Patient Information Leaflet

SCHEDULING STATUS S4

VECTIBIX® 20 mg/ml concentrate for solution for infusion

Panitumumab

Read all of this leaflet carefully before you are given VECTIBIX®.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.

What is in this leaflet

1. **What VECTIBIX® is and what it is used for**
2. **What you need to know before you use VECTIBIX®**
3. **How to use VECTIBIX®**
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1. What VECTIBIX® is and what it is used for

VECTIBIX® contains the active substance panitumumab, which belongs to a group of medicines called monoclonal antibodies. 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® is for use in adults 18 years and over.

2. What you need to know before you use VECTIBIX®

VECTIBIX® should not be administered to you:

- if you are hypersensitive (allergic) to panitumumab or any of the other ingredients of VECTIBIX®.
- 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.

- if you are pregnant or breastfeeding.

Warnings and precautions

Special care should be taken with VECTIBIX®:

- 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®.
- You should 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, sunscreen (SPF > 50), 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 appropriate supplements for you.
- Your doctor will monitor you if you have previously had or have evidence of swelling of the lungs causing coughing and difficulty breathing (interstitial pneumonitis) or scarring and thickening in the lungs with shortness of breath (pulmonary fibrosis).
- Based on your age (older than 65 years) or general health, your doctor will discuss with you your ability to tolerate VECTIBIX®.
- 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).

Using other medicines with VECTIBIX®:

Always tell your health care professional if you are taking any other medicine. (This includes complementary or traditional 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 Irinotecan plus fluorouracil/leucovorin (IFL).

Pregnancy and Breastfeeding:

VECTIBIX® should not be used during pregnancy. 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 suitable methods of contraception during treatment with VECTIBIX® and for 2 months after the last dose.

Do not breastfeed 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 breastfeed.

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional 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 0,17 % of the recommended maximum daily dietary intake of sodium for an adult.

3. How to use VECTIBIX®

Do not share medicines prescribed for you with any other person.

You will not be expected to give yourself VECTIBIX®, it 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® will be given once every two weeks. The treatment will usually be given over a period of approximately 60 minutes and if well tolerated subsequent treatment may be given over 30 to 60 minutes.

4. Possible side effects

VECTIBIX® can have side effects.

Not all side effects reported for VECTIBIX® are included in this leaflet. Should your general health worsen or if you experience any untoward effects while receiving VECTIBIX®, please consult your doctor, pharmacist or other healthcare professional for advice.

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®.

Frequent side effects:

- 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);
- 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 (increased lacrimation); 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.

These are all serious side effects. If you have them, you may have had a serious allergic reaction to VECTIBIX®. You may need urgent medical attention or hospitalisation.

Less frequent side effects:

- blue colouration of the skin and mucous membranes (cyanosis);
- inflammation of the front part of the eye (cornea);
- 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).

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Not known: frequency cannot be estimated from the available data

- a serious condition of ulceration of the front part of the eye (cornea) requiring urgent treatment (ulcerative keratitis);
- a serious condition of full-thickness ulceration through the front part of the eye (through the cornea) requiring urgent treatment (corneal perforation);
- 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).

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the “6.04 Adverse Drug Reaction Reporting Form”, found online under SAHPRA’s publications: https://www.sahpra.org.za/publications/Index/8

By reporting side effects, you help provide more information on the safety of VECTIBIX®.

Alternatively, suspected adverse events can be reported to:

Amgen South Africa (Pty) Ltd.

Tel: +27 (0)11 100 530

Email: safety-south-africa@amgen.com

5. How to store VECTIBIX®

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

Store all medicines out of reach of children.

Store at or between 2 °C – 8 °C (in a refrigerator).

Do not freeze.

Store in the original carton in order to protect from light.

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

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What VECTIBIX® contains

- The active substance is panitumumab 20 mg/ml.
- The other ingredients in VECTIBIX® are acetic acid (glacial), sodium acetate trihydrate, sodium chloride and water for injection. See section 2 “VECTIBIX® contains sodium”.

What VECTIBIC 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 of either 5 ml, 10 ml or 20 ml.

Not all pack sizes may be marketed.

Holder of certificate of registration

Amgen South Africa (Pty) Ltd.

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