Read the Patient Medication Information leaflet for the other medication as well as this one.

Serious warnings and precautions box

- **Heart problems, including heart failure:** MEKTOVI can make your heart work less well. It can also worsen any other heart problems you have. Your healthcare professional will check that your heart is working properly before and during your treatment.
- **Blood clots: Deep vein thrombosis** (blood clots in the arms or legs) or **pulmonary embolism** (blood clots in the lung) have occurred in patients taking MEKTOVI. These blood clots can be life-threatening and cause death.
- **Hemorrhage:** MEKTOVI can cause serious bleeding problems, including in your stomach, intestinal tract or brain, that can lead to death.
- **Eye problems:** MEKTOVI can cause:
 - **retinal pigment epithelial detachment** (detachment of the inner layer of the eye)
 - **retinal vein occlusion** (a blockage in the vein carrying blood away from the eye)
 These eye problems can lead to blindness.
- **Interstitial lung disease:** MEKTOVI can cause inflammation or scarring of the lungs.
- **Rhabdomyolysis** (breakdown of muscles): MEKTOVI can cause muscle problems that can be severe. Your healthcare professional will run blood tests to check for muscle problems before and during your treatment.

See the “Serious side effects and what to do about them” table, below, for more information on these serious side effects.

What MEKTOVI is used for:

MEKTOVI is used with a drug called encorafenib to treat adults with a type of skin cancer called melanoma. This type of skin cancer must have:

- a change (mutation) in the BRAF gene, and
- spread to other parts of the body, or cannot be removed by surgery.

Before taking MEKTOVI, a test will be performed. This test is to confirm that MEKTOVI is right for you. MEKTOVI is not approved for use in children and adolescents under 18 years of age.

How MEKTOVI works:

MEKTOVI targets a protein known as “MEK” that causes cancer cells to grow.

Changes in the BRAF gene can produce proteins that cause melanoma to grow. Encorafenib targets these proteins.

When MEKTOVI and encorafenib are used together, they may help to slow down or stop the growth of your melanoma.

The ingredients in MEKTOVI are:

Medicinal ingredient(s): binimetinib

Non-medicinal ingredients: colloidal silicon dioxide, croscarmellose sodium, ferric oxide yellow, ferrousferrous oxide, lactose monohydrate, magnesium stearate (vegetable source), microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, talc and titanium dioxide.

MEKTOVI comes in the following dosage form(s):

Tablets: 15 mg

Do not use MEKTOVI if:

- You are allergic to binimetinib or any of the other ingredients in this medicine.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take MEKTOVI. Talk about any health conditions or problems you may have, including if you:

- have or have had heart problems such as heart failure
- have high blood pressure
- have or have had eye problems, including:
 - **serious retinopathy** (a build-up of fluid behind the retina)
 - **uveitis** (inflammation of part of the eye wall)
 - **retinal vein occlusion**, or
 - **glaucoma** (uncontrolled high pressure in your eyes)
- have muscle pain or weakness

- have a history of blood clots
- have breathing difficulties
- have or have had liver or kidney problems
- are intolerant to lactose. This is because MEKTOVI contains lactose.

Other warnings you should know about:

Hypertension (high blood pressure): MEKTOVI can raise your blood pressure. Your healthcare professional will check your blood pressure before and during treatment with MEKTOVI. If blood pressure becomes a problem, your healthcare professional may prescribe medicine to treat your high blood pressure.

Liver problems: MEKTOVI can cause liver problems. Your healthcare professional will run blood tests before and during treatment with MEKTOVI. These blood tests will tell your healthcare professional how your liver is working.

Other eye problems: MEKTOVI can cause:

- **serous retinopathy**, including **macular edema** (swelling of the macula)
- **uveitis**, including:
 - **iritis** (inflammation of the coloured part of the eye)
 - **iridocyclitis** (inflammation of the coloured part of the eye and the muscles and tissues that help the eye to focus)

Your healthcare professional will check your eyes at each visit for new or worsening eye problems. Your doctor may send you to see an eye specialist.

Skin changes (rash and skin cancer): MEKTOVI, taken with encorafenib, can cause skin changes including rash and new skin cancers. New skin cancers include squamous cell carcinoma of the skin, keratoacanthoma and basal cell carcinoma. Throughout your treatment, your healthcare professional will check your skin. They will look for any new skin cancers during your treatment, and for up to 6 months after you stop taking MEKTOVI. Tell your healthcare professional immediately if you notice any changes in your skin both during and after treatment.

See the “Serious side effects and what to do about them” table, below, for more information on the above and other serious side effects.

Pregnancy and breastfeeding

Female patients:

- If you are pregnant, able to get pregnant or think you are pregnant, there are specific risks you should discuss with your healthcare professional.
- You should not take MEKTOVI if you are pregnant. It may harm your unborn baby.

- If you are able to become pregnant:
 - Your healthcare professional will do a pregnancy test before you start treatment with MEKTOVI.
 - Avoid becoming pregnant while you are taking MEKTOVI. Use effective birth control during treatment and for at least 1 month after your last dose of MEKTOVI. Talk to your healthcare professional about birth control methods that may be right for you during this time.
 - Tell your healthcare professional right away if you become pregnant or think you may be pregnant during treatment with MEKTOVI.
- Do NOT breastfeed during treatment and for at least 3 days after your last dose of MEKTOVI. Talk to your healthcare professional about the best way to feed your baby during this time.

Male patients:

- Avoid fathering a child while you are taking MEKTOVI.
- During your treatment with MEKTOVI, use a condom each time you have sex with a woman who is pregnant, may be pregnant or could get pregnant. Continue using condoms for at least 1 week after your last dose.
- If, during your treatment with MEKTOVI, your sexual partner becomes pregnant or thinks she may be pregnant, tell your healthcare professional right away.

Fertility: It is unknown whether MEKTOVI may affect your fertility. No human studies on fertility have been performed. Talk to your healthcare professional if you have questions about this.

Driving and using machines: MEKTOVI can cause fatigue and vision problems. Before you drive or do tasks that require special attention, wait until you know how you respond to MEKTOVI.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with MEKTOVI:

- atazanavir, a medicine used to treat HIV

As MEKTOVI is taken with encorafenib, please also read the leaflet for this product to learn about other interactions with encorafenib.

How to take MEKTOVI:

- Take exactly as your healthcare professional has told you. Check with your doctor or pharmacist if you are not sure.
- Swallow tablets whole, with water.
- Take with or without food.

- Take MEKTOVI for as long as your healthcare professional prescribes it. Do not change your dose or stop taking it unless your healthcare professional tells you to.

Usual dose:

Recommended total daily adult dose:

- 90 mg (45 mg twice daily): Take three 15 mg tablets (45 mg) twice per day, about 12 hours apart. This is a total daily dose of 90 mg.

You will also receive treatment with another medicine, encorafenib. Your healthcare professional will tell you how much of this medicine you will take and how to take it.

Your healthcare professional may lower your dose, interrupt your treatment for a period of time or recommend that you stop treatment completely. This may happen if:

- you develop certain side effects, or
- your disease gets worse, or
- your encorafenib is stopped.

Overdose:

If you think you, or a person you are caring for, have taken too much MEKTOVI, contact a healthcare professional, hospital emergency department, regional poison control centre or Health Canada's toll-free number, 1-844 POISON-X (1-844-764-7669) immediately, even if there are no signs or symptoms.

Missed dose:

- If you miss a dose and it is more than 6 hours until your next scheduled dose, take the missed dose as soon as you remember. Then continue with your next dose at your regular time.
- If it is within 6 hours of your next dose, skip the missed dose. Wait and take your next dose at your regular time. Do not take extra tablets to make up for the missed dose.
- If you vomit at any time after taking MEKTOVI, do not take another dose. Take your next dose at your regular time.

Possible side effects from using MEKTOVI:

These are not all the possible side effects you may have when taking MEKTOVI. If you experience any side effects not listed here, tell your healthcare professional.

As MEKTOVI is taken with encorafenib, please also read the leaflet for this product to learn about possible side effects caused by encorafenib.

Side effects of MEKTOVI include:

- headache, dizziness
- stomach pain, diarrhea, vomiting, nausea, constipation

- skin rash, dry skin, itchy skin
- thickening of the outer layers of the skin
- redness, chapping or cracking of the skin
- hair loss or thinning
- fever
- swelling including in the hands or feet
- fatigue
- joint pain
- muscle pain, weakness or spasm
- pain in extremities
- pain, loss of sensation or tingling in hands and feet

MEKTOVI can cause abnormal blood test results. Your healthcare professional will do blood tests during your treatment. These will tell your healthcare professional how MEKTOVI is affecting your blood, heart, pancreas, liver, kidneys and muscles.

Serious side effects described in the table below are from the combination treatment of MEKTOVI with encorafenib.

Serious side effects and what to do about them

Frequency/Side Effect/Symptom	Talk to your healthcare professional		Stop taking this drug and get immediate medical help
	Only if severe	In all cases	
Very common			
Anemia (decreased number of red blood cells): fatigue, loss of energy, irregular heartbeats, pale complexion, shortness of breath, weakness	X		
Bleeding problems, including hemorrhage: headaches, dizziness or weakness, coughing up of blood, blood clots, vomit containing blood or that looks like “coffee grounds”, red or black stools that look like tar, passing blood in the urine, stomach (abdominal) pain, unusual vaginal bleeding			X
Eye problems, including: serous retinopathy (a build-up of fluid behind the retina), including retinal pigment epithelial detachment			X

Frequency/Side Effect/Symptom	Talk to your healthcare professional		Stop taking this drug and get immediate medical help
	Only if severe	In all cases	
(detachment of the inner layer of the eye) and macular edema (swelling of the macula) • retinal vein occlusion (a blockage in the vein carrying blood away from the eye) • uveitis (inflammation of part of the eye wall), including iritis (inflammation of the coloured part of the eye) and iridocyclitis (inflammation of the coloured part of the eye and the muscles and tissues that help the eye to focus) Symptoms include: blurred vision, loss of vision or other vision changes (such as colored dots in your vision), halo (seeing blurred outline around objects), eye pain, swelling or redness. Symptoms appear suddenly and worsen quickly.			
Hypertension (high blood pressure): shortness of breath, fatigue, severe headache, dizziness or fainting, lightheaded, chest pain or pressure, swelling in your ankles and legs, bluish colour to your lips and skin, racing pulse or palpitations		X	
Kidney problems: confusion, itchiness or rash, puffiness in face and hands, swelling in feet or ankles, urinating less or not at all; weight gain		X	
Liver problems: yellowing of your skin and eyes (jaundice), right upper stomach area pain or swelling, nausea or vomiting, unusual dark urine, unusual tiredness		X	

Frequency/Side Effect/Symptom	Talk to your healthcare professional		Stop taking this drug and get immediate medical help
	Only if severe	In all cases	
Common			
Allergic reaction: difficulty swallowing or breathing, wheezing, swelling of the face, lips, tongue or throat, drop in blood pressure, feeling sick to your stomach and throwing up, hives or rash			X
Colitis (inflammation of the bowel): severe or persistent diarrhea, abdominal pain or cramping, pain in the rectum, bleeding from the rectum	X		
Deep vein thrombosis (blood clot in a deep vein of the arm or leg): pain in your legs with or without swelling, swelling in your arms and legs, or a cool, pale arm or leg, arm or leg may also be warm to the touch and may appear red			X
Dermatitis acneiform (skin/acne condition): small, raised acne-like red bumps on the face, scalp, chest, upper back; bumps may be filled with pus	X		
Facial paresis (weakness and paralysis of face muscles): loss of movement of the face; face muscles may appear to droop			X
Heart problems, including heart failure (heart does not pump blood as well as it should): feeling dizzy, fatigue and weakness, lightheaded, shortness of breath, feeling like your heart is pounding, racing, beating irregularly, fluid retention, lack of appetite, nausea, swelling in the ankles, legs and feet			X
Interstitial lung disease, including pneumonitis (inflammation or scarring of the lungs):		X	

Frequency/Side Effect/Symptom	Talk to your healthcare professional		Stop taking this drug and get immediate medical help
	Only if severe	In all cases	
cough, shortness of breath or fatigue, fever, loss of appetite, unintentional weight loss			
Pancreatitis (inflammation of the pancreas): upper abdominal pain, fever, rapid heart rate, nausea, vomiting, tenderness when touching the abdomen		X	
Panniculitis (inflammation of the fatty layer under the skin): tender, red bumps on the arms and legs, abdomen, breasts, face or buttocks	X		
Pulmonary embolism (blood clot in the lung): chest pain that may increase with deep breathing, sudden shortness of breath, trouble breathing, cough, coughing up bloody sputum			X
Rhabdomyolysis (breakdown of muscles): muscle pain, cramps, stiffness, spasm, weakness, red-brown (tea-coloured) urine.			X
Skin cancer including cutaneous squamous cell cancer, keratoacanthomas and basal cell carcinoma : skin sore, wart, or reddish bump that bleeds or does not heal		X	

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

Reporting side effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (canada.ca/drug-device-reporting) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your healthcare professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

Store at room temperature (15 to 30°C).

Keep out of reach and sight of children.

If you want more information about MEKTOVI:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes the Patient Medication Information by visiting the Health Canada Drug Product Database website ([Drug Product Database: Access the database](#)); the manufacturer's website www.pfizer.ca; or by calling 1-800-463-6001.

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