

## Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

▼ This medicine is new or being used differently. Please report side effects. See the [full CMI](#) for further details.

### 1. Why am I using MEKTOVI?

MEKTOVI contains the active ingredient binimetinib. MEKTOVI can be used

- in combination with a medicine called encorafenib (BRAFTOVI®) to treat adult patients with a type of skin cancer called melanoma, which has spread to other parts of the body, or cannot be removed by surgery.

For more information, see Section [1. Why am I using MEKTOVI?](#) in the full CMI.

### 2. What should I know before I use MEKTOVI?

Do not use if you have ever had an allergic reaction to or any of the ingredients listed at the end of the CMI.

**Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.**

For more information, see Section [2. What should I know before I use MEKTOVI?](#) in the full CMI.

### 3. What if I am taking other medicines?

Some medicines may interfere with MEKTOVI and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

### 4. How do I use MEKTOVI?

- The recommended dose of MEKTOVI, when taken in combination with BRAFTOVI, is three 15 mg tablets twice daily taken about 12 hours apart (corresponding to a daily dose of 90 mg).
- Swallow the tablets whole with a full glass of water. MEKTOVI can be taken with or without food.

More instructions can be found in Section [4. How do I use MEKTOVI?](#) in the full CMI.

### 5. What should I know while using MEKTOVI?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>• Remind any doctor, dentist or pharmacist you visit that you are using MEKTOVI.</li><li>• Tell your doctor if you are pregnant, think you may be pregnant or are planning to become pregnant before taking MEKTOVI</li><li>• Tell your doctor if you experience heart, bleeding, eye, liver or problems, or skin changes.</li></ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"><li>• Do not stop taking your medicine or lower the dosage without checking with your doctor.</li><li>• Do not take MEKTOVI to treat any other complaints unless your doctor tells you to.</li></ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"><li>• MEKTOVI can affect your ability to drive or use machines.</li></ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"><li>• Keep your MEKTOVI capsules in their original pack until it is time to take them.</li><li>• Store below 30°C in a cool and dry place.</li></ul>

For more information, see Section [5. What should I know while using MEKTOVI?](#) in the full CMI.

### 6. Are there any side effects?

When MEKTOVI was taken with encorafenib, very common side effects included fatigue, nausea, diarrhoea, vomiting, problems with vision, stomach pain, joint pain, abnormal blood test results and muscle pain. For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

▼ This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. You can report side effects to your doctor, or directly at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems).

# MEKTOVI®

Active ingredient(s): *binimetinib*

## Consumer Medicine Information (CMI)

This leaflet provides important information about using MEKTOVI. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using MEKTOVI.**

Where to find information in this leaflet:

1. [Why am I using MEKTOVI?](#)
2. [What should I know before I use MEKTOVI?](#)
3. [What if I am taking other medicines?](#)
4. [How do I use MEKTOVI?](#)
5. [What should I know while using MEKTOVI?](#)
6. [Are there any side effects?](#)
7. [Product details](#)

## 1. Why am I using MEKTOVI?

**MEKTOVI contains the active ingredient binimetinib** MEKTOVI is an anti-cancer medicine, which belongs to a group of medicines called 'MEK inhibitors'.

**MEKTOVI is used in combination with another medicine which contains the active ingredient, encorafenib (called BRAFTOVI®) to treat adult patients with a type of skin cancer called melanoma, which has spread to other parts of the body, or cannot be removed by surgery.**

**The type of melanoma which MEKTOVI and BRAFTOVI are used to treat, has a particular change (mutation) in a gene called BRAF. This mutation in the BRAF gene may have produced proteins which caused the melanoma to develop.**

Before you start treatment, your doctor will have tested you to confirm that you have this BRAF mutation.

MEKTOVI targets a protein called MEK which promotes cancer cell growth. When MEKTOVI is used in combination with BRAFTOVI (which targets the changed BRAF protein), it further slows down or stops the growth of your cancer.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

Your doctor may have prescribed it for another reason.

BRAFTOVI is not recommended for children and adolescents aged under 18 years. The safety and efficacy of this medicine has not been established in this age group.

## 2. What should I know before I use MEKTOVI?

**MEKTOVI is to be used in combination with BRAFTOVI, therefore you should also read the CMI for the other medicine you are planning to take.**

### Warnings

**Do not use MEKTOVI if:**

- you are allergic to binimetinib, or any of the ingredients listed at the end of this leaflet. Some of the symptoms of an allergic reaction may include:
  - shortness of breath
  - wheezing or difficulty breathing
  - swelling of the face, lips, tongue or other parts of the body
  - rash, itching or hives on the skin
- Always check the ingredients to make sure you can use this medicine.

**Check with your doctor if you:**

- have any other medical conditions such as:
  - heart problems
  - high blood pressure
  - muscle problems
  - blood clots
  - liver problems
  - lung or breathing problems
  - bleeding problems or if you are taking medicines that may increase your risk of bleeding
  - eye problems including glaucoma or increased pressure in your eyes
- take any medicines for any other condition

MEKTOVI contains lactose. Tell your doctor, nurse or pharmacist if you have an intolerance to some sugars.

Tell your doctor if you have had a history of blockage in the vein draining the eye (retinal vein occlusion) as MEKTOVI is not recommended in patients with a history of retinal vein occlusion.

Tell your doctor if you have had a different type of cancer than melanoma as MEKTOVI when taken with BRAFTOVI may cause progression of certain other types of cancers.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

## Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Taking MEKTOVI during pregnancy is not recommended. Tell your doctor if you are pregnant or plan to become pregnant or are breast-feeding before taking MEKTOVI.

MEKTOVI may cause permanent harm or birth defects to an unborn baby.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

MEKTOVI is not recommended while breast-feeding. If you are breastfeeding or planning to breastfeed, you must tell your doctor before taking this medicine.

It is not known if MEKTOVI passes into breastmilk.

## 3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

**Some medicines may interfere with MEKTOVI and affect how it works.**

Keep a list of the medicines you take so you can show it to your doctor, nurse or pharmacist when you get a new medicine.

**Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect MEKTOVI.**

## 4. How do I take MEKTOVI?

### How much to take

- Always take MEKTOVI exactly as your doctor has prescribed.
- The recommended dose of MEKTOVI, when taken in combination with BRAFTOVI, is three 15 mg tablets twice daily taken about 12 hours apart (corresponding to a daily dose of 90 mg).
- If you experience serious side effects (such as skin, eye, heart or lung problems), your doctor may lower the dose of MEKTOVI, or stop treatment temporarily or permanently.
- Follow the instructions provided and use MEKTOVI until your doctor tells you to stop.

### When to take MEKTOVI

- Swallow the tablets whole with a full glass of water.
- MEKTOVI can be taken with or without food.
- If vomiting occurs at any time after taking the tablets do not take an additional dose. Take the next dose as scheduled.

Continue taking MEKTOVI for as long as your doctor tells you to. Do not stop unless your doctor advises you to.

## If you forget to use MEKTOVI

If you miss a dose of MEKTOVI at the usual time, the missed dose is less than 6 hours late, take it as soon as you remember.

If the missed dose is more than 6 hours late, skip that dose and take your next dose at the usual time.

Then go back to taking your tablets as you would normally

**Do not take a double dose to make up for the dose that you missed.**

**If you are not sure what to do, ask your doctor or pharmacist.**

**If you have trouble remembering to take your medicine, ask your doctor, nurse or pharmacist for some hints.**

## If you use too much MEKTOVI

If you think that you have used too much MEKTOVI, you may need urgent medical attention.

**You should immediately:**

- phone the Poisons Information Centre (by calling 13 11 26), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

**You should do this even if there are no signs of discomfort or poisoning.**

## 5. What should I know while using MEKTOVI?

### Things you should do

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking MEKTOVI.

If you are going to have surgery, tell the surgeon or that you are taking MEKTOVI.

If you become pregnant while taking MEKTOVI, tell your doctor immediately.

If you are a woman who could become pregnant, you must use effective birth control (contraception) while you are taking MEKTOVI, and you must continue to use effective contraception for at least 1 month after taking your last dose.

Tell your doctor if you are breastfeeding while being treated with MEKTOVI.

**Call your doctor straight away if you experience the following while you are taking MEKTOVI:**

### • Skin changes

MEKTOVI when taken with BRAFTOVI may cause other types of skin cancer such as cutaneous squamous cell carcinoma.

Your doctor will periodically check for new cancers on your skin and inside your body before, during and after your treatment. Tell your doctor immediately if you detect any skin changes including new warts, skin

soreness, reddish bumps which bleed or don't heal or any changes in the size or colour of a mole.

- **Heart problems**

MEKTOVI can lower the amount of blood pumped by your heart or make existing heart problems worse. Your doctor will run tests to check that your heart is working properly before and during your treatment with this medicine.

- **Blood clots**

MEKTOVI can cause blood clots in your arms or legs which can travel to your lungs and lead to death. If necessary, your doctor may decide to interrupt or completely stop your MEKTOVI treatment.

- **Bleeding problems**

MEKTOVI may cause serious bleeding problems. Tell your doctor immediately if you have any signs of bleeding.

- **Eye problems**

MEKTOVI I may cause serious eye problems. Your doctor will examine your eyes for any new or worsening problems with your sight while you are taking these medicines.

- **Liver problems**

MEKTOVI may increase the amounts of liver enzymes in your blood. Your doctor will run blood tests to monitor your liver function before and during treatment.

- **Muscle problems**

MEKTOVI can cause breakdown of muscle (rhabdomyolysis). Your doctor will run blood tests to monitor muscle condition before and during treatment. As a precaution, drink plenty of fluids during treatment, unless otherwise advised by your doctor.

- **High blood pressure**

MEKTOVI can raise blood pressure. Your doctor or nurse will check your blood pressure before and during treatment with MEKTOVI.

- **Lung or breathing problems**

MEKTOVI may cause lung or breathing problems including inflammation of the lungs (pneumonitis or interstitial lung disease). Signs and symptoms can include: cough, shortness of breath or fatigue. If necessary, your doctor may interrupt or completely stop your MEKTOVI treatment.

If you experience the following symptoms, contact your doctor immediately as this can be a life-threatening condition: nausea, shortness of breath, irregular heartbeat, muscular cramps, seizures, clouding of urine, decrease in urine output and tiredness. These may be caused by a group of metabolic complications that can occur during treatment of cancer that are caused by the breakdown products of dying cancer cells (Tumour lysis

syndrome (TLS)) and can lead to changes in kidney function (see also Section 6: Possible side effects).

Remind any doctor, dentist or pharmacist you visit that you are using MEKTOVI. Keep all of your doctor's appointments so that your progress can be checked.

### **Things you should not do**

- Do not take MEKTOVI to treat any other complaints unless your doctor tells you to.
- Do not give your medicine to anyone else, even if their symptoms seem similar to yours or they have the same condition as you.
- Do not stop taking your medicine or lower the dosage without checking with your doctor

### **Driving or using machines**

#### **Be careful before you drive or use any machines or tools until you know how MEKTOVI affects you.**

MEKTOVI can affect your ability to drive or use machines.

If you experience any problems with your vision, or any other side-effects that may affect your ability, avoid driving or using machines. Talk to your doctor if you are not sure if you should drive.

### **Looking after your medicine**

- Keep your MEKTOVI capsules in their original pack until it is time to take them.
- Keep your MEKTOVI capsules in a place where the temperature stays below 30°C.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

#### **Keep it where young children cannot reach it.**

#### **Getting rid of any unwanted medicine**

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Do not throw any medicines away via wastewater or household waste.

## **6. Are there any side effects?**

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

### **Less serious side effects**

**When MEKTOVI was taken with BRAFTOVI the following side effects were reported.**

Less serious side effects	What to do
<p><b>Head and neurology related:</b></p> <ul style="list-style-type: none"> <li>• problems with nerves that can cause pain, loss of sensation or tingling in hands and feet</li> <li>• headache</li> <li>• dizziness</li> <li>• fever</li> <li>• fatigue</li> <li>• changes in the way things taste</li> <li>• weakness and paralysis of the face muscles (facial paresis)</li> </ul> <p><b>Bleeding related:</b></p> <ul style="list-style-type: none"> <li>• reduced red blood cell count (anaemia)</li> <li>• bleeding at various sites in the body</li> </ul> <p><b>Heart related:</b></p> <ul style="list-style-type: none"> <li>• high blood pressure</li> <li>• abnormal blood test results related to blood creatine kinase, indicating damage to the heart and muscle</li> <li>• swelling of the hands or feet (peripheral oedema), localised swelling</li> </ul> <p><b>Eyes related:</b></p> <ul style="list-style-type: none"> <li>• problems with your vision (visual impairment)</li> <li>• inflammation of the eye (uveitis)</li> </ul> <p><b>Gastrointestinal related:</b></p> <ul style="list-style-type: none"> <li>• stomach pain</li> <li>• diarrhoea</li> <li>• being sick (vomiting)</li> <li>• feeling sick (nausea)</li> <li>• constipation</li> <li>• abnormal blood test results for liver function</li> <li>• inflammation of the colon (colitis)</li> <li>• kidney failure</li> <li>• abnormal kidney test results (creatinine elevations)</li> <li>• abnormal blood test results for liver function (blood alkaline phosphatase)</li> <li>• abnormal blood test results for pancreas function (amylase, lipase)</li> <li>• inflammation of the pancreas (pancreatitis) causing severe abdominal pain</li> </ul> <p><b>Muscle related:</b></p> <ul style="list-style-type: none"> <li>• joint pain (arthralgia)</li> </ul>	<p><b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b></p>

Less serious side effects	What to do
<ul style="list-style-type: none"> <li>• muscle pain (myalgia), weakness or spasm</li> <li>• back pain</li> <li>• pain in the hands and feet</li> </ul> <p><b>Skin and hair related:</b></p> <ul style="list-style-type: none"> <li>• itching</li> <li>• dry skin</li> <li>• abnormal hair loss or thinning (alopecia)</li> <li>• skin rash of various types</li> <li>• thickening of the outer layers of the skin</li> <li>• some types of benign (non-cancerous) skin tumours such as skin papilloma</li> <li>• type of skin cancer such as basal cell carcinoma</li> <li>• redness, chapping or cracking of the skin</li> <li>• inflammation of the fatty layer under the skin, symptoms include tender skin nodules</li> <li>• skin rash with flat discoloured area or raised bumps like acne (dermatitis acneiform)</li> <li>• redness, skin peeling or blisters on hands and feet (called palmar-plantar erythrodysesthesia or hand and foot syndrome)</li> <li>• increased skin sensitivity to sunlight</li> </ul>	

### Serious side effects

Serious side effects	What to do
<p><b>Heart related</b></p> <p>MEKTOVI can affect how well your heart pumps (left ventricular dysfunction). Signs and symptoms can include:</p> <ul style="list-style-type: none"> <li>• feeling dizzy, tired or lightheaded</li> <li>• shortness of breath</li> <li>• feeling like your heart is pounding, racing or beating irregularly</li> <li>• swelling in the legs</li> </ul>	<p><b>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</b></p>
<p><b>Blood pressure related</b></p> <p>MEKTOVI can increase blood pressure. Tell your doctor immediately if you experience severe headache, feel dizzy or lightheaded, or if your blood pressure is much higher than usual (if you are self-</p>	<p><b>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of</b></p>

Serious side effects	What to do
<p>monitoring your blood pressure at home).</p> <p><b>Allergy related:</b></p> <p>allergic reaction that may include swelling of the face and difficulty breathing</p> <p><b>Blood clot related</b></p> <p>MEKTOVI may cause blood clots (venous thromboembolism including pulmonary embolism). Signs and symptoms can include:</p> <ul style="list-style-type: none"> <li>• chest pain</li> <li>• sudden shortness of breath or trouble breathing</li> <li>• pain in your legs with or without swelling</li> <li>• swelling in your arms and legs</li> <li>• a cool, pale arm or leg</li> </ul> <p>Eye related</p> <p>MEKTOVI may induce fluid leakage under the retina in the eye that results in detachment of different layers in the eye (retinal pigment epithelial detachment), which could lead to the following symptoms:</p> <ul style="list-style-type: none"> <li>• blurred vision, loss of vision or other vision changes (e.g. coloured dots in your vision)</li> <li>• halo (seeing blurred outline around objects)</li> <li>• eye pain, swelling or redness</li> </ul> <p><b>Muscle related</b></p> <p>MEKTOVI may lead to breakdown of muscles (rhabdomyolysis) which can lead to kidney damage and can be fatal. Signs and symptoms can include:</p> <ul style="list-style-type: none"> <li>• muscle pain, cramps, stiffness or spasm</li> <li>• dark urine</li> </ul> <p><b>Bleeding related</b></p> <p>Taking MEKTOVI can cause serious bleeding problems. Tell your doctor immediately if you have any unusual bleeding or signs of bleeding including:</p> <ul style="list-style-type: none"> <li>• headaches, dizziness or weakness</li> <li>• coughing up of blood or blood clots</li> <li>• vomit containing blood or that looks like “coffee grounds”</li> <li>• red or black stools that look like tar</li> </ul>	<p><b>these serious side effects.</b></p>

Serious side effects	What to do
<ul style="list-style-type: none"> <li>• passing blood in the urine</li> <li>• stomach (abdominal) pain</li> <li>• unusual vaginal bleeding</li> </ul> <p>Other skin cancers</p> <p>MEKTOVI when taken with BRAFTOVI may cause other types of skin cancer</p> <p><b>Tumour lysis syndrome</b></p> <p>Mektovi can cause a rapid breakdown of cancer cells which in some people may be fatal. Symptoms may include nausea, shortness of breath, irregular heartbeat, muscular cramps, seizures, clouding of urine, decrease in urine output and tiredness.</p>	

**Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.**

Other side effects not listed here may occur in some people.

### Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems). By reporting side effects, you can help provide more information on the safety of this medicine.

**Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.**

## 7. Product details

This medicine is only available with a doctor's prescription.

### What MEKTOVI contains

<b>Active ingredient (main ingredient)</b>	15 mg of binimetinib as the active ingredient
<b>Other ingredients (inactive ingredients)</b>	<p><b>Tablet core:</b></p> <ul style="list-style-type: none"> <li>• lactose monohydrate</li> <li>• microcrystalline cellulose</li> <li>• colloidal anhydrous silica</li> <li>• croscarmellose sodium</li> <li>• magnesium stearate</li> </ul> <p><b>Tablet coating:</b></p> <ul style="list-style-type: none"> <li>• polyvinyl alcohol</li> <li>• macrogol 3350</li> <li>• titanium dioxide</li> <li>• purified talc</li> <li>• iron oxide yellow</li> <li>• iron oxide black</li> </ul>
<b>Potential allergens</b>	Lactose monohydrate

**Do not take this medicine if you are allergic to any of these ingredients.**

### **What MEKTOVI looks like**

MEKTOVI 15 mg tablets are supplied in blister packs of 84 tablets (7 strips of 12 tablets).

The 15 mg tablets are yellow/dark yellow, unscored biconvex, oval and film-coated, with "A" debossed on one face and "15" on the opposite face.

AUST R 295440

### **Who distributes MEKTOVI**

Pierre Fabre Australia Pty Limited

Level 7, 32 Walker St

North Sydney, NSW 2060

Australia

® = Registered Trademark

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