

WARNING: DERMATOLOGIC TOXICITY

Dermatologic Toxicity: Dermatologic toxicities occurred in 90% of patients and were severe (NCI-CTC grade 3 and higher) in 15% of patients receiving Vectibix® monotherapy [See *Dosage and Administration (2.3), Warnings and Precautions (5.1), and Adverse Reactions (6.1)*].

In Study 20020408, dermatologic toxicities occurred in 90% of patients and were severe (NCI-CTC grade 3 and higher) in 15% of patients with mCRC receiving Vectibix®. The clinical manifestations included, but were not limited to, acneiform dermatitis, pruritus, erythema, rash, skin exfoliation, paronychia, dry skin, and skin fissures.

Monitor patients who develop dermatologic or soft tissue toxicities while receiving Vectibix® for the development of inflammatory or infectious sequelae. Life-threatening and fatal infectious complications including necrotizing fasciitis, abscesses, and sepsis have been observed in patients treated with Vectibix®. Life-threatening and fatal bullous mucocutaneous disease with blisters, erosions, and skin sloughing has also been observed in patients treated with Vectibix®. It could not be determined whether these mucocutaneous adverse reactions were directly related to EGFR inhibition or to idiosyncratic immune-related effects (eg, Stevens Johnson syndrome or toxic epidermal necrolysis). Withhold or discontinue Vectibix® for dermatologic or soft tissue toxicity associated with severe or life-threatening inflammatory or infectious complications. Dose modifications for Vectibix® concerning dermatologic toxicity are provided in the product labeling.

Vectibix® is not indicated for the treatment of patients with colorectal cancer that harbor somatic *RAS* mutations in exon 2 (codons 12 and 13), exon 3 (codons 59 and 61), and exon 4 (codons 117 and 146) of either *KRAS* or *NRAS* and hereafter is referred to as “*RAS*.”

Retrospective subset analyses across several randomized clinical trials were conducted to investigate the role of *RAS* mutations on the clinical effects of anti-EGFR-directed monoclonal antibodies (panitumumab or cetuximab). Anti-EGFR antibodies in patients with tumors containing *RAS* mutations resulted in exposing those patients to anti-EGFR related adverse reactions without clinical benefit from these agents. Additionally, in Study 20050203, 272 patients with *RAS*-mutant mCRC tumors received Vectibix® in combination with FOLFOX and 276 patients received FOLFOX alone. In an exploratory subgroup analysis, OS was shorter (HR = 1.21, 95% CI: 1.01-1.45) in patients with *RAS*-mutant mCRC who received Vectibix® and FOLFOX versus FOLFOX alone.

Progressively decreasing serum magnesium levels leading to severe (grade 3-4) hypomagnesemia occurred in up to 7% (in Study 20080763) of patients across clinical trials. Monitor patients for hypomagnesemia and hypocalcemia prior to initiating Vectibix® treatment, periodically during Vectibix® treatment, and for up to 8 weeks after the completion of treatment. Other electrolyte disturbances, including hypokalemia, have also been observed. Replete magnesium and other electrolytes as appropriate.

In Study 20020408, 4% of patients experienced infusion reactions and 1% of patients experienced severe infusion reactions (NCI-CTC grade 3-4). Infusion reactions, manifesting as fever, chills, dyspnea, bronchospasm, and hypotension, can occur following Vectibix® administration. Fatal infusion reactions occurred in postmarketing experience. Terminate the infusion for severe infusion reactions.

Severe diarrhea and dehydration, leading to acute renal failure and other complications, have been observed in patients treated with Vectibix® in combination with chemotherapy.

Fatal and nonfatal cases of interstitial lung disease (ILD) (1%) and pulmonary fibrosis have been observed in patients treated with Vectibix®. Pulmonary fibrosis occurred in less than 1% (2/1467) of patients enrolled in clinical studies of Vectibix®. In the event of acute onset or worsening of pulmonary symptoms interrupt Vectibix® therapy. Discontinue Vectibix® therapy if ILD is confirmed.

In patients with a history of interstitial pneumonitis or pulmonary fibrosis, or evidence of interstitial pneumonitis or pulmonary fibrosis, the benefits of therapy with Vectibix® versus the risk of pulmonary complications must be carefully considered.

Exposure to sunlight can exacerbate dermatologic toxicity. Advise patients to wear sunscreen and hats and limit sun exposure while receiving Vectibix®.

Serious cases of keratitis, ulcerative keratitis, and corneal perforation have occurred with Vectibix® use. Monitor for evidence of keratitis, ulcerative keratitis, or corneal perforation. Interrupt or discontinue Vectibix® therapy for acute or worsening keratitis, ulcerative keratitis, or corneal perforation.

In an interim analysis of an open-label, multicenter, randomized clinical trial in the first-line setting in patients with mCRC, the addition of Vectibix® to the combination of bevacizumab and chemotherapy resulted in decreased OS and increased incidence of NCI-CTC grade 3-5 (87% vs 72%) adverse reactions. NCI-CTC grade 3-4 adverse reactions occurring at a higher rate in Vectibix®-treated patients included rash/acneiform dermatitis (26% vs 1%), diarrhea (23% vs 12%), dehydration (16% vs 5%), primarily occurring in patients with diarrhea, hypokalemia (10% vs 4%), stomatitis/mucositis (4% vs < 1%), and hypomagnesemia (4% vs 0).

NCI-CTC grade 3-5 pulmonary embolism occurred at a higher rate in Vectibix®-treated patients (7% vs 3%) and included fatal events in three (< 1%) Vectibix®-treated patients. As a result of the toxicities experienced, patients randomized to Vectibix®, bevacizumab, and chemotherapy received a lower mean relative dose intensity of each chemotherapeutic agent (oxaliplatin, irinotecan, bolus 5-FU, and/or infusional 5-FU) over the first 24 weeks on study, compared with those randomized to bevacizumab and chemotherapy.

Vectibix® can cause fetal harm when administered to a pregnant woman. Advise pregnant women and females of reproductive potential of the potential risk to a fetus. Advise females of reproductive potential to use effective contraception during treatment, and for at least 2 months after the last dose of Vectibix®.

In monotherapy, the most commonly reported adverse reactions (≥ 20%) in patients with Vectibix® were skin rash with variable presentations, paronychia, fatigue, nausea, and diarrhea.

The most commonly reported adverse reactions (≥ 20%) with Vectibix® + FOLFOX were diarrhea, stomatitis, mucosal inflammation, asthenia, paronychia, anorexia, hypomagnesemia, hypokalemia, rash, acneiform dermatitis, pruritus, and dry skin. The most common serious adverse reactions (≥ 2% difference between treatment arms) were diarrhea and dehydration.

Dimensions Flat: 26.125"x11.75"
Dimensions Finished: 8.5"x11"

Indication

Vectibix® is indicated for the treatment of patients with wild-type *RAS* (defined as wild-type in both *KRAS* and *NRAS* as determined by an FDA-approved test for this use) metastatic colorectal cancer (mCRC):

- As first-line therapy in combination with FOLFOX.
- As monotherapy following disease progression after prior treatment with fluoropyrimidine-, oxaliplatin-, and irinotecan-containing chemotherapy.

Limitation of Use

Vectibix® is not indicated for the treatment of patients with *RAS*-mutant mCRC or for whom *RAS* mutation status is unknown.

Item	Coding Information (HCPCS/CPT/ICD-10-CM ³)	Notes
Vectibix®	J9303, injection, panitumumab, 10 mg	Vectibix® is supplied in single-use vials containing 100 mg in 5 mL (20 mg/mL), 200 mg in 10 mL (20 mg/mL), and 400 mg in 20 mL (20 mg/mL) of panitumumab The NDC numbers for Vectibix®, in the 11-digit format, are as follows: - 5-mL vial: 55513-0954-01 - 10-mL vial: 55513-0955-01 - 20-mL vial: 55513-0956-01
Administration	96413, chemotherapy administration, IV infusion technique; up to 1 hour, single or initial substance/drug* 96415, each additional hour (list separately in addition to code for primary procedure)	In addition to 96413, report 96415 when the infusion interval is > 30 minutes beyond the 1 hour represented by 96413
Office visit	Relevant Evaluation and Management (E&M) code ^{1,‡}	See payer guidelines
Diagnosis/Condition	Appropriate ICD-10-CM code(s) for patient condition	Example: C18.4 Malignant neoplasm of the transverse colon

¹The recommended dose of Vectibix® is 6 mg/kg, administered as an intravenous infusion over 60 minutes, every 14 days. Doses higher than 1,000 mg should be administered over 90 minutes.
²Bill relevant E&M code only if a separately identifiable E&M service is performed. Document accordingly.
³Some payers, including Medicare, will not allow a Level 1 office visit to be billed with an injection/infusion code for the same date of service, and only allow for other levels when Modifier 25 is billed.

1. Centers for Medicare & Medicaid Services. July 2021 Alpha-Numeric HCPCS File. Page last modified July 23, 2021. Accessed September 12, 2021. <https://www.cms.gov/Medicare/Coding/HCPCSReleaseCodeSets/HCPCS-Quarterly-Update>
2. American Medical Association. Current Procedural Terminology (CPT®) 2021 Professional Edition. Copyright 2020. All rights reserved.
3. Centers for Disease Control and Prevention. ICD-10-CM FY 2022 List of Codes and Descriptions. Accessed September 12, 2021. https://ftp.cdc.gov/pub/Health_Statistics/NCHS/Publications/ICD10CM/2022/

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Contact Amgen Assist® at 1-888-4ASSIST for assistance.
www.AmgenAssistOnline.com

Please see Important Safety Information, including Boxed WARNING, on pages 3 and 4.

Please see enclosed Vectibix® package insert for full Prescribing Information, including Boxed WARNING.



Please see enclosed Vectibix® package insert for full Prescribing Information, including Boxed WARNING.

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The CMS 1500 for Physician Office

Sample CMS 1500 Form — Physician Office Administration

HEALTH INSURANCE CLAIM FORM		CARRIER	
APPROVED BY NATIONAL UNIFORM CLAIM COMMITTEE (NUCC) 02/12			
1. MEDICARE <input type="checkbox"/> MEDICAID <input type="checkbox"/> TRICARE <input type="checkbox"/> CHAMPVA <input type="checkbox"/> GROUP HEALTH PLAN <input type="checkbox"/> FECA <input type="checkbox"/> OTHER <input type="checkbox"/>		1a. INSURED'S I.D. NUMBER (For Program in Item 1)	
2. PATIENT'S NAME (Last Name, First Name, Middle Initial) Doe, John D		4. INSURED'S NAME (Last Name, First Name, Middle Initial) Doe, John D	
3. PATIENT'S BIRTH DATE (MM/DD/YY) XX XX XX SEX <input type="checkbox"/> M <input type="checkbox"/> F		7. INSURED'S ADDRESS (No., Street)	
5. PATIENT'S ADDRESS (No., Street) 5555 Any Street		8. RESERVED FOR NUCC USE	
6. PATIENT RELATIONSHIP TO INSURED Self <input type="checkbox"/> Spouse <input type="checkbox"/> Child <input type="checkbox"/> Other <input type="checkbox"/>		CITY	
CITY Anytown STATE AS		STATE	
ZIP CODE 01010 TELEPHONE (Include Area Code) (XXX) XXX-XXXX		ZIP CODE TELEPHONE (Include Area Code)	
9. OTHER INSURED'S NAME (Last Name, First Name, Middle Initial)		11. INSURED'S POLICY GROUP OR FECA NUMBER	
a. OTHER INSURED'S POLICY OR GROUP NUMBER		a. INSURED'S DATE OF BIRTH (MM/DD/YY) SEX <input type="checkbox"/> M <input type="checkbox"/> F	
b. RESERVED FOR NUCC USE		b. OTHER CLAIM ID (Designated by NUCC)	
c. RESERVED FOR NUCC USE		c. INSURANCE PLAN NAME OR PROGRAM NAME	
d. INSURANCE PLAN NAME OR PROGRAM NAME PRODUCT CODE (BOX 24D)		d. IS THERE ANOTHER HEALTH BENEFIT PLAN? <input type="checkbox"/> YES <input type="checkbox"/> NO <i>If yes, complete items 9, 9a, and 9d.</i>	
10. IS PATIENT'S CONDITION RELATED TO: a. EMPLOYMENT? (Current or Previous) <input type="checkbox"/> YES <input type="checkbox"/> NO b. AUTO ACCIDENT? <input type="checkbox"/> YES <input type="checkbox"/> NO PLACE (State) c. OTHER ACCIDENT? <input type="checkbox"/> YES <input type="checkbox"/> NO		13. INSURED'S OR AUTHORIZED PERSON'S SIGNATURE I authorize payment of medical benefits to the undersigned physician or supplier for services described below.	
14. DATE OF CURRENT ILLNESS, INJURY, or PREGNANCY (LMP) (MM/DD/YY) QUAL. XX XX XX		15. OTHER DATE (MM/DD/YY) QUAL. XX XX XX	
17. NAME OF REFERRING PROVIDER OR OTHER SOURCE 17a. XX XX XX 17b. NPI		19. ADDITIONAL CLAIM INFORMATION (Designated by NUCC)	
21. DIAGNOSIS OR NATURE OF ILLNESS OR INJURY (Relate A-L to service line below (24E)) A. C18.4		20. SIGNATURE DATE	
24. A. DATE(S) OF SERVICE (From MM/DD/YY To MM/DD/YY) B. PLACE OF SERVICE (EMG) C. PROCEDURE, SERVICE, OR SUPPLIES (Explain Unusual Circumstances) D. DIAGNOSIS POINTER XX XX XX XX XX XX 11 J9303 A		F. \$ CHARGES XXX XX X	
1. XX XX XX XX XX XX 11 96413 A XXX X		G. DAYS OF LIMITS	
2. XX XX XX XX XX XX 11 96413 A XXX X		H. SPECIAL RATE	
3. XX XX XX XX XX XX 11 96413 A XXX X		I. L	
4. XX XX XX XX XX XX 11 96413 A XXX X		J. J.	
5. XX XX XX XX XX XX 11 96413 A XXX X		K. K.	
6. XX XX XX XX XX XX 11 96413 A XXX X		L. L.	
25. FEDERAL TAX I.D. NUMBER		28. TOTAL CHARGE \$	
31. SIGNATURE OF PHYSICIAN OR SUPPLIER INCLUDING DEGREES OR CREDENTIALS (I certify that the statements on the reverse apply to this bill and are a part thereof.)		29. AMOUNT PAID \$	
32. SERVICE CENTER INFORMATION		30. Rsvd for NUCC Use	
33. BILLING PROVIDER INFO & PH #			

PRODUCT CODE (BOX 24D)
Document use of product with J9303, injection, panitumumab, 10 mg.

DIAGNOSIS CODE (BOX 21)
Document appropriate ICD-10-CM diagnosis code(s) corresponding to patient's diagnosis. Line A — primary diagnosis code. Example diagnosis code includes: C18.4, malignant neoplasm of the transverse colon.

DIAGNOSIS CODE (BOX 24E)
Specify diagnosis, from Box 21, relating to each CPT/HCPCS code listed in Box 24D.

SERVICE UNITS (BOX 24G)
Report unit of service. 1 unit for J9303 corresponds to 10 mg of Vectibix®.

PROCEDURE CODE (BOX 24D)
Document product administration with appropriate CPT code. Use CPT code representing procedure performed, such as 96413, chemotherapy administration, IV infusion technique; up to 1 hour, single or initial substance/drug.

This sample form is intended as a reference for coding and billing for product and associated services. It is not intended to be directive; the use of the recommended codes does not guarantee reimbursement. Healthcare providers may deem other codes or policies more appropriate and should select the coding options that most accurately reflect their internal system guidelines, payer requirements, practice patterns, and the services rendered. Healthcare providers are responsible for ensuring the accuracy and validity of all billing and claims for appropriate reimbursement.

Please see Important Safety Information, including Boxed WARNING, on pages 3 and 4.

Indication

Vectibix® is indicated for the treatment of patients with wild-type *RAS* (defined as wild-type in both *KRAS* and *NRAS* as determined by an FDA-approved test for this use) metastatic colorectal cancer (mCRC):

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Office visit	Relevant Evaluation and Management (E&M) code ^{†,‡}	See payer guidelines
Diagnosis/ Condition	Appropriate ICD-10-CM code(s) for patient condition	Example: C18.4 Malignant neoplasm of the transverse colon

[†] The recommended dose of Vectibix® is 6 mg/kg, administered as an intravenous infusion over 60 minutes, every 14 days. Doses higher than 1,000 mg should be administered over 90 minutes.

[‡] Bill relevant E&M code only if a separately identifiable E&M service is performed. Document accordingly.

[‡] Some payers, including Medicare, will not allow a Level 1 office visit to be billed with an injection/infusion code for the same date of service, and only allow for other levels when Modifier 25 is billed.

1. Centers for Medicare & Medicaid Services. July 2021 Alpha-Numeric HCPCS File. Page last modified July 23, 2021. Accessed September 12, 2021. <https://www.cms.gov/Medicare/Coding/HCPCSReleaseCodeSets/HCPCS-Quarterly-Update>

2. American Medical Association. Current Procedural Terminology (CPT®) 2021 Professional Edition. Copyright 2020. All rights reserved.

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www.AmgenAssistOnline.com

Please see Important Safety Information, including Boxed WARNING, on pages 3 and 4.



The CMS 1500 for Physician Office

Sample CMS 1500 Form — Physician Office Administration



HEALTH INSURANCE CLAIM FORM
 APPROVED BY NATIONAL UNIFORM CLAIM COMMITTEE (NUCC) 02/12

PICA PICA

1. MEDICARE <input type="checkbox"/> (Medicare#)	MEDICAID <input type="checkbox"/> (Medicaid#)	TRICARE <input type="checkbox"/> (ID#/DoD#)	CHAMPVA <input type="checkbox"/> (Member ID#)	GROUP HEALTH PLAN <input type="checkbox"/> (ID#)	FECA BLK LUNG <input type="checkbox"/> (ID#)	OTHER <input type="checkbox"/> (ID#)	1a. INSURED'S I.D. NUMBER (For Program in Item 1)
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2. PATIENT'S NAME (Last Name, First Name, Middle Initial) Doe, John D	3. PATIENT'S BIRTH DATE MM DD YY XX XX XX	SEX M <input type="checkbox"/> F <input type="checkbox"/>	4. INSURED'S NAME (Last Name, First Name, Middle Initial) Doe, John D
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5. PATIENT'S ADDRESS (No., Street) 5555 Any Street	6. PATIENT RELATIONSHIP TO INSURED Self <input type="checkbox"/> Spouse <input type="checkbox"/> Child <input type="checkbox"/> Other <input type="checkbox"/>	7. INSURED'S ADDRESS (No., Street)
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CITY Anytown	STATE AS	CITY	STATE
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ZIP CODE 01010	TELEPHONE (Include Area Code) (xxx) xxx-xxxx	ZIP CODE	TELEPHONE (Include Area Code) ()
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9. OTHER INSURED'S NAME (Last Name, First Name, Middle Initial)	10. IS PATIENT'S CONDITION RELATED TO:	11. INSURED'S POLICY GROUP OR FECA NUMBER
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a. OTHER INSURED'S POLICY OR GROUP NUMBER	a. EMPLOYMENT? (Current or Previous) <input type="checkbox"/> YES <input type="checkbox"/> NO	a. INSURED'S DATE OF BIRTH MM DD YY M <input type="checkbox"/> F <input type="checkbox"/>
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b. RESERVED FOR NUCC USE	b. AUTO ACCIDENT? PLACE (State) <input type="checkbox"/> YES <input type="checkbox"/> NO	b. OTHER CLAIM ID (Designated by NUCC)
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c. RESERVED FOR NUCC USE	c. OTHER ACCIDENT? <input type="checkbox"/> YES <input type="checkbox"/> NO	c. INSURANCE PLAN NAME OR PROGRAM NAME
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d. INSURANCE PLAN NAME OR PROGRAM NAME PRODUCT CODE (BOX 24D)	10d. CLAIM CODES (Designated by NUCC)	d. IS THERE ANOTHER HEALTH BENEFIT PLAN? <input type="checkbox"/> YES <input type="checkbox"/> NO <i>If yes, complete items 9, 9a, and 9d.</i>
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Document use of product with J9303, injection, panitumumab, 10 mg.

LETING & SIGNING THIS FORM.
 I authorize the release of any medical or other information necessary either to myself or to the party who accepts assignment

13. INSURED'S OR AUTHORIZED PERSON'S SIGNATURE I authorize payment of medical benefits to the undersigned physician or supplier for services described below.

SIGNED _____	DATE _____
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14. DATE OF CURRENT ILLNESS, INJURY, or PREGNANCY (LMP) MM DD YY XX XX XX	15. OTHER DATE QUAL. MM DD YY	16. DATE OF BIRTH MM DD YY
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17. NAME OF REFERRING PROVIDER OR OTHER SOURCE	17a. _____ 17b. NPI _____
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19. ADDITIONAL CLAIM INFORMATION (Designated by NUCC)

21. DIAGNOSIS OR NATURE OF ILLNESS OR INJURY Relate A-L to service line below (24E)
A. C18.4
B. _____
C. _____
D. _____
E. _____
F. _____
G. _____
H. _____
I. _____
J. _____
K. _____
L. _____

DIAGNOSIS CODE (BOX 21)
 Document appropriate ICD-10-CM diagnosis code(s) corresponding to patient's diagnosis. Line A — primary diagnosis code. Example diagnosis code includes: C18.4, malignant neoplasm of the transverse colon.

DIAGNOSIS CODE (BOX 24E)
 Specify diagnosis, from Box 21, relating to each CPT/HCPCS code listed in Box 24D.

24. A.	DATE(S) OF SERVICE	From	To	B. PLACE OF SERVICE	C. EMG	D. PROCEDURES, SERVICES, OR SUPPLIES (Explain Unusual Circumstances)	E. DIAGNOSIS POINTER	F. \$ CHARGES	G. DAYS OR UNITS	H. ICD-10-CM Code	I. J. _____
1	XX XX XX	XX	XX	XX	11	J9303	A	XXX XX	X		
2	XX XX XX	XX	XX	XX	11	96413	A	XXX			
3											NPI
4											NPI
5											NPI
6											NPI

SERVICE UNITS (BOX 24G)
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25. FEDERAL TAX I.D. NUMBER	28. TOTAL CHARGE \$	29. AMOUNT PAID \$	30. Rsvd for NUCC Use
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31. SIGNATURE OF PHYSICIAN OR SUPPLIER INCLUDING DEGREES OR CREDENTIALS (I certify that the statements on the reverse apply to this bill and are made a part thereof.)

SIGNED _____	DATE _____	a. NPI _____	b. NPI _____
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NUCC Instruction Manual available at: www.nucc.org PLEASE PRINT OR TYPE APPROVED OMB-0938-1197 FORM 1500 (02-12)

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Serious cases of keratitis, ulcerative keratitis, and corneal perforation have occurred with Vectibix® use. Monitor for evidence of keratitis, ulcerative keratitis, or corneal perforation. Interrupt or discontinue Vectibix® therapy for acute or worsening keratitis, ulcerative keratitis, or corneal perforation.

Please [click here](#) to see Vectibix® package insert for full Prescribing Information, including Boxed WARNING.



In an interim analysis of an open-label, multicenter, randomized clinical trial in the first-line setting in patients with mCRC, the addition of Vectibix® to the combination of bevacizumab and chemotherapy resulted in decreased OS and increased incidence of NCI-CTC grade 3-5 (87% vs 72%) adverse reactions. NCI-CTC grade 3-4 adverse reactions occurring at a higher rate in Vectibix®-treated patients included rash/acneiform dermatitis (26% vs 1%), diarrhea (23% vs 12%), dehydration (16% vs 5%), primarily occurring in patients with diarrhea, hypokalemia (10% vs 4%), stomatitis/mucositis (4% vs < 1%), and hypomagnesemia (4% vs 0).

NCI-CTC grade 3-5 pulmonary embolism occurred at a higher rate in Vectibix®-treated patients (7% vs 3%) and included fatal events in three (< 1%) Vectibix®-treated patients. As a result of the toxicities experienced, patients randomized to Vectibix®, bevacizumab, and chemotherapy received a lower mean relative dose intensity of each chemotherapeutic agent (oxaliplatin, irinotecan, bolus 5-FU, and/or infusional 5-FU) over the first 24 weeks on study, compared with those randomized to bevacizumab and chemotherapy.

Vectibix® can cause fetal harm when administered to a pregnant woman. Advise pregnant women and females of reproductive potential of the potential risk to a fetus. Advise females of reproductive potential to use effective contraception during treatment, and for at least 2 months after the last dose of Vectibix®.

In monotherapy, the most commonly reported adverse reactions ($\geq 20\%$) in patients with Vectibix® were skin rash with variable presentations, paronychia, fatigue, nausea, and diarrhea.

The most commonly reported adverse reactions ($\geq 20\%$) with Vectibix® + FOLFOX were diarrhea, stomatitis, mucosal inflammation, asthenia, paronychia, anorexia, hypomagnesemia, hypokalemia, rash, acneiform dermatitis, pruritus, and dry skin. The most common serious adverse reactions ($\geq 2\%$ difference between treatment arms) were diarrhea and dehydration.

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