

# VECTIBIX®

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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 receiving VECTIBIX?

VECTIBIX contains the active ingredient panitumumab. It is used to treat adult patients with metastatic colorectal cancer.

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

### 2. What should I know before I am given VECTIBIX?

Do not use VECTIBIX if you have a genetic *RAS* mutation, or do not know your *RAS* tumour status, or if you are receiving oxaliplatin-based chemotherapy, or if you are allergic to any of the ingredients listed at the end of the CMI.

**Talk to your doctor if you have swelling of the lungs causing coughing and difficulty breathing, scarring and thickening in the lungs with shortness of breath, any other medical conditions, take any**

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**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 VECTIBIX?](#) in the full CMI.

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

Some medicines may interfere with VECTIBIX 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 will I be given VECTIBIX?**

You will be given VECTIBIX as an infusion (slow injection or "drip" into a vein) every 2 weeks. The infusion usually takes 1 hour.

More information is in Section [4. How will I be given Vectibix?](#) in the full CMI.

### **5. What should I know during treatment with VECTIBIX?**

#### **Things you should do**

- Limit sun exposure. Wear SPF 15+ sunscreen and a hat if you are going out in the sun.
- Remind any doctor, dentist or pharmacist you visit that you are

	<p>having treatment with VECTIBIX.</p> <ul style="list-style-type: none"> <li>• If you are a woman of child bearing potential, use suitable methods of contraception during treatment with VECTIBIX and for 6 months after your last dose.</li> </ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"> <li>• Do not breastfeed during Vectibix treatment and for 2 months after your last dose.</li> </ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"> <li>• VECTIBIX may cause dizziness in some people. Be careful until you know how VECTIBIX affects you.</li> </ul>

For more information, see Section [5. What should I know during treatment with VECTIBIX?](#) in the full CMI.

## 6. Are there any side effects?

Common side effects include fatigue, weakness, frequent urination, acne type spots, itching, redness, rash, flaking or dry skin, cracks in the skin, nail infections, hair loss, dry lips, excess sweating, swollen runny eyes, diarrhoea, loss of appetite, vomiting or feeling sick, and/or sore mouth.

Serious side effects include Infusion reactions; allergic reactions; hives; skin swelling and/or pain; blistering of the skin, mouth, eyes and/or genitals; peeling of the skin; swelling of the face, lips, mouth or throat which may cause difficulty in swallowing or breathing; chest pain or tightness; wheezing; coughing; shortness of breath; problems breathing; a cough that doesn't go away or keeps coming back; vision changes or eye problems; sensitivity to light; stomach cramps; severe diarrhoea; signs of dehydration; rectal bleeding.

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.

# VECTIBIX<sup>®</sup> (VEK-tih-bix)

**Active ingredient:** *panitumumab* (pan-i-TUE-moo-mab)

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## Consumer Medicine Information (CMI)

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

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

- [1. Why am I receiving VECTIBIX?](#)
- [2. What should I know before I am given VECTIBIX?](#)
- [3. What if I am taking other medicines?](#)
- [4. How will I be given VECTIBIX?](#)
5. What should I know during treatment with VECTIBIX?
- [6. Are there any side effects?](#)
- [7. Product details](#)

## 1. Why am I receiving VECTIBIX?

**VECTIBIX contains the active ingredient panitumumab. It is used to treat adult patients with metastatic colorectal (bowel) cancer.** Metastatic means the cancer has spread to other parts of the body from where it started. Your cancer began in either the colon (large bowel) or rectum (back passage).

Panitumumab works by blocking messages that tell cancer cells to grow and divide. It attaches to a specific protein called epidermal growth factor receptor (EGFR) found on the surface of some cancer cells. This stops cancer cells from receiving signals needed for growth. Panitumumab only works on cancers that have a normal (unmutated) *RAS* gene.

Your doctor may add other anti-cancer medicines to your VECTIBIX treatment.

## **2. What should I know before I am given VECTIBIX?**

Before you take VECTIBIX, your doctor will order tests to see whether VECTIBIX is suitable for you. These will include checking:

- for any mutations in the *RAS* genes. If your tumour is non-*RAS* mutant (“wild-type *RAS*”), you are suitable for this medicine.
- Salt levels in your blood (such as magnesium, calcium and potassium).

Based on your age or general health, your doctor will discuss your ability to tolerate VECTIBIX with your chemotherapy treatment.

## Warnings

### Do not use VECTIBIX if you:

- have an *RAS*-positive mutant tumour. Please ask your doctor if you are unsure of your *RAS* tumour status.
- have an allergy to panitumumab, or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine.
- are receiving oxaliplatin-based chemotherapy.

### Check with your doctor if you:

- have or previously had any of the following:
  - **interstitial pneumonitis** (swelling of the lungs causing coughing and difficulty breathing) or
  - **pulmonary fibrosis** (scarring and thickening in the lungs with shortness of breath).
  - **have a history of eye problems**, such as severe dry eye, inflammation of the front part of the eye (cornea) or ulcers involving the front part of the eye.

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

VECTIBIX has not been tested in pregnant women.

If you are a woman of childbearing potential, you should use suitable methods of contraception during treatment with VECTIBIX and for 6 months after your last VECTIBIX dose.

## **Breastfeeding**

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

Do not breast-feed your baby during treatment with VECTIBIX and for 2 months after your last dose.

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

Tell your healthcare professional if you are receiving a chemotherapy treatment called "IFL". IFL contains irinotecan (I), 5-fluorouracil (F), and leucovorin (L). IFL is used to treat certain cancers. If IFL is used with VECTIBIX, you may experience severe diarrhoea.

Tell your healthcare professional if you are taking:

- bevacizumab, which is a medicine used to treat several cancers.
- any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

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



## **4. How will I be given VECTIBIX?**

### **When you will be given VECTIBIX**

You will be given VECTIBIX every 2 weeks by a healthcare professional.

### **How much VECTIBIX you will be given**

The dose depends on your body weight. Your doctor will determine exactly how much VECTIBIX you will be given.

### **How VECTIBIX is given**

VECTIBIX is given as a slow infusion ("drip") into a vein, through a tube, using an infusion pump. For most patients, the first dose will usually be given over a period of approximately 60 minutes. After that, your doctor may adjust your dose and infusion time, based on how well you tolerate the medicine.

## **5. What should I know during treatment with VECTIBIX**

### **Allergic reactions**

Rare serious allergic (hypersensitivity) reactions involving symptoms similar to infusion reactions have occurred more than 24 hours after VECTIBIX treatment.

Seek medical attention immediately if you experience symptoms of an allergic reaction to VECTIBIX, including but not limited to:

- difficulty breathing
- chest tightness
- a sensation of choking
- dizziness, or
- fainting.

### **Infusion reactions**

During or following treatment, some patients may experience a mild, moderate, or severe infusion reaction.

Notify your doctor immediately if you experience symptoms including:

- headache
- rashes
- itching or hives
- flushing
- swelling (face, lips, mouth, around the eyes, and throat area)
- rapid and irregular heartbeat
- fast pulse
- sweating
- nausea
- vomiting
- dizziness
- difficulty breathing or swallowing.

## Skin reactions

Skin-related reactions are very common and usually mild to moderate. The skin rash commonly resembles acne and often involves the face, upper chest and back, but can affect any area of the body. Some rashes have been associated with redness, itching and flaking of the skin which can become severe.

In some cases, these may cause:

- infected sores requiring medical and/or surgical treatment, or
- severe skin infections that in rare cases could be fatal.

In rare cases, patients may experience:

- blistering of the skin, mouth, eyes and genitals, which may indicate a severe skin reaction called “Stevens-Johnson syndrome”
- blistering of the skin, which may indicate a severe skin reaction called “toxic epidermal necrolysis”.

If you experience **blistering**, you should notify your doctor immediately.

Prolonged exposure to the sun can worsen the rash.

Also, dry skin, fissures (cracks in the skin) on the fingers or toes, fingernail bed or toenail bed infection (paronychia) or inflammation have been reported.

Once treatment is withheld or discontinued, the skin reactions will generally resolve.

## Things you should do

Always follow your doctor's instructions carefully.

Remind any doctor, dentist or pharmacist you visit that you are having VECTIBIX.

**Keep all of your doctor and test appointments so that your progress can be checked.** If you miss one, call your healthcare provider as soon as possible to reschedule.

Some patients taking VECTIBIX had low levels of certain electrolytes, including magnesium, calcium, and/or potassium. So, your doctor may check your electrolytes during your treatment, and for up to 8 weeks after you have finished receiving VECTIBIX. If the levels are low, your doctor may prescribe appropriate supplements.

**Limit sun exposure while receiving VECTIBIX and for 2 months after your treatment ends.** Wear sunscreen and a hat if you are going out in the sun.

Sunlight can worsen any skin reactions that may occur. Your doctor may ask you to use a moisturiser, SPF 15+ sun screen, topical steroid cream, and/or antibiotics to help manage skin side effects that may occur.

You may experience skin reactions or severe swelling and tissue damage while receiving VECTIBIX treatment. If you experience a severe skin reaction, the doctor may adjust your dose of VECTIBIX.

**Tell your doctor or nurse if you:**

- have skin reactions, including skin rash, that worsen or become intolerable. Your doctor may stop your treatment with VECTIBIX if you develop a severe infection or fever as a result of skin reactions.
- experience severe diarrhoea, as you may lose a lot of water from your body (become dehydrated) and this could damage your kidneys.

**Call your doctor straight away if you:**

- develop acute or worsening redness and pain in the eye, increased eye watering, blurred vision and/or sensitivity to light. You may need urgent treatment (see “Possible side effects” below).

**Driving or using machines**

VECTIBIX may cause dizziness in some people. Be careful before you drive, use machines/tools, or take part in activities that need you to be alert until you know how VECTIBIX affects you.

**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</b></p> <ul style="list-style-type: none"><li>• fatigue</li></ul> <p><b>Skin</b></p> <ul style="list-style-type: none"><li>• acne type spots</li><li>• cracks in the skin</li><li>• dry lips</li><li>• dry skin</li><li>• excess sweating</li><li>• flaking skin</li><li>• hair loss</li><li>• infection of nail bed(s)</li><li>• itching</li><li>• redness</li><li>• rash</li></ul> <p><b>Eye</b></p> <ul style="list-style-type: none"><li>• swollen runny eyes</li></ul> <p><b>Gut</b></p> <ul style="list-style-type: none"><li>• diarrhoea</li><li>• loss of appetite</li><li>• sore mouth</li><li>• vomiting or feeling sick (nausea)</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><b>Muscular</b></p> <ul style="list-style-type: none"> <li>• weakness</li> </ul> <p><b>Urinary</b></p> <ul style="list-style-type: none"> <li>• strong and/or frequent urge to urinate</li> </ul>	

## **Serious side effects**

<b>Serious side effects</b>	<b>What to do</b>
<p><b>Infusion reactions</b></p> <ul style="list-style-type: none"> <li>• chills</li> <li>• fever</li> <li>• shortness of breath</li> </ul> <p><b>Allergic reactions</b></p> <ul style="list-style-type: none"> <li>• chest pain or tightness</li> <li>• swelling of the face, lips, mouth or throat which may cause difficulty in swallowing or breathing</li> </ul> <p><b>Skin</b></p> <ul style="list-style-type: none"> <li>• blistering of the skin, mouth, eyes and genitals</li> <li>• hives (an itchy rash on the skin)</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>● peeling of the skin.</li> <li>● skin redness, heat, swelling and/or pain</li> </ul> <p><b>Lungs</b></p> <ul style="list-style-type: none"> <li>● a cough that doesn't go away or keeps coming back</li> <li>● coughing</li> <li>● problems breathing</li> <li>● shortness of breath</li> <li>● wheezing</li> </ul> <p><b>Eyes</b></p> <ul style="list-style-type: none"> <li>● acute or worsening eye redness and pain with or without vision loss</li> <li>● blurred vision and/or</li> <li>● increased eye watering</li> <li>● sensitivity to light</li> </ul> <p><b>Gut</b></p> <ul style="list-style-type: none"> <li>● difficulty swallowing</li> <li>● producing more saliva than usual</li> <li>● rectal bleeding</li> <li>● severe diarrhoea</li> <li>● signs of dehydration (e.g. severe dizziness, feeling very thirsty,</li> </ul>	



Serious side effects	What to do
dry mouth, fatigue, rapid breathing, rapid heartbeat) • stomach cramps	

**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 seeking medical advice, please report any side effects you experience 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 VECTIBIX contains

Active ingredient	panitumumab
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<b>(main ingredient)</b>	
<b>Other ingredients (inactive ingredients)</b>	sodium chloride sodium acetate trihydrate and water for injections

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

## **What VECTIBIX looks like**

VECTIBIX is a colourless solution that may contain visible translucent to white particles.

VECTIBIX is supplied in a glass vial. Each pack contains one vial.

VECTIBIX panitumumab 100mg/5mL concentrated injection vial (Aust R 128270)

VECTIBIX panitumumab 400mg/20mL concentrated injection vial (Aust R 128332).

## **Who distributes VECTIBIX?**

Amgen Australia Pty Ltd

ABN 31 051 057 428

Level 7, 123 Epping Road

NORTH RYDE NSW 2113

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