BRAFTOVI®

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.

1. Why am I taking BRAFTOVI?

BRAFTOVI contains the active ingredient encorafenib. BRAFTOVI can be used:

- in combination with a medicine called binimetinib (MEKTOVI®) 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;
- in combination with a medicine called binimetinib (MEKTOVI®) to treat adult patients with a type of lung cancer called non-small-cell lung cancer (NSCLC) when the cancer has spread to other parts of the body; or
- in combination with a medicine called cetuximab to treat adults with cancer of the large intestine (colorectal cancer) that has been previously treated with other anticancer medicines.

For more information, see Section 1. Why am I using BRAFTOVI? in the full CMI.

2. What should I know before I use BRAFTOVI?

Do not use if you have ever had an allergic reaction to Braftovi 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 BRAFTOVI? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with BRAFTOVI 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 BRAFTOVI?

- Melanoma and NSCLC - The recommended dose of BRAFTOVI, when taken in combination with MEKTOVI, is six 75 mg capsules once daily (corresponding to a daily dose of 450 mg).
- Colorectal cancer - The recommended dose of BRAFTOVI, when taken in combination with cetuximab is four 75 mg capsules once daily (corresponding to a daily dose of 300 mg).
- Swallow the capsules whole with a full glass of water. BRAFTOVI can be taken with or without food. Avoid grapefruit juice.

More instructions can be found in Section 4. How do I take BRAFTOVI? in the full CMI.

5. What should I know while using BRAFTOVI?

Things you should do	• Remind any doctor, dentist or pharmacist you visit that you are using BRAFTOVI. • Tell your doctor if you are pregnant, think you may be pregnant or are planning to become pregnant before taking BRAFTOVI • Tell your doctor if you experience heart, bleeding, eye, liver or problems, or skin changes.
Things you should not do	• Do not stop taking your medicine or lower the dosage without checking with your doctor. • Do not take BRAFTOVI to treat any other complaints unless your doctor tells you to.
Driving or using machines	• BRAFTOVI can affect your ability to drive or use machines.
Looking after your medicine	• Keep your BRAFTOVI capsules in their original pack until it is time to take them. • Store below 25°C in a cool and dry place.

For more information, see Section 5. What should I know while using Braftovi? in the full CMI.

6. Are there any side effects?

When BRAFTOVI was taken with binimetinib, very common side effects included fatigue, nausea, diarrhoea, vomiting, problems with vision, stomach pain, joint pain, abnormal blood test results and muscle pain. When BRAFTOVI was taken with cetuximab, very common side effects included fatigue, nausea, diarrhoea, acne type rash, rash, stomach pain, decreased appetite 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.

Braftovi®

Active ingredient(s): encorafenib

Consumer Medicine Information (CMI)

This leaflet provides important information about using BRAFTOVI. **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 BRAFTOVI.**

Where to find information in this leaflet:

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

1. Why am I taking BRAFTOVI?

BRAFTOVI contains the active ingredient encorafenib.

BRAFTOVI is an anti-cancer medicine, which belongs to a group of medicines called 'BRAF inhibitors'.

BRAFTOVI can be used in combination with binimetinib (called MEKTOVI) to treat adult patients who have a type of skin cancer called melanoma, which has spread to other parts of the body, or cannot be removed by surgery, and which has a particular change (mutation) in the gene that produces a protein called BRAF.

BRAFTOVI can be used in combination with binimetinib (called MEKTOVI) to treat adult patients who have a type of lung cancer called non-small cell lung cancer (NSCLC), when the cancer, which has spread to other parts of the body and which has a particular change (mutation) in the gene that produces a protein called BRAF.

BRAFTOVI can also be used in combination with cetuximab to treat adult patients who have previously been treated with other anticancer medicines, and who have a type of large intestine cancer (colorectal cancer), which has spread to other parts of the body, and which has a particular change (mutation) in the gene that produces a protein called BRAF.

BRAFTOVI can only be used to treat patients whose cancer has one of these particular mutations in the BRAF gene.

Before you start treatment, your doctor will have tested your tumour to confirm that it has one of these BRAF mutations.

When BRAFTOVI is used in combination with MEKTOVI or cetuximab, it can slow down or stop the growth of your cancer.

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

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 take BRAFTOVI?

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

Warnings

Do not take BRAFTOVI if:

- you are allergic to encorafenib, 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, including alteration of the electrical activity of your heart (QT prolongation)
  - liver problems
  - kidney problems
  - bleeding problems, or if you are taking medicines that may increase your risk of bleeding
  - eye problems
- have had a different type of cancer other than melanoma, large intestine cancer or NSCLC, as Braftovi may worsen certain other types of cancers.
- take any medicines for any other condition

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.

Talk to your doctor if you are breastfeeding or intend to breastfeed. BRAFTOVI is not recommended while breast-feeding. It is not known if BRAFTOVI 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 BRAFTOVI and affect how it works. These include:

- some medicines to treat fungal infections (such as itraconazole, posaconazole, fluconazole)
- some medicines to treat bacterial infections (such as rifampicin, clarithromycin, telithromycin, erythromycin, penicillin)
- medicines typically used to treat epilepsy (seizures) (such as phenytoin, carbamazepine)
- medicines typically used to treat cancer (such as methotrexate, imatinib)
- medicines typically used to treat high cholesterol (such as rosuvastatin, atorvastatin)
- a herbal treatment for depression called St. John's wort
- some medicines for HIV treatment such as ritonavir, amprenavir, raltegravir or dolutegravir
- birth control medicines containing hormones
- medicines typically used to treat high blood pressure (such as diltiazem, bosentan, furosemide)
- medicines used to treat an uneven heartbeat such as amiodarone.

These medicines may be affected by BRAFTOVI or these medicines may affect how well BRAFTOVI works. You may need different amounts of your medicines, or you may need to take different medicines.

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 BRAFTOVI.

4. How do I take BRAFTOVI?



Instructions to open the blister:

- Do not push the capsule through the blister.
- Separate one blister cell by bending it and gently tearing along the perforations.
- Carefully peel off the blister foil starting at the corner labelled with an arrow.
- Gently remove the capsule.

How much to take

- Always take BRAFTOVI exactly as your doctor has prescribed.
- The recommended dose of BRAFTOVI to treat melanoma and NSCLC, when taken in combination with MEKTOVI, is six 75 mg capsules once daily (corresponding to a daily dose of 450 mg).
- The recommended dose of BRAFTOVI to treat colorectal cancer, when taken in combination with cetuximab, is four 75 mg capsules once daily (corresponding to a daily dose of 300 mg).
- Be aware that your dose of BRAFTOVI may change during treatment, depending on your response to treatment.
- If you have liver or kidney problems, your doctor may start you on a lower dose of BRAFTOVI. If you experience serious side effects (such as skin, heart, liver, eye or bleeding problems), your doctor may lower the dose of BRAFTOVI, or stop treatment temporarily or permanently.
- Follow the instructions provided and use BRAFTOVI until your doctor tells you to stop.

When to take BRAFTOVI

- BRAFTOVI can be taken with or without food. Avoid grapefruit juice.
- If vomiting occurs at any time after taking the capsules, do not take an additional dose. Take the next dose as scheduled.

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

How to take BRAFTOVI

- Swallow the capsules whole with a full glass of water.
- If you cannot swallow the capsules whole, you may open and disperse them in a small quantity (approximately 20 mL, roughly 1 tablespoon) of apple sauce and take all the dose immediately. If not used within 30 minutes, discard the mixture and prepare a new one.

If you forget to take BRAFTOVI

If you miss your dose at the usual time, the missed dose is less than 12 hours late, take it as soon as you remember.

If the missed dose is more than 12 hours late, skip that dose and take your next dose at the usual time. Then go back to taking your capsules as you would normally.

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Do not take a double dose to make up for the dose 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 take too much BRAFTOVI

If you think that you have used too much BRAFTOVI, 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 taking BRAFTOVI?

Things you should do

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

Tell any other doctors, dentists, and pharmacists who treat you that you are taking BRAFTOVI.

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

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

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

Birth control medicines containing hormones (such as pills, injections, patches, implants and certain intrauterine devices (IUDs) which release hormones) may not work as well as expected while you are taking BRAFTOVI. You will need to use another reliable method of birth control such as a barrier method (e.g. condom) to prevent falling pregnant while you are taking BRAFTOVI. Ask your doctor, pharmacist or nurse for advice.

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

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

- **Skin changes**

  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.

  BRAFTOVI may cause other types of skin cancer such as cutaneous squamous cell carcinoma. New melanoma lesions may also occur while taking BRAFTOVI.

  Your doctor will periodically check for new cancers on your skin and inside your body before, during and after your treatment with BRAFTOVI.

- **Heart problems**

  BRAFTOVI may lower the amount of blood pumped by your heart, alter the electrical activity of 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 these medicines.

- **Bleeding problems**

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

- **Eye problems**

  BRAFTOVI 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**

  BRAFTOVI 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.

- **Kidney problems**

  BRAFTOVI may alter your kidney activity (often it may cause abnormal blood tests, but more rarely it can cause dehydration and vomiting, or kidney failure). Your doctor will run blood tests to monitor your kidneys before and during treatment. Drink plenty of fluids during treatment. Tell your doctor immediately if you vomit and become dehydrated.

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

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

Things you should not do

- Do not take BRAFTOVI 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 BRAFTOVI affects you.

BRAFTOVI 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 BRAFTOVI capsules in their original pack until it is time to take them.
- Keep your BRAFTOVI capsules in a place where the temperature stays below 25°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 you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

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.

When BRAFTOVI was taken with MEKTOVI by patients with melanoma or NSCLC, the following side effects were reported.

Less serious side effects

Less serious side effects	What to do
Head and neurology related: • problems with nerves that can cause pain, loss of sensation or tingling in hands and feet • headache • dizziness • fever • fatigue • changes in the way things taste • weakness and paralysis of the face muscles (facial paresis) **Bleeding related:** • reduced red blood cell count (anaemia) • bleeding at various sites in the body • blood clots **Heart related:** • high blood pressure • abnormal blood test results related to blood creatine kinase, indicating damage to the heart and muscle **Eyes related:** • problems with your vision (visual impairment) • inflammation of the eye (uveitis **Gastrointestinal related:** • stomach pain • diarrhoea • being sick (vomiting) • feeling sick (nausea) • constipation • abnormal blood test results for liver function • inflammation of the colon (colitis) • kidney failure • abnormal kidney test results (creatinine elevations) • abnormal blood test results for liver function (blood alkaline phosphatase) • abnormal blood test results for pancreas function (amylase, lipase) • inflammation of the pancreas (pancreatitis) causing severe abdominal pain **Muscle related:** • joint pain (arthralgia) • muscle pain (myalgia), weakness, inflammation or spasm • back pain • pain in the hands and feet **Skin and hair related:** • itching • dry skin • abnormal hair loss or thinning (alopecia) • thickening of the outer layers of the skin • some types of benign (non-cancerous) skin tumours such as skin papilloma • type of skin cancer such as basal cell carcinoma • redness, chapping or cracking of the skin • inflammation of the fatty layer under the skin, symptoms include tender skin nodules	**Speak to your doctor if you have any of these less serious side effects and they worry you.**

• skin rash with flat discoloured area or raised bumps like acne (dermatitis acneiform) • redness, skin peeling or blisters on hands and feet (called palmar-plantar erythrodysaesthesia or hand and foot syndrome) • increased skin sensitivity to sunlight	

Serious side effects

Serious side effects	What to do
Heart related: BRAFTOVI can affect the strength with which your heart pumps blood into your arteries or makes existing heart problems worse. Signs and symptoms can include: • feeling dizzy, tired or lightheaded • shortness of breath feeling like your heart is pounding, racing or beating irregularly • swelling in the legs **Bleeding related:** • headaches, dizziness or weakness • coughing up of blood or 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 • blood clots **Allergy related:** • swelling of the hands or feet (peripheral oedema), localised swelling • allergic reaction that may include swelling of the face and difficulty breathing **Other skin cancers related:** • BRAFTOVI may cause other types of skin cancer such as cutaneous squamous cell carcinoma or new melanomas. Usually these skin cancers can be removed with surgery.	**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.**
Tumour lysis syndrome • Braftovi 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.	

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. 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 BRAFTOVI contains

Active ingredient (main ingredient)	50 or 75 mg of encorafenib
Other ingredients (inactive ingredients)	Capsule fill: • copovidone • poloxamer • microcrystalline cellulose • succinic acid • crospovidone • colloidal anhydrous silica • magnesium stearate **Capsule shell:** • gelatin • titanium dioxide • iron oxide red • iron oxide yellow • iron oxide black **Printing ink:** • shellac • iron oxide black • propylene glycol
Potential allergens	No

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

What BRAFTOVI looks like

BRAFTOVI 50 mg hard capsules are supplied in blister packs of 28 capsules (7 strips of 4 capsules).

The 50 mg capsules have an orange opaque cap and a flesh-coloured opaque body, with a stylised “A” printed on the cap and “LGX 50 mg” printed on the body.

50 mg: AUST R 295764

BRAFTOVI 75 mg hard capsules are supplied in blister packs of 42 capsules (7 strips of 6 capsules).

The 75 mg capsules have a flesh-coloured opaque cap and a white opaque body, with a stylised “A” printed on the cap and “LGX 75 mg” printed on the body.

75 mg: AUST R 295441

Who distributes BRAFTOVI

Pierre Fabre Australia Pty Limited

Level 7, 32 Walker St

North Sydney, NSW 2060

® = Registered Trademark

This leaflet was prepared in May 2026.