Vectibix®

Panitumumab (rch) pan i TUE moo mab

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about Vectibix.

It does not contain all the available information.

It does not take the place of talking to your doctor, nurse or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you receiving Vectibix treatment against the benefits they expect it will have for you.

If you have any concerns about using this medicine, ask your doctor, nurse or pharmacist.

Read this leaflet carefully before you start Vectibix treatment.

Keep this leaflet.
You may need to read it again.

What Vectibix is used for

Vectibix is used in the treatment of metastatic carcinoma (cancer which has spread) of the colon (large bowel) or rectum (the back passage). Vectibix is used alone or in combination with chemotherapy (medicines used to treat cancer).

The cancer cells of some patients with colon or rectal cancer have mutations in genes called RAS (KRAS and NRAS). Mutations in the RAS genes can be detected by testing a sample of the tumour. Vectibix is used to treat colon or rectal cancer in patients whose tumours have no mutation in the RAS genes.

How it works

Vectibix contains the active substance panitumumab, which belongs to a group of medicines called monoclonal antibodies. Monoclonal antibodies are proteins that specifically recognise and attach (bind) to other unique proteins in the body.

Panitumumab recognises and binds specifically to a protein known as epidermal growth factor receptor (EGFR), which is found on the surface of certain types of cancer cells. When growth factors (other body proteins) attach to the EGFR, the cancer cell is stimulated to grow and replicate. Panitumumab binds to the EGFR instead of these growth factors and prevents the cancer cell from receiving the messages it needs for growth and replication.

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

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

Before you are given Vectibix

When you must not be given it

Do not have Vectibix if you have an allergy to any medicine containing panitumumab 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.

Do not have Vectibix if you do not know the RAS gene status of your colon or rectal tumour and you are being given oxaliplatin-based chemotherapy (consisting of fluorouracil, leucovorin and oxaliplatin together).

Do not have Vectibix if you have a colon or rectal tumour that has a mutation in the RAS gene and you are being given oxaliplatin-based chemotherapy (consisting of fluorouracil, leucovorin and oxaliplatin together).

If you are not sure if this applies to your treatment, talk to your doctor.

Do not use it after the expiry date (EXP) printed on the pack.
If you use it after the expiry date has passed, it may have no effect, or an unexpected effect.

Do not use it if the packaging is torn or shows signs of tampering.

If you are not sure whether you should be given this medicine, talk to your doctor or pharmacist.

Before you are given it

Tell your doctor if

1. **you have allergies to:**
   - any other medicines, including medicines obtained without a prescription
   - any other substances, such as foods, preservatives or dyes.
2. **you have previously had or have evidence of interstitial pneumonitis (swelling of the lungs causing coughing and**

difficulty breathing) or pulmonary fibrosis (scarring and thickening in the lungs with shortness of breath).

3. **you are pregnant, may be pregnant, or intend to become pregnant.**

- Vectibix has not been tested in pregnant women.
- You should avoid becoming pregnant if you are a woman of reproductive potential.
- You should use suitable methods of contraception during treatment with Vectibix and for 6 months after your last dose if you are a woman of childbearing potential.

4. **you are breast-feeding or planning to breast-feed. Do not breast-feed your baby during treatment with Vectibix and for 2 months after your last dose.**

During treatment you may experience skin reactions.

Tell your doctor immediately if these worsen or become intolerable.

If you have not told your doctor about any of the above, tell them before you are given Vectibix.

Taking other medicines

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

Tell your doctor or pharmacist if you are:

- **receiving treatment with bolus (intravenous) 5-fluorouracil, leucovorin and irinotecan, known as the IFL regimen.** If IFL is used with Vectibix, you may experience severe diarrhoea
- **receiving treatment with chemotherapy together with a medicine containing bevacizumab.**

How it is given

Vectibix is given by a doctor or nurse as an injection into a vein, called an intravenous injection, with an infusion pump (a machine which gives a slow injection).

How much to be given

The usual dose of Vectibix is 6 mg/kg given once every two weeks.

The treatment will usually be given over a period of approximately 60 minutes.

Your doctor or nurse will determine exactly how much to inject.

While you are being given it

Things you must do

Always follow your doctor's instructions carefully.

Tell your doctor, nurse or pharmacist who treats you that you are taking this medicine.

Use suitable methods of contraception during treatment with Vectibix and for 6 months after your last dose.

Tell your doctor if you become pregnant during your Vectibix treatment or within 6 months of your last dose.

While receiving Vectibix

- **wear sunscreen and a hat if you are outdoors**
- **limit sun exposure.**

Sunlight can worsen any skin reactions that may occur. Your doctor may ask you to use moisturiser, sun screen (SPF greater than 15), topical steroid cream, and/or oral antibiotics which may help you manage skin toxicities that can occur when using Vectibix.

Things you must not do

Avoid becoming pregnant if you are a woman of reproductive potential.

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

Side effects

Tell your doctor as soon as possible if you do not feel well after being given Vectibix.

All medicine can have side effects. Sometimes they are serious and need medical attention. Other side effects are minor and are likely to be temporary. You may also experience side effects caused by other medicines you are having at the same time as Vectibix.

Your doctor has weighed the risks of using this medicine against the benefits they expect it will have for you.

Ask your doctor, nurse or pharmacist to answer any questions you may have.

Tell your doctor, nurse or pharmacist if you notice any of the following:

- diarrhoea
- fatigue
- skin reactions such as acne type spots, itching, redness, rash, flaking skin, dry skin, cracks in the skin, and infection of a nail bed
- weakness
- loss of appetite
- vomiting or feeling sick, also called nausea
- swollen runny eyes
- sore mouth
- hair loss
- excess sweating
- strong and frequent urge to urinate
- dry lips

If any of the following happen, stop having Vectibix and tell your doctor immediately or seek medical attention:

- swelling of the face, lips, mouth or throat which may cause

difficulty in swallowing or breathing
- chills
- hives (an itchy rash on the skin)
- fever
- coughing and difficulty breathing
- shortness of breath
- limb swelling or pain
- chest pain or tightness
- eye redness and pain with or without loss of vision
- skin redness, heat, swelling and/or pain
- blistering of the skin, mouth, eyes and genitals and peeling of the skin
- watery eyes, diarrhoea, stomach cramps, sweating more than usual or producing a lot of saliva

These can be very serious side effects.

You may need urgent medical attention or hospitalisation.

Other side effects not listed above may occur in some patients. Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

Do not be alarmed by this list of possible side effects.
You may not experience any of them.

Storing Vectibix

Vectibix is usually stored in the hospital pharmacy. However, if you need to store Vectibix:

Keep it where children cannot reach it.

Keep it in the refrigerator, between 2°C and 8°C, until it is time for it to be given. Do not freeze it.

Keep it in the original pack, protected from light.

Do not shake or vigorously agitate the vial.

Product description

What it 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.

Each vial contains

- 100 mg of panitumumab in 5 mL of solution OR
- 400 mg of panitumumab in 20 mL of solution.

Ingredients

The active ingredient in Vectibix is panitumumab. Each vial contains 20 mg/mL of panitumumab.

Other ingredients in Vectibix are sodium chloride, sodium acetate trihydrate and water for injections.

Vectibix does not contain lactose, gluten, tartrazine or any other azo dyes.

Supplier

Vectibix is supplied in Australia by:

Amgen Australia Pty Ltd
ABN 31 051 057 428
Level 7, 123 Epping Road
NORTH RYDE NSW 2113

Australian Registration Number:
100 mg/5 mL: AUST R 128270
400 mg/20 mL: AUST R 128332

This leaflet was prepared in September 2016.