

What to expect during treatment with Vectibix®

Indication

Vectibix® (panitumumab) is for treating patients with wild-type *RAS* metastatic colorectal cancer (cancer that has spread outside of the colon and rectum). *RAS* status is determined by an FDA-approved test. Wild-type *RAS* is a cancer without mutations in the *KRAS* and *NRAS* genes.

Vectibix® can be used:

- As a first-time treatment given with chemotherapy called FOLFOX (folinic acid, fluorouracil, oxaliplatin)
- Alone, following disease progression with the following chemotherapies: fluoropyrimidine-, oxaliplatin-, and irinotecan-containing chemotherapy

Vectibix® is not to be used to treat patients with tumors that have mutations in the *RAS* gene (called *RAS* mutant), or when the *RAS* mutation status is unknown. Talk to your doctor about your *RAS* status.

Important Safety Information

In a clinical study, nearly all patients (90%) taking Vectibix® experienced skin rash or other skin reactions. Skin reactions included but were not limited to:

- Acne-like skin rash
- Itching
- Redness
- Skin rash

- Nail infections at the side of the nail beds of the fingers or toes
- Dry skin
- Openings in the skin
- Skin peeling

Of these patients, 15% had severe skin reactions that involved, for some, pain, disfigurement, ulceration, or loss of outer layers of skin when receiving Vectibix® alone. Some patients who developed severe skin reactions also developed infections in the blood, skin, fat, or tissue that sometimes resulted in death.

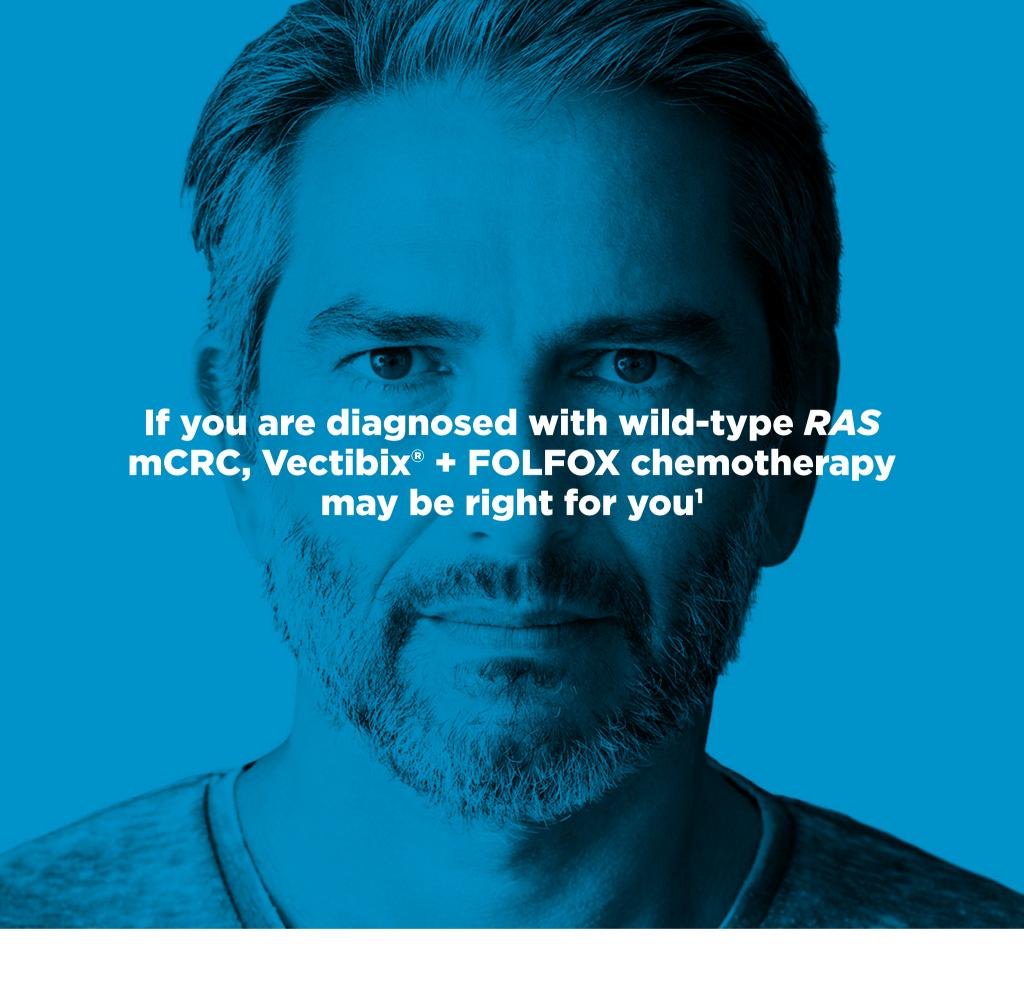


WHAT YOU CAN FIND IN THIS BROCHURE

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Important Safety Information

Your doctor may need to make changes to your dose to address your side effects or, in the event of severe or life-threatening side effects, stop Vectibix® treatment. It is important that you tell your doctor right away if you have any skin reactions or any signs of infection (such as chills, fever, or increased redness or swelling of an existing skin reaction).



Patients who have metastatic colorectal cancer with *RAS*-mutant tumors should not receive Vectibix[®]. Several clinical trials have been done evaluating treatments that block part of the pathway that increases tumor cell growth (anti-epidermal growth factor receptor [EGFR]).

Anti-EGFR treatments include Vectibix® and Erbitux® (cetuximab). In studies of these medicines, patients with *RAS*-mutant tumors experienced serious side effects without any benefit from the treatment. In one study, patients with *RAS*-mutant tumors who received Vectibix® + FOLFOX did not live as long as patients who received FOLFOX alone.

VECTIBIX® IS A TREATMENT OPTION FOR WILD-TYPE RAS mCRC¹

Not all metastatic colorectal cancer (mCRC) is the same³



What is metastatic colorectal cancer?

Metastatic colorectal cancer refers to cancer cells that have broken off and spread to other parts of the body.⁴



Some tumor types may respond to certain treatments, while others do not.⁵ It's important that your doctor does biomarker testing to find out which type of mCRC you have before choosing an appropriate treatment.

Why testing the type of mCRC you have is important



Only a RAS biomarker test shows if you have a RAS mutant or wild-type RAS gene.²

If your *RAS* gene has a mutation (change), this is called *RAS* mutant⁶

If your *RAS* gene does not have a mutation, this is called wild-type *RAS*⁶



About half of patients with mCRC have wild-type *RAS*, the type of mutation that Vectibix® can be used for⁷

Vectibix® should not be used to treat patients with mutant *RAS*, or whose *RAS* status is not known.

Important Safety Information

Some patients who were taking Vectibix® developed low levels of certain electrolytes, including:

- Magnesium
- Calcium
- Potassium

Your doctor may check the levels of these electrolytes in your blood while you are on treatment and for up to 2 months after you finish treatment. Your doctor may add other oral or intravenous medications to your Vectibix® treatment.



Vectibix® is designed to stop cancer cells from having the ability to grow and multiply¹

Important Safety Information

Vectibix® is given by infusion into a vein. Some patients may develop an infusion reaction, which can be severe and in rare cases has resulted in death. In one clinical study, infusion reactions developed in 4% of patients, and 1% of patients experienced serious infusion reactions. Infusion reactions included:

Fever

• Throat spasms

Chills

- Low blood pressure
- Shortness of breath

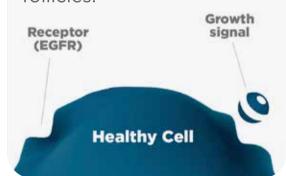


HOW VECTIBIX® WORKS

Vectibix® helps keep growth signals from reaching the cancer

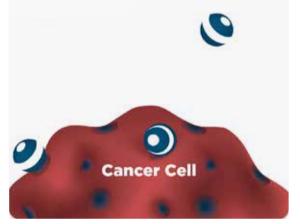
Cells receive signals that tell them to create new cells¹

Cells have some receptors that can receive signals telling the cell to grow and divide. One of these receptors is called epidermal growth factor receptor (EGFR) and can be found on normal cells, including skin and hair follicles.



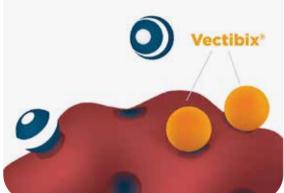
In mCRC, cells divide too much due to too many receptors¹

EGFR can also be found on cancer cells. Some cancer cells have more than normal amounts of EGFR, allowing them to grow and divide out of control.



Vectibix® blocks growth signals from getting to the receptors¹

Vectibix® is designed to block growth signals from getting to EGFR on both cancer cells and normal cells. In cancer cells, this blockage may help prevent these cells from growing and surviving.

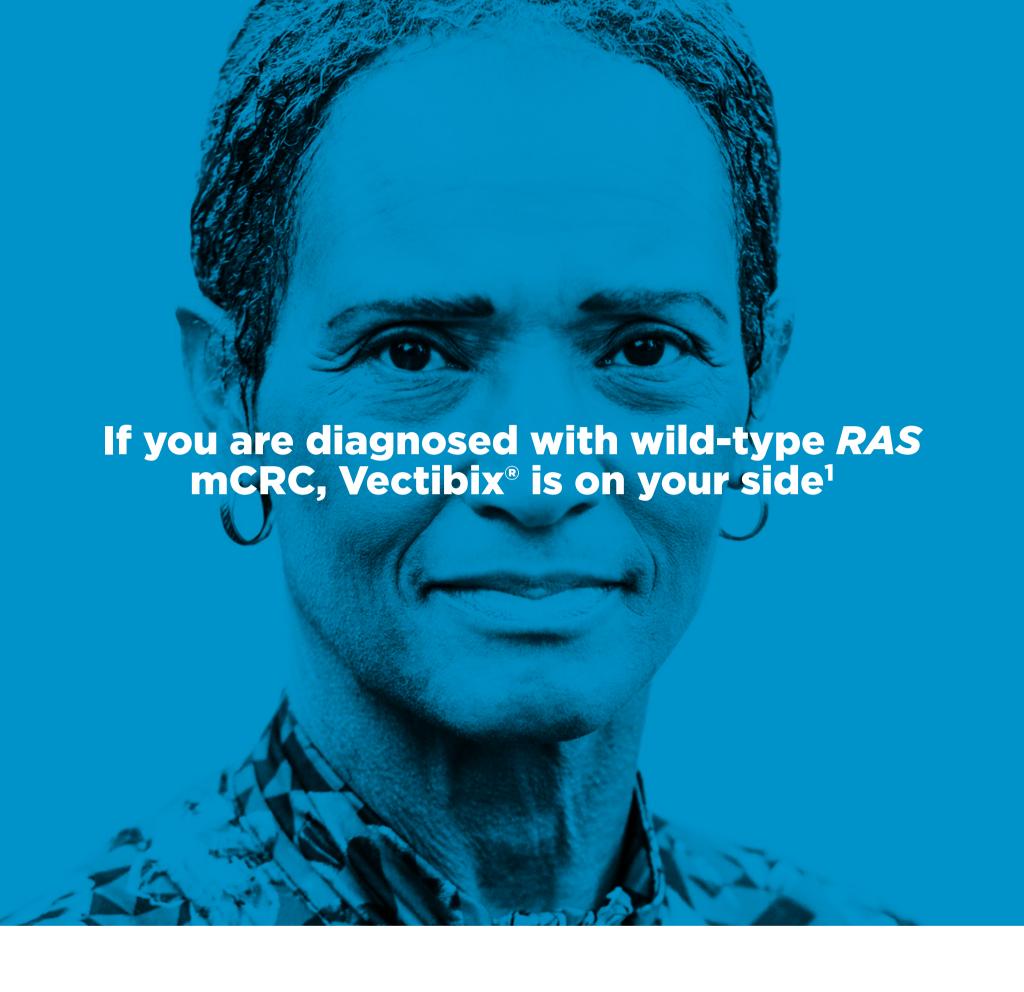


Important Safety Information

Depending on how severe the reaction is, your doctor may decide to slow the rate of the infusion, stop the infusion, or stop your Vectibix® treatment completely.

Tell your doctor right away if you experience severe diarrhea or dehydration. Some patients treated with Vectibix® and chemotherapy developed kidney failure and other complications because of severe diarrhea and dehydration.





Lung disease, including fatal lung disease, occurred in 1% or less of patients who had taken Vectibix[®]. Tell your doctor if you have problems breathing, wheezing, or a cough that doesn't go away or keeps coming back. If you have had lung problems in the past, be sure to tell your doctor. Your doctor may decide to stop Vectibix[®] treatment.

Being in the sun may make skin reactions worse. Wear sunscreen and protective clothing (such as a hat) and avoid direct sunlight while you are on treatment with Vectibix[®]. Tell your doctor if you have new or worsening skin reactions.



BENEFITS OF VECTIBIX®



Vectibix® in combination with chemotherapy* is proven to help patients with wild-type RAS mCRC1



Patients with wild-type mCRC treated with Vectibix® + FOLFOX chemotherapy¹

Vectibix® + FOLFOX chemotherapy (259 patients)

FOLFOX chemotherapy alone (253 patients)

Lived longer* (Half of patients were still alive) months

months

Went longer without having their cancer grow in half of patients

10.1 months

vs **7.9**

More saw their tumors shrink by at least 30%

58% vs **45**%

Important Safety Information

Inflammation of the eye and injury to the cornea have been reported. Tell your doctor if you have any vision changes or eye problems. If you experience any of these side effects or they worsen, your doctor should interrupt or discontinue Vectibix®.

In a study of patients treated for mCRC, the addition of Vectibix® to the combination of Avastin® (bevacizumab) and chemotherapy caused patients to experience severe side effects and to not live as long as patients receiving only Avastin® and chemotherapy. Do not take Avastin® with Vectibix®.

• Some moderate to severe side effects happened at a higher rate for Vectibix® patients, including acne-like rash, diarrhea, dehydration, painful ulcers and mouth sores, and abnormally low levels of potassium and magnesium in the blood.



^{*}Survival events were measured in 82% of patients.

BENEFITS OF VECTIBIX® (continued)



A large clinical study of patients with mCRC evaluated the benefits of Vectibix® + FOLFOX chemotherapy vs FOLFOX chemotherapy alone¹

Of 512 patients with wild-type *RAS* mCRC, 259 were given Vectibix® + FOLFOX chemotherapy and 253 were given FOLFOX chemotherapy alone.

How the clinical trial was designed¹



The study included patients with mutant *RAS* and **wild-type** *RAS* **mCRC**.

About half of the patients were given **Vectibix® plus FOLFOX chemotherapy**, and about half were given **FOLFOX chemotherapy alone**.

After initial data were reported, the investigators looked at how well Vectibix® worked in the 512 patients with **wild-type** *RAS* **tumors**.

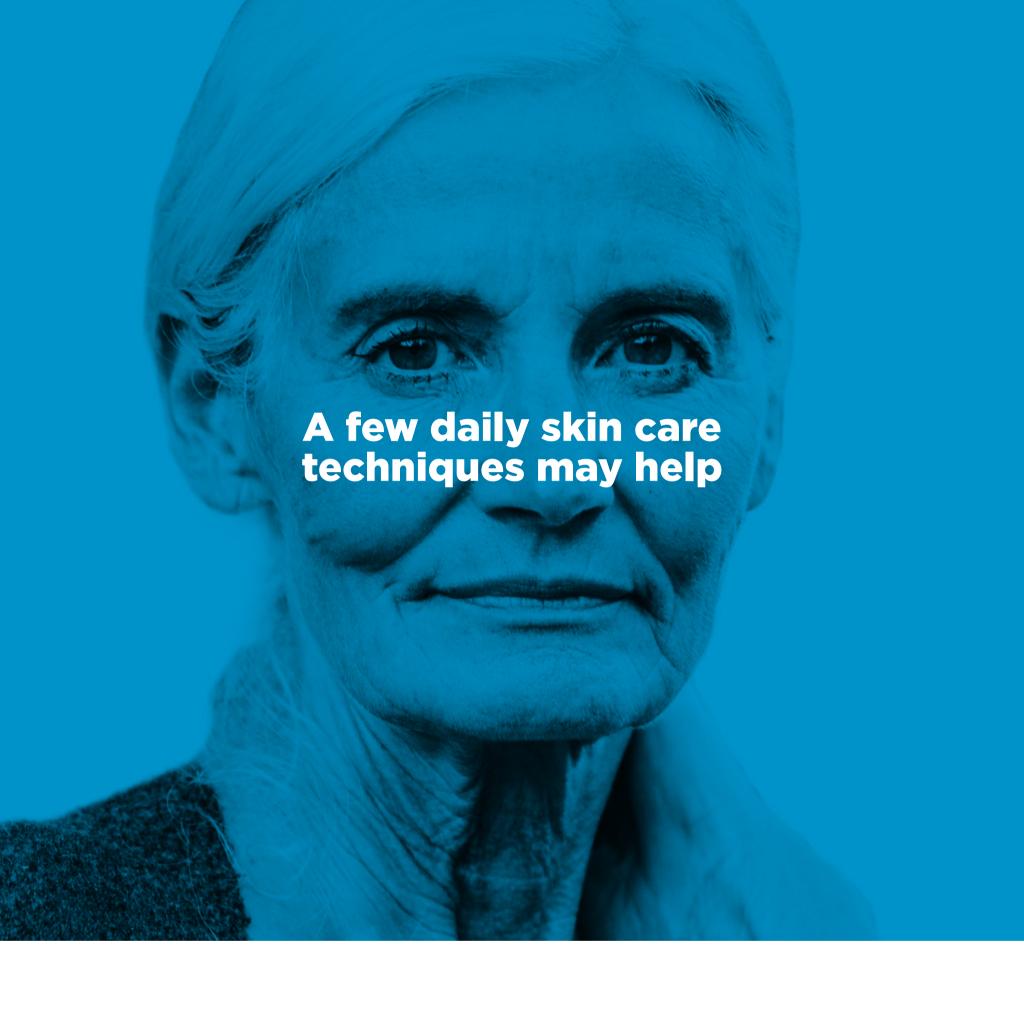
• The investigators found that Vectibix® did not work for patients with mutant RAS. Vectibix® should not be used to treat patients with mutant RAS, or whose RAS status is not known.¹ The results shown are only the patients who were wild-type

Important Safety Information

- Serious or potentially fatal blood clots that traveled to the lungs occurred more in Vectibix®-treated patients, and less than 1% of Vectibix®-treated patients died.
- Because of the side effects experienced, patients receiving Vectibix®, Avastin®, and chemotherapy received less chemotherapy for the first 24 weeks of the study compared with those receiving Avastin® and chemotherapy.

Vectibix® can cause harm to an unborn child. Use effective birth control to avoid pregnancy while taking Vectibix® and for at least 2 months after the last dose.





In patients who received Vectibix® alone, the most commonly reported side effects (experienced by 20% or more of patients) were different types of skin rash, infections at the side of the nail beds of the fingers or toes, fatigue (extreme tiredness), nausea, and diarrhea.

In patients who received Vectibix® + FOLFOX, the most commonly reported side effects (experienced by 20% or more of patients) were diarrhea, sore mouth, inflammation of mucous membranes, weakness, infection of the nail beds, loss of appetite, low magnesium, low potassium, rash, acne-like skin rash, itching, and dry skin. The most common serious side effects were diarrhea and dehydration.

POSSIBLE SKIN REACTIONS



Take care of your skin while Vectibix® takes control of your mCRC

In clinical studies, 90% of patients using Vectibix® experienced some form of skin rash or other skin reactions. Severe or life-threatening skin reactions have been reported.¹



Why do skin reactions occur when taking Vectibix®?

Vectibix® is designed to block certain growth signals on cancer cells. It also blocks growth signals on normal cells, like the ones found in your skin and hair.¹

Some skin reactions you may experience include¹:

- Acne-like rash
- Skin rash
- Nail infections
- Dry skin
- Redness
- Skin peeling
- Openings in the skin
- Itching

Fifteen percent of these patients had severe skin reactions, which involved pain, disfigurement, ulceration, or loss of outer layers of skin. Some patients who developed severe skin reactions also developed infections in the blood, skin, fat, or tissue that sometimes resulted in death.

Important Safety Information

In a clinical study, nearly all patients (90%) taking Vectibix® experienced skin rash or other skin reactions. Skin reactions included but were not limited to:

- Acne-like skin rash
- Itching
- Redness
- Skin rash
- Skin peeling
- Nail infections at the side of the nail beds of the fingers or toes
- Dry skin
- Openings in the skin



POSSIBLE SKIN REACTIONS (continued)



What precautions should I take while receiving Vectibix®?

While you are on treatment and for 2 months after treatment ends, you should:



Avoid the sun when possible, and wear a hat and sunscreen when you are out in the sun¹



Use mild lotions or



Apply over-thecounter topical treatments such as hydrocortisone ointment8

Always talk to your doctor about any side effects you experience, including skin rash.

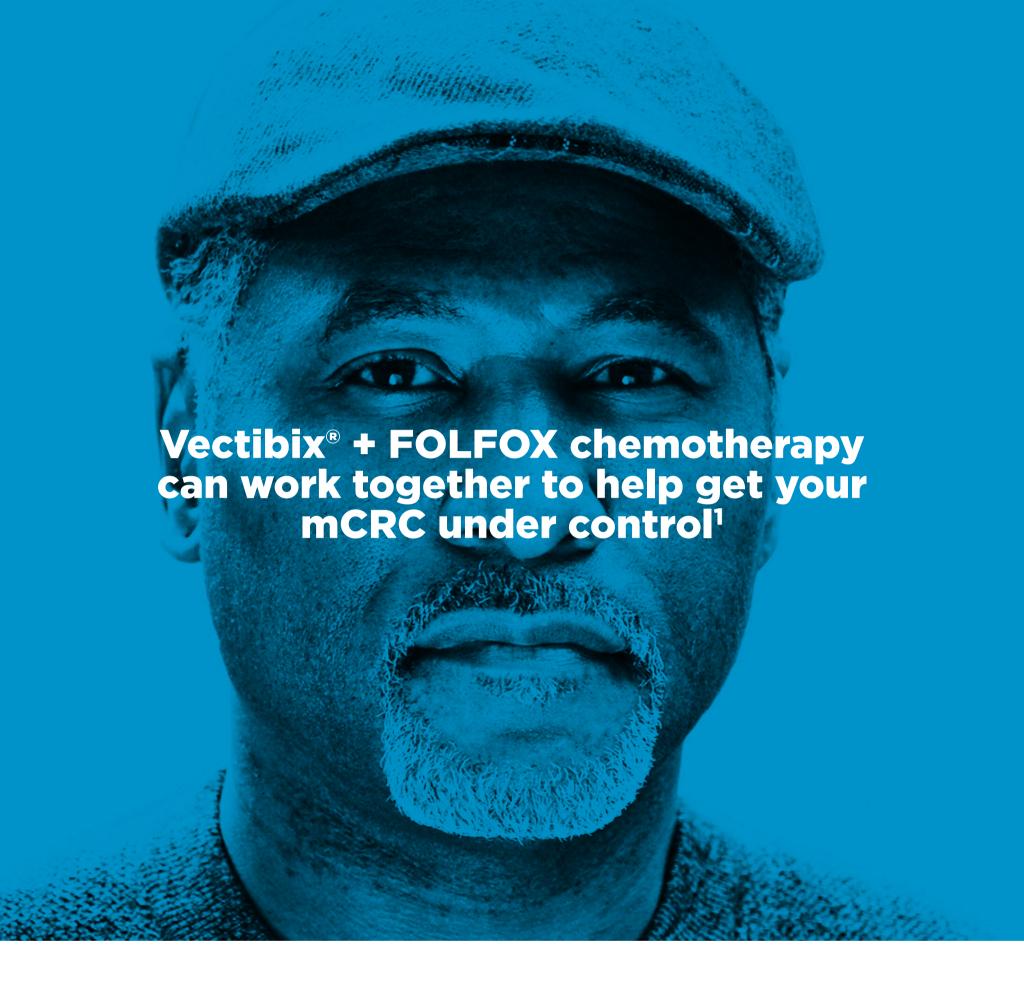
• Depending on the severity of the reaction, your doctor may choose to adjust or delay your dose or stop your treatment. Your doctor may also prescribe a topical steroid cream or antibiotic to mitigate any reactions^{1,8}

Important Safety Information

Of these patients, 15% had severe skin reactions that involved, for some, pain, disfigurement, ulceration, or loss of outer layers of skin when receiving Vectibix® alone. Some patients who developed severe skin reactions also developed infections in the blood, skin, fat, or tissue that sometimes resulted in death.

Your doctor may need to make changes to your dose to address your side effects or, in the event of severe or life-threatening side effects, stop Vectibix® treatment. It is important that you tell your doctor right away if you have any skin reactions or any signs of infection (such as chills, fever, or increased redness or swelling of an existing skin reaction).





Patients who have metastatic colorectal cancer with *RAS*-mutant tumors should not receive Vectibix[®]. Several clinical trials have been done evaluating treatments that block part of the pathway that increases tumor cell growth (anti-epidermal growth factor receptor [EGFR]).

Anti-EGFR treatments include Vectibix® and Erbitux® (cetuximab). In studies of these medicines, patients with *RAS*-mutant tumors experienced serious side effects without any benefit from the treatment. In one study, patients with *RAS*-mutant tumors who received Vectibix® + FOLFOX did not live as long as patients who received FOLFOX alone.

VECTIBIX® IS GIVEN EVERY 2 WEEKS WITH FOLFOX CHEMOTHERAPY¹

Information you'll need to know about taking Vectibix®

How do I receive Vectibix®?

- Vectibix® is given as an infusion into a vein¹
- It may be given during the same visit as your FOLFOX chemotherapy¹

How long will it take?



- 1st dose: For most patients, Vectibix® infusion will take 60 minutes¹
- Following doses:

 Vectibix® infusion may take 30-60 minutes, depending on how you tolerate the medicine¹
- For patients who need a larger dose, Vectibix® infusion will take
 90 minutes or more¹

How will my dose be adjusted?



Your doctor may adjust your dose and infusion time based on how you tolerate the medicine¹

Important Safety Information

Some patients who were taking Vectibix® developed low levels of certain electrolytes, including:

- Magnesium
- Calcium
- Potassium

Your doctor may check the levels of these electrolytes in your blood while you are on treatment and for up to 2 months after you finish treatment. Your doctor may add other oral or intravenous medications to your Vectibix® treatment.



VECTIBIX® CAN HELP IN YOUR FIGHT AGAINST mCRC



We have financial resources available for you



If you've been prescribed an Amgen medication, you might have questions about your medicine, how it may be covered by your insurance, or resources within your community.* That's why we created Amgen Assist 360™—to support you in every way we can, so you can focus on what's most important to you.

See how we can help

CALL 1-888-4ASSIST (1-888-427-7478)

Monday to Friday 9:00 am to 8:00 pm ET

www.amgenassist360.com/patient/vectibix-costassistance/



The Amgen FIRST STEP™ Program can help eligible commercially insured patients cover their out-of-pocket prescription costs, including deductible, co-insurance, and co-payment.†

- \$0 out of pocket for first dose or cycle
- \$5 out of pocket for subsequent doses or cycles, up to the brand program benefit maximum
- No income eligibility

[†]Terms, conditions, and program maximums apply. This program is not open to patients receiving prescription reimbursement under any federal-, state-, or government-funded healthcare program. Not valid where prohibited by law.



^{*}Resources include referrals to independent nonprofit patient assistance programs. Eligibility for resources provided by independent nonprofit patient assistance programs is based on the nonprofits' criteria. Amgen has no control over these programs and provides referrals as a courtesy only.

MORE INFORMATION ABOUT mCRC





American Cancer Society

Cancer information, programs, and services for patients and caregivers

Call: 800-227-2345
Visit: www.cancer.org



Colorectal Cancer Alliance

A leader in patient support and empowerment, offering information, resources, and tools to help patients and families

(all: 877-422-2030

Visit: www.ccalliance.org



Fight Colorectal Cancer

An organization championing the fight against colorectal cancer and the relentless pursuit of finding a cure

(all: 877-427-2111

Visit: www.fightcolorectalcancer.org



Colontown

An online support organization for patients and caregivers

Visit: www.colontown.org

These third-party cancer support resources are for your information only. Amgen does not endorse and is not responsible for the content included in these resources.



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- Fever
- Chills
- Shortness of breath
- Throat spasms
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IMPORTANT SAFETY INFORMATION (continued)

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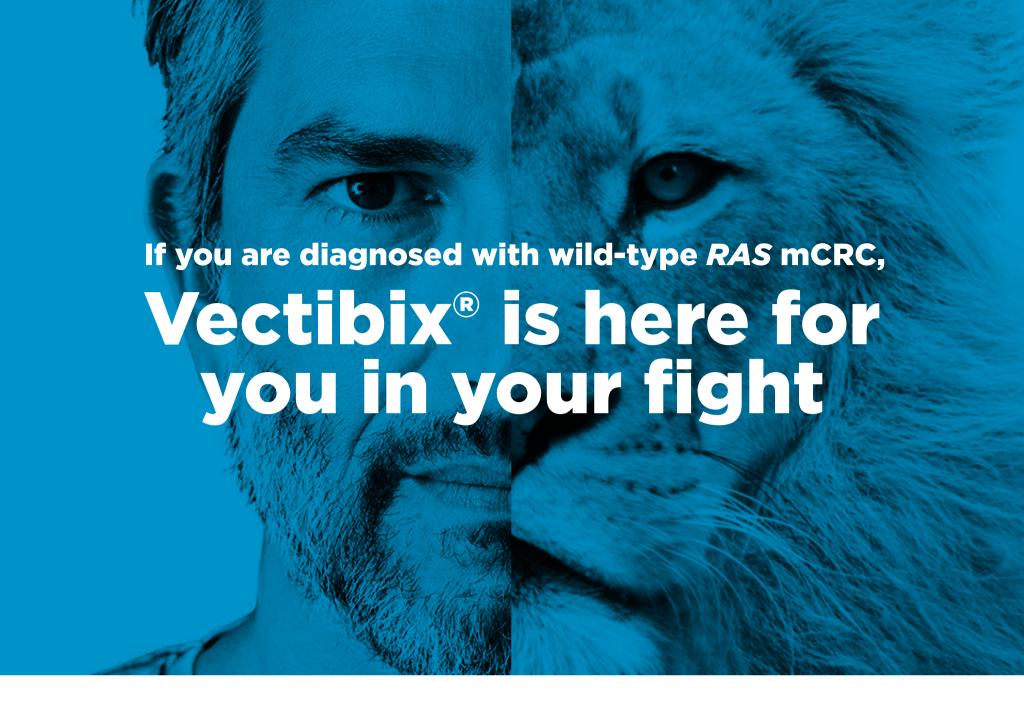
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References: 1. Vectibix® (panitumumab) prescribing information, Amgen. 2. Allegra CJ, Rumble RB, Hamilton SR, et al. Extended *RAS* gene mutation testing in metastatic colorectal carcinoma to predict response to anti-epidermal growth factor receptor monoclonal antibody therapy: American Society of Clinical Oncology provisional clinical opinion update 2015. *J Clin Oncol*. 2016;34:179-185. 3. Kim ST, Lee S, Lee J, et al. The impact of microsatellite instability status and sidedness of the primary tumor on the effect of cetuximab-containing chemotherapy in patients with metastatic colorectal cancer. *J Cancer*. 2017;8(14):2809-2815. doi:10.7150/jca.18286. 4. American Cancer Society. https://www.cancer.org/treatment/understanding-your-diagnosis/advanced-cancer/what-is. html. Accessed October 4, 2021. 5. Boeckx N, Koukakis R, Op de Beeck K, et al. Primary tumor sidedness has an impact on prognosis and treatment outcome in metastatic colorectal cancer: results from two randomized first-line panitumumab studies. *Ann Oncol*. 2017;28:1862-1868. doi:10.1093/annonc/mdx119. 6. National Cancer Institute. https://www.cancer.gov/publications/dictionaries/cancer-terms/def/wild-type-gene. Accessed October 4, 2021. 7. Zhao B, Wang L, Qiu H, et al. Mechanisms of resistance to anti-EGFR therapy in colorectal cancer. *Oncotarget*. 2016;8(3):3980-4000. 8. Lacouture ME, Anadkat M, Jatol A, et al. Dermatologic toxicity occurring during anti-EGFR monoclonal inhibitor therapy in patients with metastatic colorectal cancer: a systematic review. *Clin Colorectal Cancer*. 2018:17(2);85-96. doi:10.1016/j.clcc.2017.12.004.





Indication

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- Alone, following disease progression with the following chemotherapies: fluoropyrimidine-, oxaliplatin-, and irinotecan-containing chemotherapy

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Please visit Vectibix.com for more information.

Please see full Important Safety Information on pages 17-18.



