Package Leaflet: Information for the user

Vectibix 20 mg/mL concentrate for solution for infusion
panitumumab

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor.
- If you get any side effects talk to your doctor. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Vectibix is and what it is used for

Vectibix is used in the treatment of metastatic colorectal cancer (cancer of the bowel) for adult patients with a certain type of tumour known as a "Wild-type *RAS* tumour". Vectibix is used alone or in combination with other anti-cancer medicines.

Vectibix contains the active substance panitumumab, which belongs to a group of medicines called monoclonal antibodies. Monoclonal antibodies are proteins, which 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 some cancer cells. When growth factors (other body proteins) attach to the EGFR, the cancer cell is stimulated to grow and divide. Panitumumab binds onto the EGFR and prevents the cancer cell from receiving the messages it needs for growth and division.

2. What you need to know before you use Vectibix

Do not use Vectibix:

- if you are allergic to panitumumab or any of the other ingredients of this medicine (listed in section 6).
- if 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).
- in combination with oxaliplatin-based chemotherapy, if your *RAS* test shows that you have mutant *RAS* tumour, or if your *RAS* tumour status is unknown. Please consult your doctor if you are unsure of your *RAS* tumour status.

Warnings and precautions

You may experience skin reactions or severe swelling and tissue damage, if these worsen or become intolerable please tell your doctor or nurse immediately. If you experience a severe skin reaction, your doctor may recommend an adjustment of the dose of Vectibix. If you develop a severe infection or fever as a result of skin reactions, your doctor may stop your treatment with Vectibix.

It is recommended that you limit sun exposure whilst receiving Vectibix and if you are experiencing skin reactions as sunlight can worsen these. Wear sunscreen and a hat if you are going to be exposed to sunlight. Your doctor may ask you to use a moisturiser, sun screen (SPF > 15), topical steroid, and/or oral antibiotics which may help in the management of skin toxicities that can be associated with the use of Vectibix.

Your doctor will check your blood levels of several substances such as magnesium, calcium and potassium in your blood before you start Vectibix treatment. Your doctor will also check your blood levels of magnesium and calcium periodically during your treatment, and for up to 8 weeks after you have finished your treatment. If these levels are too low, your doctor may prescribe you appropriate supplements.

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.

Tell your doctor 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 (see "Possible side effects" below).

Based on your age (older than 65 years) or general health, your doctor will discuss with you your ability to tolerate taking Vectibix with your chemotherapy treatment.

Other medicines and Vectibix

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription and herbal medicines.

Vectibix should not be used in combination with bevacizumab (another monoclonal antibody used in cancer of the bowel) or with a chemotherapy combination known as "IFL".

Pregnancy and breast-feeding

Vectibix has not been tested in pregnant women. It is important to tell your doctor if you are pregnant; think you may be pregnant; or plan to get pregnant. Vectibix 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 with Vectibix and for 2 months after the last dose.

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

Ask your doctor or pharmacist for advice before taking any medicine.

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.

Vectibix contains sodium

This medicine contains 3.45 mg sodium (main component of cooking/table salt) in each mL unit. This is equivalent to 0.017% of the recommended maximum daily dietary intake of sodium for an adult.

3. How to use Vectibix

Vectibix will be administered in a healthcare facility under the supervision of a doctor experienced in the use of anti-cancer medicines.

Vectibix is administered intravenously (into a vein) with an infusion pump (a device that gives a slow injection).

The recommended dose of Vectibix is 6 mg/kg (milligrams per kilogram of body weight) given once every two weeks. The treatment will usually be given over a period of approximately 60 minutes.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

The most serious side effects and main side effects for Vectibix are listed below:

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 Vectibix), or severe (likely to occur in 1 out of 100 people who take Vectibix). 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, or a 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 with Vectibix.

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 Vectibix, 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 Vectibix and are 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, 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 with Vectibix.

Other side effects include:

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 (leucopenia); 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); 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.

Uncommon: may affect up to 1 in 100 people
- blue colouration of the skin and mucous membranes (cyanosis);
- ulcerative keratitis (a serious condition of ulceration of the front part of the eye (cornea) requiring urgent treatment);
- keratitis (inflammation of the front part of the eye (cornea));
- skin cell death (skin necrosis);
- severe skin reaction with blistering of the skin, mouth, eyes and genitals (Stevens-Johnson syndrome);
- severe skin reaction with blistering of the skin (toxic epidermal necrolysis);
- eyelid irritation; chapped lips and/or dry lips; eye infection; eyelid infection; nasal dryness; loosening of the nails (onycholysis); ingrowing nail; excessive hair growth (hirsutism);
- inflammation of the lungs (interstitial lung disease).

Reporting of side effects

If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Vectibix

Vectibix will be stored in the healthcare facility where it is used.

Keep this medicine out of the sight and reach of children.

Store in a refrigerator (2°C – 8°C).
Do not freeze.
Store in the original carton in order to protect from light.

Do not use this medicine after the expiry date which is stated on the label and carton after EXP. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Vectibix contains

- Each mL of concentrate contains 20 mg panitumumab. Each vial contains either 100 mg of panitumumab in 5 mL, or 400 mg of panitumumab in 20 mL.
- The other ingredients are: sodium chloride, sodium acetate trihydrate, acetic acid (glacial) and water for injections. See section 2 "Vectibix contains sodium".

What Vectibix looks like and contents of the pack

Vectibix is a colourless liquid that may contain visible particles and is supplied in a glass vial. Each pack contains one vial.

Not all presentations may be marketed.

Site of Manufacture of the Drug Product:
Amgen Manufacturing Limited
State Road 31
Kilometer 24.6
Juncos 00777 - 4060
Puerto Rico
USA

Marketing Authorisation Holder and Manufacturer
Amgen Europe B.V.
Minervum 7061
4817 ZK Breda
The Netherlands

For any information about this medicinal product, please contact the local representative of the Marketing Authorisation Holder.

This leaflet was last revised in September 2019.

Detailed information on this medicine is available on the European Medicines Agency web site: http://www.ema.europa.eu/

The following information is intended for healthcare professionals only:

Vectibix is intended for single use only. Vectibix should be diluted in sodium chloride 9 mg/mL (0.9%) solution for injection by healthcare professional using aseptic technique. Do not shake or vigorously agitate the vial. Vectibix should be inspected visually prior to administration. The solution should be colourless and may contain visible translucent-to-white, amorphous, proteinaceous particulates (which will be removed by in-line filtration). Do not administer Vectibix if its appearance is not as described above. Using only a 21-gauge or smaller diameter hypodermic needle, withdraw the necessary amount of Vectibix for a dose of 6 mg/kg. Do not use needle-free devices (e.g. vial adapters) to withdraw vial contents. Dilute in a total volume of 100 mL. Doses higher than 1,000 mg should be diluted in 150 mL sodium chloride 9 mg/mL (0.9%) solution for injection. The final concentration should not exceed 10 mg/mL. The diluted solution should be mixed by gentle inversion, do not shake.

Discard the vial and any liquid remaining in the vial after the single-use.

The infusion line should be flushed with sodium chloride solution before and after Vectibix administration to avoid mixing with other medicinal products or intravenous solutions.

Vectibix must be administered as an intravenous infusion via an infusion pump, using a low protein binding 0.2 or 0.22 micrometre in-line filter, through a peripheral line or indwelling catheter. The recommended infusion time is approximately 60 minutes. Doses higher than 1,000 mg should be infused over approximately 90 minutes.

No incompatibilities have been observed between Vectibix and sodium chloride 9 mg/mL (0.9%) solution for injection in polyvinyl chloride bags or polyolefin bags.

THIS MEDICINE

Is a product, which affects your health, and its consumption contrary to instructions is dangerous for you.
Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicine.
- The doctor and the pharmacist are the experts in medicines, their benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed.
- Do not repeat the same prescription without consulting your doctor.
- Keep all medicines out of reach of children.

Council of Arab Health Ministers,
Union of Arab Pharmacists.