

# Zelboraf®

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## 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.

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### 1. Why am I using Zelboraf?

Zelboraf contains the active ingredient vemurafenib. Zelboraf is used to treat a type of skin cancer called melanoma that has spread to other parts of the body. For more information, see Section [1. Why am I using Zelboraf?](#) in the full CMI.

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

Do not use if you have ever had an allergic reaction to Zelboraf 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 Zelboraf?](#) in the full CMI.

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

Some medicines may interfere with Zelboraf 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 Zelboraf?

- Take Zelboraf exactly as prescribed by your doctor. The recommended dose is 4 tablets twice a day. Take 4 tablets in the morning, then 4 tablets in the evening, about 12 hours later.

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

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

<b>Things you should do</b>	<ul style="list-style-type: none"><li>• Remind any doctor (including a surgeon or anaesthetist), dentist or pharmacist you visit that you are using Zelboraf.</li></ul>
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	<ul style="list-style-type: none"> <li>• Tell your doctor straight away if you become pregnant or have changes to your vision while taking Zelboraf.</li> <li>• Check your skin and tell your doctor right away about any changes. Avoid going out in the sun.</li> <li>• Tell your doctor if you feel your medicine is not helping your condition.</li> </ul>
<p><b>Things you should not do</b></p>	<ul style="list-style-type: none"> <li>• Do not stop taking Zelboraf or change the dose</li> </ul>

	<p>without first checking with your doctor.</p> <ul style="list-style-type: none"> <li>• Do not let yourself run out of medicine over the weekend or on holidays.</li> </ul>
<p><b>Driving or using machines</b></p>	<ul style="list-style-type: none"> <li>• Be careful driving or operating machinery until you know how Zelboraf affects you. If Zelboraf affects your vision, consult your doctor before driving or operating machinery. Zelboraf may affect your vision.</li> </ul>

**Looking  
after your  
medicine**

- Keep your tablets in the blister pack until it is time to take them.
- Keep the tablets in a cool dry place where the temperature stays below 30°C.
- Do not store Zelboraf in the bathroom or near a sink. Do not leave it on a window sill or in the car.

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

## 6. Are there any side effects?

This medicine helps most people who have metastatic melanoma, but it may have unwanted side effects in some people (see the full CMI for more details). Tell your doctor or pharmacist if you notice any of the following and they worry you. Common side effect may include diarrhoea, constipation, nausea, vomiting, fever, chills, cough, fatigue, sunburn or sun sensitivity, skin problems including rashes, itching, dry or scaly skin, and skin problems including warts. Tell your doctor or nurse immediately or go to the nearest hospital Emergency Department if you experience signs or symptoms of a serious allergic reaction such as swelling of the face, lips, tongue or other parts of the body, shortness of breath or difficulty breathing, rash, itching or hives on the skin. Some other serious side effects may include blisters or peeling skin, bleeding, dizziness, heart problems and/or vision problems. 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.

**Zelboraf<sup>®</sup>** (ZEL-bor-af)

**Active ingredient(s):** *vemurafenib*

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## Consumer Medicine Information (CMI)

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

**Where to find information in this leaflet:**

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

### 1. Why am I using Zelboraf?

**Zelboraf contains the active ingredient vemurafenib.**

Zelboraf belongs to a group of medicines called anti-neoplastic (or anti-cancer) agents.

Zelboraf is used to treat metastatic melanoma (a type of skin cancer that has spread to other parts of the body). It can only be used if your melanoma has a change (mutation) in the BRAF gene. Your doctor will have tested you for this gene. This change has been shown to be involved in the development of melanoma.

Zelboraf works by targeting proteins made from the BRAF gene to slow down the development of your cancer.

Ask your doctor if you have any questions about why Zelboraf has been prescribed for you. Your doctor may have prescribed it for another reason.

Zelboraf is not addictive. This medicine is available only with a doctor's prescription.

## **2. What should I know before I use Zelboraf?**

### **Warnings**

#### **Do not use Zelboraf if:**

1. You are allergic to vemurafenib, or any of the ingredients listed at the end of this leaflet.
  - Always check the ingredients to make sure you can use this medicine.

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.
2. The package is torn or shows signs of tampering. If the package is damaged, return it to your pharmacist for disposal.



3. The expiry date (EXP) printed on the pack has passed.

- If you take this medicine after the expiry date has passed it may not work as well.

## **Check with your doctor if you:**

### **1. You have a heart disorder**

Your doctor will test to check that your heart is working properly before and during your treatment with Zelboraf. If necessary, your doctor may decide to interrupt your treatment temporarily or stop it altogether.

### **2. You have liver problems**

Before and regularly during your treatment, your doctor will do some blood tests to monitor your liver function. If necessary, your doctor may decide to reduce your dose, interrupt your treatment temporarily or stop it altogether.

### **3. You have any problem with your kidneys.**

Kidney problems may affect the activity of Zelboraf. Your doctor will do some blood tests to monitor your kidney function.

### **4. You have been told that you have low blood levels of potassium, calcium, or magnesium in your blood.**

These levels may need to be corrected before treatment with Zelboraf begins.

### **5. You have been previously diagnosed with other types of cancer**

### **6. You have previously received radiation treatment**

## **7. You are allergic to any other medicines, foods, dyes or preservatives**

**If you have not told your doctor about any of the above, tell him or her before you start taking Zelboraf.**

Zelboraf is not recommended for use in children and adolescents. The safety and effectiveness of Zelboraf in children younger than 18 years have not been established.

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.

Zelboraf is not recommended for use during pregnancy. There is no information about the safety of Zelboraf in pregnant women. However if there is a need to take Zelboraf when you are pregnant your doctor will discuss the risks and benefits to you and the unborn baby.

Women of childbearing potential and men should use adequate contraception during treatment and for 6 months after the end of treatment with Zelboraf.

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

It is not known whether Zelboraf passes into breast milk. Breast-feeding is not recommended during treatment with Zelboraf.

### **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 Zelboraf and affect how it works. These include:**

- Ipilimumab, a medicine used to treat metastatic melanoma
- warfarin, a medicine used to prevent blood clots
- medicines that are mainly eliminated by or affect a metabolising protein called CYP3A4 such as;
  - ketoconazole, itraconazole or voriconazole, medicines used to treat fungal infections
  - atazanavir, saquinavir, ritonavir, nelfinavir or indinavir, medicines used to treat HIV infection
  - phenytoin, carbamazepine or phenobarbital, medicines used to treat convulsions
  - rifampicin, rifabutin, rifapentine, clarithromycin or telithromycin, medicines used to treat bacterial infections
  - nefazodone or herbal medicines derived from St. John's Wort, used to treat depression

- some oral, injectable, or implantable contraceptives, for example "the Pill", used for birth control
- medicines that are mainly eliminated by a metabolizing protein called CYP1A2 such as;
  - caffeine, a stimulant
  - olanzapine, clozapine, medicines used in treat schizophrenia and depression
  - theophylline, a medicine used to treat asthma
  - tizanidine, a medicine used as muscle relaxant
- medicines that influence, or are affected by, a protein called P-glycoprotein such as;
  - verapamil, a medicine used to treat high blood pressure and angina (chest pain)
  - cyclosporin, a medicine used to suppress the immune system
  - dronedarone or digoxin, medicines used treat heart problems
- medicines that may affect your heartbeat such as:
  - those used to treat heart rhythm problems, such as amiodarone
  - those used to treat depression, such as amitriptyline or imipramine
  - those used to treat bacterial infections, such as azithromycin and clarithromycin
  - ondansetron or domperidone, medicines used to treat nausea and vomiting.
- medicines that influence, or are affected by, a protein called BCRP such as:

- methotrexate, medicine used to treat arthritis and some types of cancer
- mitoxantrone, a medicine used to treat some types of cancer
- rosuvastatin, a medicine used to lower high cholesterol

These medicines may be affected by Zelboraf or may affect how well it works. You may need different amounts

of your medicines, or you may need to take different medicines.

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

## 4. How do I use Zelboraf?

### How to use Zelboraf

- Take Zelboraf exactly as your doctor has prescribed.
- The recommended dose is 4 tablets twice a day. Take 4 tablets in the morning, then 4 tablets in the evening, about 12 hours later.
- If you have trouble remembering when to take your medicine, ask your pharmacist for some hints.
- If you experience any side effects, your doctor may need to lower the dose to carry on your treatment.
- Swallow the tablets whole with a glass of water.

- Do not chew or crush the tablets.
- Take Zelboraf on an empty stomach either at least 1 hour before or at least 2 hours after a meal in the morning and evening.
- Food may interfere with the absorption of Zelboraf.
- How long you will be treated with Zelboraf depends on how you are responding to treatment. Your doctor will discuss this with you.
- Continue taking Zelboraf until your doctor tells you to stop.

## **When to take Zelboraf**

- Take your medicine at about the same time each day.
- Taking it at the same time each day will have the best effect. It will also help you remember when to take it.

## **If you vomit after taking Zelboraf**

- If you vomit after taking Zelboraf, do not take the same dose again. Then take the next dose at the usual time.

## **If you forget to use Zelboraf**

- Zelboraf should be used regularly at the same time each day. If you miss your dose at the usual time, take your dose as soon as you remember it.
- If it is less than 4 hours before your next dose, skip the missed dose. Then take the next dose at the usual time.

- Do not take a double dose to make up for a forgotten dose. This may increase the chance of getting an unwanted side effect.
- If you are not sure what to do, ask your doctor or pharmacist.
- If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

## **If you use too much Zelboraf**

If you think that you or anyone else has taken too much Zelboraf, you may need urgent medical attention. Keep the following telephone numbers handy.

### **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 Zelboraf?**

### **Things you should do**

- If you are about to be started on any new medicine or start radiation treatment, remind your doctor and pharmacist that you are taking Zelboraf.

- Tell any other doctors, dentists, and pharmacists who treat you that you are taking Zelboraf.
- If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine.
- Check your skin and tell your doctor right away about any changes such as a new wart, a skin sore or reddish bump, sore that bleeds or does not heal.
- Regularly during treatment and for up to 6 months after your treatment, your doctor needs to check your skin for a type of cancer called cutaneous squamous cell carcinoma. There is a high risk of developing these skin cancers while taking Zelboraf.
- In clinical trials, one in four patients developed these skin cancers. These skin cancers may develop as early as the first month of Zelboraf treatment. Factors that increase your risk of developing these cancers are being 65 years old or older, prior skin cancer and long-term sun exposure.
- Usually, this change appears on sun damaged skin, remains local and can be cured by surgical removal. If your doctor finds this type of skin cancer, they may treat it or may send you to another doctor for treatment.
- In addition, check your skin and tell your doctor right away about any changes.
- You may develop new melanomas while taking Zelboraf. These lesions are usually removed by surgery and you can continue your treatment.
- Avoid going out in the sun.
- If you are taking Zelboraf you may become more sensitive to sunlight and get symptoms of sunburn



(such as redness, itching, swelling and blistering) more easily or get sunburns that can be severe.

- To help protect against sunburn, if you do plan to go into the sun wear clothing which protects your skin, including head, face, arms and legs. Use a broad spectrum (UVA/UVB) sunscreen and lip balm (minimum of SPF 30+, re-applied every 2 - 3 hours).
- Women of childbearing potential and men should use adequate contraception during treatment and for 6 months after the end of treatment with Zelboraf.
- Tell your doctor if you are breast-feeding while being treated with Zelboraf.
- Tell your doctor if, for any reason, you have not taken your medicine exactly as prescribed. Otherwise, your doctor may think that it was not effective and change your treatment unnecessarily.
- Tell your doctor if you feel your medicine is not helping your condition.
- Be sure to keep all of your appointments with your doctor so that your progress can be checked.

## **Things you should not do**

- Do not stop taking Zelboraf or change the dose without first checking with your doctor.
- Do not let yourself run out of medicine over the weekend or on holidays.
- Do not take any other medicines whether they require a prescription or not without first telling your doctor or consulting a pharmacist.

- Do not give Zelboraf to anyone else even if they have the same condition as you.
- You should not breast-feed your infant during treatment with Zelboraf. It is not known whether Zelboraf crosses into human breast milk.

## **Driving or using machines**

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

Zelboraf may affect the ability to drive or operate machinery due to side effects, which may be experienced while taking Zelboraf, as such

- feeling tired
- dizziness
- eye problems.

## **Looking after your medicine**

- Keep your tablets in the blister pack until it is time to take them. If you take the tablets out of the blister pack they may not keep well.
- Keep the tablets in a cool dry place where the temperature stays below 30°C.
- Do not store Zelboraf or any other medicine in the bathroom, near a sink, on a window sill or in the car. Heat and dampness can destroy some medicines.
- Follow the instructions in the carton on how to take care of your medicine properly.

- Keep it where young children cannot reach it. A locked cupboard at least 1.5 m above the ground is a good place to store medicines.

## 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.

### Less serious side effects

Less serious side effects	What to do
<p><b>General signs and symptoms</b></p> <ul style="list-style-type: none"> <li>• fever</li> <li>• feeling tired (fatigue), unusual weakness or lacking energy</li> <li>• frequent infections such as fever, severe chills,</li> </ul>	<p><b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b></p>

<b>Less serious side effects</b>	<b>What to do</b>
<p>sore throat or mouth ulcers</p> <ul style="list-style-type: none"> <li>● joint, muscle, or back pain</li> <li>● excess fluid (swelling), usually in the legs</li> </ul> <p><b>Signs and symptoms of nervous system problems:</b></p> <ul style="list-style-type: none"> <li>● headache</li> <li>● tingling, burning feelings, or pain in your hands or feet</li> <li>● drooping eyelid and sagging muscles on one side of the face caused by a paralysed nerve in the face (often reversible)</li> <li>● thickening or appearance of visible cords, bands or lumps in the palm of one or both hands or feet</li> </ul> <p><b>Signs and symptoms of skin problems:</b></p> <ul style="list-style-type: none"> <li>● sunburn or sun sensitivity</li> </ul>	

<b>Less serious side effects</b>	<b>What to do</b>
<ul style="list-style-type: none"> <li>● increased sensitivity to light</li> <li>● red skin rashes</li> <li>● itching</li> <li>● dry or scaly skin</li> <li>● hardened or thickened areas of the skin</li> <li>● painful red lumps or warts</li> <li>● hair loss</li> </ul> <p><b>Signs and symptoms of respiratory problems:</b></p> <ul style="list-style-type: none"> <li>● coughing</li> </ul> <p><b>Signs and symptoms of gastro-intestinal problems:</b></p> <ul style="list-style-type: none"> <li>● diarrhoea</li> <li>● nausea</li> <li>● vomiting</li> <li>● constipation</li> <li>● changes in the way things taste</li> <li>● loss of appetite and weight loss</li> <li>● sore mouth or mouth ulcers, inflammation</li> </ul>	

<b>Less serious side effects</b>	<b>What to do</b>
of mucus membranes (stomatitis)	

## **Serious side effects**

<b>Serious side effects</b>	<b>What to do</b>
<p><b>Signs and symptoms of severe skin problems:</b></p> <ul style="list-style-type: none"> <li>• severe skin rash, itching, hives</li> <li>• severe blisters or bleeding of your lips, mouth, nose, or eyes</li> <li>• a severe skin reaction starting with painful red areas, then large blisters and ends with peeling of layers of skin. This is accompanied by fever and chills, aching muscles and generally feeling unwell.</li> <li>• fever associated with a mild to severe skin rash</li> </ul> <p><b>Signs and symptoms of muscle damage:</b></p> <ul style="list-style-type: none"> <li>• muscle aches</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>

<b>Serious side effects</b>	<b>What to do</b>
<ul style="list-style-type: none"> <li>● dark coloured urine</li> </ul> <p><b>Signs and symptoms of eye or vision problem:</b></p> <ul style="list-style-type: none"> <li>● blurred vision, loss of vision or other vision changes</li> <li>● irritated eyes</li> <li>● eye pain or redness</li> <li>● yellowing of the skin and eyes</li> </ul> <p><b>Signs and symptoms of heart problems:</b></p> <ul style="list-style-type: none"> <li>● severe light headedness or dizziness or feel your heart is beating irregularly or fast</li> <li>● difficulty breathing, chest tightness or wheezing.</li> <li>● shortness of breath</li> </ul> <p><b>Signs and symptoms of gastro-intestinal problems:</b></p> <ul style="list-style-type: none"> <li>● severe upper stomach pain, often with nausea and vomiting (signs of inflammation of the pancreas)</li> </ul>	

<b>Serious side effects</b>	<b>What to do</b>
<ul style="list-style-type: none"> <li>• light coloured bowel motion</li> </ul>	

**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 Zelboraf contains**

<b>Active ingredient (main ingredient)</b>	vemurafenib
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<p><b>Other ingredients (inactive ingredients)</b></p>	<p>croscarmellose sodium colloidal anhydrous silica magnesium stearate hydroxypropylcellulose hypromellose acetate succinate</p> <p>The film-coating contains: polyvinyl alcohol titanium dioxide CI77891 macrogol 3350 talc, purified iron oxide red CI77491</p>
<p><b>Potential allergen</b></p>	<p>None</p>

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

### **What Zelboraf looks like**

Zelboraf tablets are oval, biconvex, pinkish white to orange white tablets with "VEM" engraved on one side. (AUST R 183674)

### **Who distributes Zelboraf**

Roche Products Pty Limited

ABN 70 000 132 865

Level 8, 30-34 Hickson Road

Sydney NSW 2000

AUSTRALIA

Medical enquiries: 1800 233 950

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