PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PrVectibix®

panitumumab for injection

Pronounced Vek-ti-bicks

Read this carefully before you start taking **VECTIBIX**. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **VECTIBIX**.

Serious Warnings and Precautions

- **Dermatologic and Soft Tissue Toxicity:** Dermatologic toxicities (skin reactions) related to VECTIBIX (panitumumab) blockade of EGFR occurred in 92% (N = 842) of patients and were severe in 13% of patients receiving VECTIBIX monotherapy (use of single medication). In patients receiving VECTIBIX in combination with FOLFOX, dermatologic toxicities occurred in 97% (N = 256) of patients and were severe in 41% of patients. The signs and symptoms include: skin rash resembling acne, severe itching, redness, rash, flaking skin, minor nail infection, dry skin, and cracks in the skin. If you have severe skin or soft tissue reactions your doctor will monitor you for inflammation or infection and may decide to stop or discontinue treatment with VECTIBIX. Life-threatening and fatal infectious complications including events of necrotizing fasciitis, pus formation, and/or sepsis have been observed in patients treated with VECTIBIX. In the postmarketing setting, rare cases of severe skin reactions called “Stevens-Johnson syndrome” (SJS), skin necrosis, and “toxic epidermal necrolysis” (TEN) have been reported in patients treated with VECTIBIX. Symptoms can include blistering or peeling of the skin. **If you experience these symptoms, please contact your doctor immediately**.

  It is recommended that patients wear sunscreen and a hat and limit sun exposure while receiving VECTIBIX as sunlight can worsen any skin toxicity.

- **Infusion Reactions:** Severe infusion reactions, including anaphylactic reactions (severe allergic reactions that occur rapidly), bronchospasm (difficulty in breathing caused by tightening of airways), dyspnea (shortness of breath), fever (high temperature), chills, and low blood pressure, have been reported in 0.6% of patients receiving VECTIBIX monotherapy (use of single medication) and in 2.7% of patients receiving VECTIBIX in combination with FOLFOX, with very rarely a fatal outcome. Fatal reactions have also been observed in patients with a history of hypersensitivity to VECTIBIX. Your doctor may stop the infusion if a severe or life-threatening infusion reaction occurs. Depending on the severity and/or persistence of the reaction, your doctor may consider permanently discontinuing VECTIBIX.

What is VECTIBIX used for?

VECTIBIX is used to treat epidermal growth factor receptor (EGFR)-expressing metastatic colorectal cancer (mCRC)

- in combination with FOLFOX chemotherapy (medicines used to treat cancer) in patients with non-mutated (wild-type) *RAS*
- after failure of fluoropyrimidine-, oxaliplatin-, and irinotecan-containing chemotherapy regimens (medicines used to treat cancer) in patients with non-mutated (wild-type) *RAS*

Metastatic colorectal cancer is cancer of the colon or rectum that has spread to other organs in the body.

How does VECTIBIX work?

VECTIBIX is a monoclonal antibody (protein) that recognizes the cancer cells in the body by attaching to a protein known as EGFR. When VECTIBIX attaches to the EGFR-expressing cancer cells, it may prevent the cancer cells from growing and dividing.

What are the ingredients in VECTIBIX?

Medicinal ingredients: panitumumab

Non-medicinal ingredients: sodium acetate, sodium chloride, and water for injection.

VECTIBIX comes in the following dosage forms:

VECTIBIX is supplied as a sterile, colourless and preservative-free solution (20 mg/mL) containing 100 or 400 mg of panitumumab in 5 and 20 mL single-use vials, respectively. VECTIBIX is provided in a dispensing pack containing one vial.

Do not use VECTIBIX if:

- you are allergic (hypersensitive) to this drug or to any of the ingredients in the formulation (see **What are the ingredients in VECTIBIX?**).
- your *RAS* test shows that you have mutant *RAS* tumour or if your *RAS* tumour status is unknown. Consult your doctor if you are unsure of your *RAS* tumour status.
- 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).

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take VECTIBIX. Talk about any health conditions or problems you may have, including if you:

- have previously had or had 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).
- are receiving the IFL regimen (5-fluorouracil, leucovorin and irinotecan) since when used with VECTIBIX, severe diarrhea has been observed.
- are taking or have recently taken any other medicines, including medicines obtained without a prescription.

- are pregnant, think you may be pregnant, or are planning to get pregnant as VECTIBIX has not been tested in pregnant women.

During treatment, you may experience dermatologic and/or eye toxicities (skin and/or eye reactions). Serious cases of keratitis/ulcerative keratitis [inflammation and/or ulcers involving the clear and protective outer layer of the eye (cornea)] and corneal perforation [a serious condition of full-thickness ulceration through the front part of the eye (through the cornea) requiring urgent treatment] have been reported. Contact lens use is also a risk factor for keratitis and ulceration.

These reactions should be monitored by your doctor to avoid and/or treat any potential infections that may develop from these reactions. If your symptoms worsen or become intolerable, please tell your doctor or nurse immediately.

Lung complications, such as interstitial pneumonitis or pulmonary fibrosis, which are treatable but in some cases have resulted in permanent lung damage or death have been observed rarely in patients receiving VECTIBIX.

Symptoms of hypersensitivity reactions have been observed, including difficulty breathing, sweating, swelling of the face, lips, mouth, tongue or throat (angioedema), and hives. If you think you are having a hypersensitivity reaction, stop taking VECTIBIX and notify your doctor or emergency medical personnel immediately.

If you experience loose or watery stools which are present for a day or more, or you have diarrhea with fever, decreased urination or dizziness contact your doctor immediately.

VECTIBIX contains 0.150 mmol sodium (which is 3.45 mg sodium) per ml of concentrate. This should be taken into consideration if you are on a controlled sodium diet.

If you experience treatment-related symptoms affecting vision and/or ability to concentrate and react, it is recommended that you do not drive or use machines until the effect subsides.

It is not known whether VECTIBIX is present in human milk. Do not use VECTIBIX if you are breast-feeding.

VECTIBIX can change the normal levels of salts (electrolytes) in your blood such as magnesium, potassium, and calcium. Your doctor will test your blood as appropriate before and regularly during and after treatment with VECTIBIX.

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

Other warnings you should know about:

VECTIBIX should not be administered to patients with mutant *RAS* (*KRAS* and *NRAS*) mCRC or for whom *RAS* (*KRAS* and *NRAS*) status is unknown.

VECTIBIX is not indicated for use in combination with bevacizumab with or without chemotherapy. The addition of VECTIBIX to the combination of bevacizumab and chemotherapy resulted in decreased overall survival and increased incidence of severe adverse reactions.

Administration of VECTIBIX in combination with irinotecan, bolus 5-fluorouracil, and leucovorin, known as the IFL regimen, resulted in an increase in severe diarrhea. VECTIBIX is not indicated for use in combination with IFL.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with VECTIBIX:

Drug interactions between VECTIBIX and other drugs have not been studied.

How to take VECTIBIX:

VECTIBIX will be given to you by a healthcare professional in a healthcare setting.

Where may I receive the infusion:

Your doctor will decide where you will receive the infusion. Amgen Entrust™ Patient Support Programs can facilitate the administration of VECTIBIX through Infusion clinics that are staffed by qualified healthcare professionals specially trained in the administration of VECTIBIX infusions. Information about Entrust™ Patient Support Program can be obtained by calling VICTORY® by Amgen Entrust™ at 1-888-706-4717.

Usual dose:

The recommended dose of VECTIBIX is 6 mg/kg given once every two weeks (milligrams per kilogram of body weight).

A doctor experienced in the use of anti-cancer medicines will supervise your VECTIBIX treatment. VECTIBIX is administered intravenously (into a vein) with an infusion pump (a machine that gives a slow injection). The first treatment will be given very slowly over a period of approximately 60 minutes.

Overdose:

If an overdosage occurs, you should be monitored by your doctor and appropriate supportive treatment given.

If you think you, or a person you are caring for, have taken too much VECTIBIX, contact a healthcare professional, hospital emergency department, or regional poison control centre immediately, even if there are no symptoms.

Missed Dose:

It is very important that you receive VECTIBIX within 3 days before or 3 days after each scheduled dose (except if the dose is adjusted because of skin reactions). If you miss a dose, your doctor will administer VECTIBIX as soon as possible and your next dose will be rescheduled relative to the day you received that last dose (every 2 weeks for a dose of 6 mg/kg of VECTIBIX).

What are possible side effects from using VECTIBIX?

Like all medicines, VECTIBIX can cause unwanted side effects. The most commonly reported side effects are skin reactions. Some patients experience infusion-type reactions. Symptoms of infusion-type reactions may include but are not limited to new onset facial swelling, chills, fever, dyspnea (breathing difficulties), rash (possibly including hives), low blood pressure, increased heart rate and sweating.

These are not all the possible side effects you may have when taking VECTIBIX. If you experience any side effects, including those not listed here, tell your healthcare professional.

Serious side effects and what to do about them			
Symptom / effect*	**Talk to your healthcare professional**		**Stop taking drug and get immediate medical help**
	Only if severe	**In all cases**	
VERY COMMON			
Diarrhea		√	
Other gastrointestinal disorders such as nausea, vomiting, abdominal pain, and stomatitis (inflammation of the mouth and lips)		√	
Skin toxicity (skin disorder) such as rash, severe itching, redness, flaking skin, cracks in the skin, severe nail disorder or infection, severe skin infection on or below the skin, and severe skin reactions known as Stevens-Johnson Syndrome or toxic epidermal necrolysis that may cause blisters, erosions, sloughing of the skin		√	
Hypokalemia (low potassium levels in the blood) which may cause muscle weakness and cramps, abnormal heart rhythm. Hypokalemia can be detected and/or confirmed with a blood test.		√	
Hypomagnesemia (low magnesium levels in the blood) may be symptomless, but when symptoms occur, they commonly include weakness and fatigue. Hypomagnesemia can be detected and/or confirmed with a blood test.		√	
COMMON			
Reactions associated with VECTIBIX administration such as chills, fever, shortness of breath, dizziness, decreased blood pressure, swelling of face and eyelids and abnormal sensation – burning, prickling, tingling sensation		√	
Swelling, pain or tenderness in one or both legs		√	
Ocular toxicities (eye disorders) such as increased growth of eyelashes, teary/itchy/ dry/red eyes, blurry vision, eye irritation, eye infection, eyelid infection, keratitis and/or ulcerative keratitis [inflammation and/or ulcers involving the front part of the eye (cornea)], corneal perforation [a serious condition of full-thickness ulceration through the front part of the eye (through the cornea) requiring urgent treatment]		√	
Hypocalcemia (low calcium levels in the blood) which may cause weakness, numbness, abnormal heart rhythm, and in severe cases seizure. Hypocalcemia can be detected and/or confirmed with a blood test.		√	
Dehydration		√	
Pulmonary embolism (blood clot in the lung)		√	

Serious side effects and what to do about them			
Symptom / effect*	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
UNCOMMON			
Acute renal failure (kidney failure)		√	
Interstitial lung disease (an inflammatory lung disease that could cause progressive scaring of lung tissue)		√	

* The side effects within each group may not occur at the same frequency. The frequency category is based on the side effect that occurs most often within each group.

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, tell your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

VECTIBIX should be stored in the refrigerator at 2°C to 8°C (36°F to 46°F) until time of use. Protect from light. **Do not freeze VECTIBIX.** Do not shake. Since VECTIBIX does not contain preservatives, any unused portion remaining in the vial must be discarded.

Keep out of reach and sight of children.

If you want more information about VECTIBIX:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website: (https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html; the manufacturer's website [www.amgen.ca], or by calling 1-866-502-6436.

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