A guide for patients prescribed Vectibix® (panitumumab)

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at **https://yellowcard.mhra.gov.uk** or search for MHRA Yellow Card in the Google Play or Apple Store.

By reporting side effects you can help provide more information on the safety of this medicine. Side effects should also be reported to Amgen Limited on +44 (0)1223 436441.

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AMGEN

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To access our patient website go to
https://www.amgencare.co.uk/vectibix
or scan the following QR code:

Contents

Contact list

Doctor's name:

Clinical Nurse Specialist's name:

Hospital telephone number:

Out of hours telephone number:

Patient support organisations

Bowel Cancer UK
Beating bowel cancer together

Bowel Cancer UK
Tel: 020 7940 1760

MacMillan Cancer Support
Helpline: 0808 808 00 00

The purpose of this booklet

This booklet has been given to you because you have been prescribed Vectibix® (panitumumab) for the treatment of metastatic colorectal cancer (bowel cancer).

Please also read the patient information leaflet (PIL) for this medicine. If you do not have a copy, your doctor or nurse should be able to provide one or you can access it at https://www.medicines.org.uk/emc/product/6178/pil.

If you have any questions, or feel unsure about any aspect of your treatment, please speak to your doctor, nurse or pharmacist.

This booklet aims to provide some answers to the following questions:

- What is metastatic colorectal cancer and how is it treated?
- What is panitumumab and how does it work?
- How is this treatment given?
- What are the main side effects of treatment?
- Is there anything else to consider when receiving treatment?

What is metastatic colorectal cancer (mCRC)?

Colorectal cancer, also known as 'bowel cancer' is a cancer of the large intestine. It is called 'metastatic' when cancer cells spread to other parts of the body and form a new tumour or 'metastasis'.

Although the cancer may now be in a different organ, it is still named after the place where it originated. So, if the cancer spreads to the lungs, it will still be referred to as metastatic colorectal cancer. Colon or rectal cancer most commonly spreads to the liver. It can also spread to the lungs and bones, as well as other body organs.

How is mCRC treated?

Your medical team will assess your case carefully. They will develop a treatment plan, which may include chemotherapy, and/or immunotherapy, and/or targeted therapy, and/or surgery. This treatment plan will depend on:

- Where the tumours are in your body.
- How accessible the tumours are to surgery.
- Your general health and well-being.
- Other aspects of the cancer.

The type of treatment that is recommended by your doctor will aim to meet your specific needs. Usually, treatment will consist of chemotherapy that may be used in combination with targeted therapy. It is possible that your treatment may not be continuous:

- Chemotherapy may be started then stopped and restarted later, sometimes in combination with other drugs.

What is Vectibix® (panitumumab) and how does it work?[1]

This medicine is used for the treatment of metastatic colorectal cancer (bowel cancer) for adult patients with a type of tumour known as 'wild type *RAS* tumour'. A test is done to confirm that you have this type of tumour.

This medicine contains the active substance panitumumab, a type of medicine known as a monoclonal antibody. Monoclonal antibodies are often referred to as targeted therapies, because they target specific protein receptors on the surface of cells that are involved in the spreading and growth of the cancer cells.

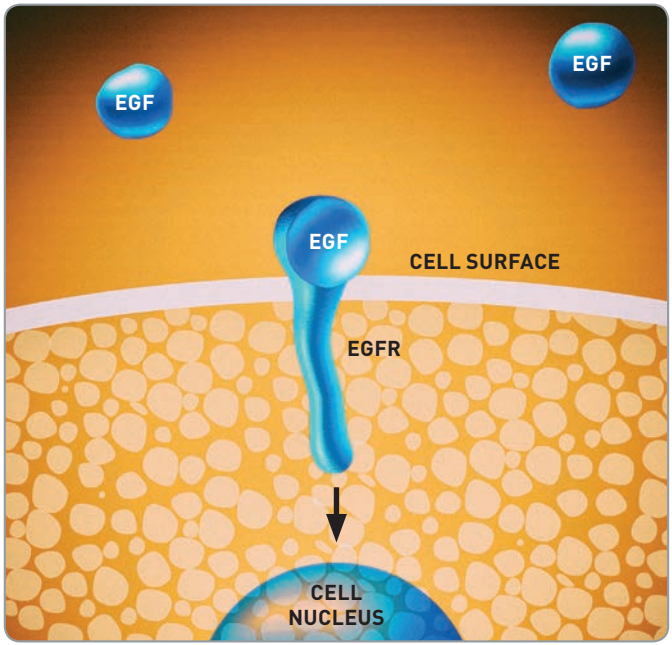
Panitumumab works by attaching itself to the epidermal growth factor receptors (EGFR) found on the surface of some cancer cells. By doing this, it blocks epidermal growth factor (EGF) from attaching to the cancer cell. If EGF can't attach, the cancer cell can't receive the messages it needs to grow and divide.

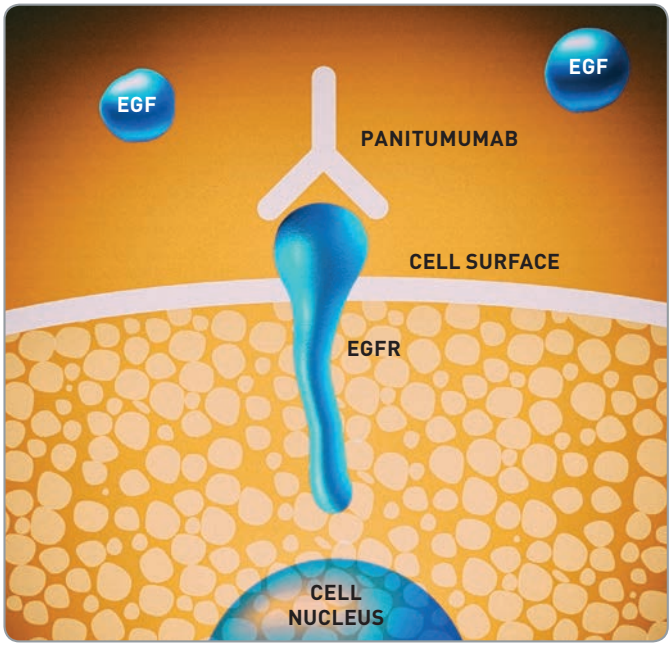
Without pantiumumab[3]

Epidermal growth (EGF) molecules bind to the epidermal growth factor receptor (EGFR) on the surface of the cancer cell and signal the cell to grow and divide.

With pantiumumab[3]

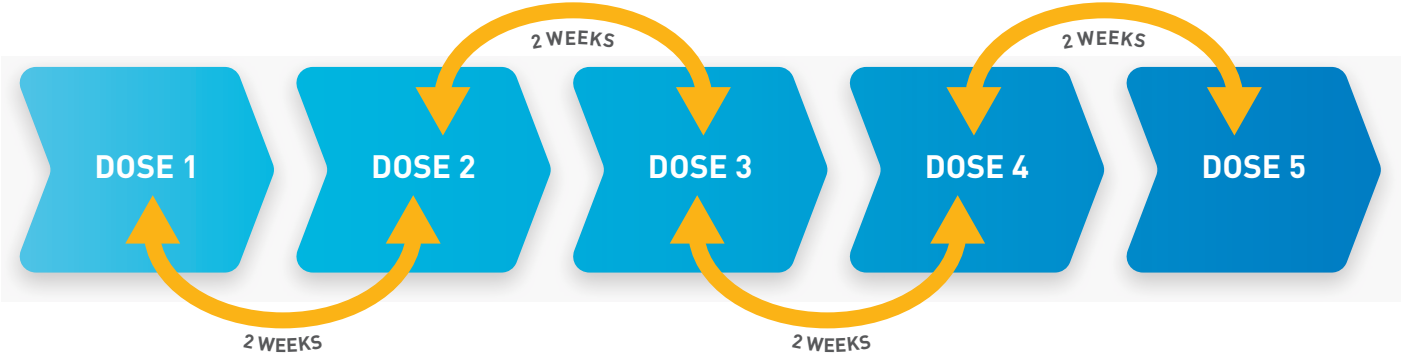
Panitumumab blocks the binding of EGF to the EGFR.





How is this treatment given?[1,2]

- Panitumumab is a colourless liquid given by infusion into your arm (a drip). You will need to come into hospital to have this medicine. Infusions are given once every two weeks.
- Treatment is given using an infusion pump - a device which gives a slow injection. The first infusion may take between 60 and 90 minutes. If your doctor advises, future infusions may be given more quickly, taking between 30 and 60 minutes.
- This medicine may be used alone or in combination with other anticancer medicines.
- You will have a blood test before starting treatment and regularly during treatment with this medicine.



What are the possible side effects?[1]

Like all medicines, panitumumab can cause side effects although not everybody gets them. If you experience any side effects, talk to your doctor or nurse who may be able to recommend ways to prevent or limit the side effect.

Some side effects of the medicine include:

Infusion reactions
During or following treatment you may experience an infusion reaction. These can be mild or moderate (likely to occur in approximately 5 out of 100 people who take panitumumab), or severe (likely to occur in less than 1 out of 100 people who take panitumumab).

Symptoms may include:

- 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
- Decrease in blood pressure that may be severe or life-threatening and, very rarely, may lead to death

If you experience any of these symptoms, you should notify your doctor immediately. Your doctor may decide to reduce the rate of your infusion or discontinue your treatment.

Allergic reactions
Very rarely, serious allergic (hypersensitivity) reactions involving symptoms similar to an infusion reaction (see "Infusion reactions") have occurred more than 24 hours after treatment and resulted in a fatal outcome. Seek medical attention immediately if you experience symptoms of an allergic reaction to panitumumab, including but not limited to difficulty breathing, chest tightness, a sensation of choking, dizziness, or fainting.

Skin reactions
Skin-related reactions are likely to occur in approximately 94 out of 100 people who take panitumumab and are usually mild to moderate **(for more information please refer to page 14 of this booklet)**.

What are the possible side effects?[1]

Other side effects of this medicine are:

Very Common: May affect more than 1 in 10 people

- Low red blood cell numbers (anaemia).
- Low potassium levels in the blood (hypokalaemia).
- Low magnesium levels in the blood (hypomagnesaemia).
- Eye inflammation (conjunctivitis).
- Local or widespread rash which may be bumpy (with or without spots), itchy, red or flaky.
- Hair loss (alopecia).
- Mouth ulcers and cold sores (stomatitis).
- Inflammation of the mouth (mucosal inflammation).
- Diarrhoea.
- Nausea.
- Vomiting.
- Abdominal pain.
- Constipation.
- Decreased appetite.
- Decreased weight.
- Extreme tiredness (fatigue).
- Fever or high temperature (pyrexia).
- Lack or loss of strength (asthenia).
- Accumulation of fluid in the extremities (oedema peripheral).
- Back pain.
- Inability to sleep (insomnia).
- Cough; dyspnoea (breathing difficulties).

Common: May affect up to 1 in 10 people

- Low white blood numbers (leukopenia).
- Low calcium levels in the blood (hypocalcaemia).
- Low phosphates in the blood (hypophosphataemia).
- High glucose in the blood (hyperglycaemia).
- Growth of eyelashes.
- Flow of tears (lacrimation increased).
- Redness of the eye (ocular hyperaemia).
- Dry eye.
- Itchy eyes (eye pruritus).
- Eye irritation.
- Eyelid inflammation (blepharitis).
- Skin ulcer.
- Scab.
- Excess hair growth (hypertrichosis).
- Redness and swelling of palms of hands or soles of feet (hand-foot syndrome).
- Excess sweating (hyperhidrosis).
- Skin reaction (dermatitis).
- Spreading infection below the skin (cellulitis).

What are the possible side effects?[1]

Common: May affect up to 1 in 10 people

- Hair follicle inflammation (folliculitis).
- Localised infection.
- Skin rash with pus-filled blisters (rash pustular).
- Urinary tract infection.
- Nail disorder.
- Breaking of the nails (onychoclasis).
- Dehydration.
- Dry mouth.
- Indigestion (dyspepsia).
- Rectal bleeding (rectal haemorrhage).
- Lip inflammation (cheilitis).
- Heartburn (gastroesophageal reflux).
- Chest pain.
- Pain.
- Chills.
- Pain in the extremity.
- Immune reaction (hypersensitivity).
- Rapid heart rate (tachycardia).
- Blood clot in the lung (pulmonary embolism) the symptoms of which may be sudden onset of shortness of breath or chest pain.
- Nose bleed (epistaxis).
- Blood clot in a deep vein (deep vein thrombosis).
- High blood pressure (hypertension).
- Flushing.
- Headache.
- Dizziness.
- Anxiety.

This is not a complete list of side effects. Please refer to the Patient Information Leaflet for more information.

What skin reactions should I look out for?[1]

Approximately 94 out of 100 people experience skin reactions while receiving treatment with panitumumab. If you experience skin reactions or severe swelling tell your nurse or doctor as soon as possible so that they can take the necessary action.

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.

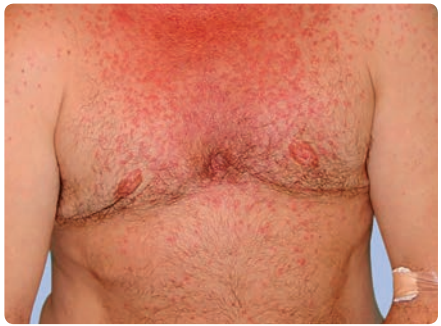
In some cases, it may cause infected sores requiring medical and/or surgical treatment, or cause severe skin infections that in rare cases could be fatal.

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" or 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 make the rash worse.

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

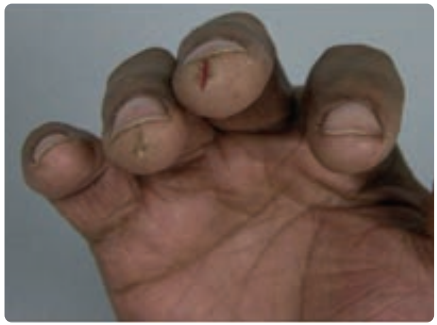
Once treatment is withheld or discontinued, the skin reactions will generally resolve. Your doctor may decide to treat the rash, adjust the dose or discontinue your treatment.

What skin reactions should I look out for?[4]



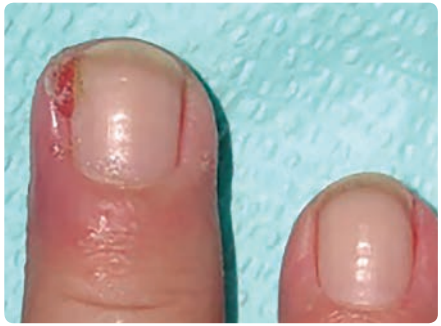
Rash

- Rash normally appears on the face, neck and torso.
- It usually develops within 2 weeks of starting treatment.
- The rash usually clears up after treatment has finished.



Fissures

- Fissures are characterised by paper-cut like cuts on the fingers and toes.
- Fissures usually develop 6-7 weeks after starting treatment.



Nail Changes (Paronychia)

- Nail changes are characterised by redness and inflammation of the sides of the nails which may become sore and tender and may result in infection.
- The thumb and big toe are the two areas most likely to be affected.
- It usually develops 4-8 weeks after starting treatment.

Upon starting treatment how should I look after my skin and nails?

Avoid the Sun

- Avoid the sun; use a sunscreen with a high sun protection factor (SPF) even on cloudy days. Ideally the SPF should be at least 15.
- Put sunscreen on 20 minutes before going outside and reapply every 2 hours, or more frequently if sweating or swimming.
- Use a broad-brimmed hat if going outside.

Follow the Advice Given by your Doctor or Nurse

- Contact your doctor or nurse right away if you experience rash or any other side effects as these can be managed if they are recognised and treated early.

For your Skin and Hair

- Use moisturising creams (water-based) on limbs including hands and feet and apply daily.
- Use mild skin care products.
- Use tepid water when showering or bathing.
- When rubbing cream in, do so in the direction of the hair.
- Use a gentle or anti-dandruff shampoo and leave for three minutes and wash off.
- Use an electric razor as this is less traumatic on the skin. If wet shaving is preferred use a gentle wash instead of shaving foam.
- If you experience trichomegaly (long, curly, rigid eyelashes) please get them trimmed by your doctor or nurse or a competent individual.

For your Finger and Toe Nails

- Avoid pushing back cuticles or biting your nails.
- Do not use artificial nails.
- Use a nail file instead of cutting nails and cotton-lined gloves when washing dishes or cleaning.
- Do not wear tight shoes.
- Please consult your doctor or nurse before going to a chiropodist.
- If there are any changes to your nails please consult your doctor or nurse.

Is there anything else to consider when receiving treatment?[1]

Eyes
Tell your doctor or nurse if you use contact lenses and/or 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. If you develop acute or worsening redness and pain in the eye, increased eye watering, blurred vision and/or sensitivity to light, please tell your doctor or nurse immediately as you may need urgent treatment.

Other medicines
It is important to tell your doctor or nurse about any other medication you are taking. This includes vitamins, herbal supplements and over the counter medicines. Some drugs do not work well together, so it is important that you discuss this with your doctor or nurse before starting treatment.

While receiving treatment it is advisable not to take any additional medicines without first checking with your healthcare team.

Vaccinations
Speak with your doctor or nurse prior to any vaccinations to check if this will affect your treatment.

Pregnancy and breast-feeding
This medicine has not been tested in pregnant women. It is important to tell your doctor or nurse if you are pregnant; think you may be pregnant; or plan to get pregnant. This medicine could affect your unborn baby or ability to stay pregnant.

If you are a woman of child bearing potential, you should use effective methods of contraception during treatment and for 2 months after the last dose.

It is not recommended to breast-feed your baby during treatment and for 2 months after the last dose. It is important to tell your doctor if you plan to breast-feed.

Diarrhoea
If you experience severe diarrhoea please tell your doctor or nurse since you may lose a lot of water from your body (become dehydrated) and this could damage your kidneys.

Driving and using machines
You should speak with your doctor before driving or using machines, as some side effects may impair your ability to do so safely.

For more information please contact Amgen® on 01223 436441.

Appointment dates

Clinic contact No: .....

Date: ..... **Time:** .....

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Date: ..... **Time:** .....

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Notes

References
1. Patient Information Leaflet for Vectibix®. Available at https://www.medicines.org.uk/emc/product/6178/pil
2. Vectibix®. Summary of Product Characteristics
3. Berg M, Soreide K. Discov Med 2012;14:207–14; Freeman D, et al. J Clin Oncol 2008;26(Suppl15):abstract 14536 (and poster).
4. Lacouture et al. Dermatologic toxicity occurring during anti-EGFR monoclonal inhibitor therapy in patients with metastatic colorectal cancer: a systematic review. Clin Col Cancer 2018; 17 (2): 85-96

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