אפריל 2018

VECTIBIX (Panitumumab) 20 mg/ml

Concentrate for solution for infusion

רופא/ה נכבד/ה, רוקח/ת נכבד/ה,

אמג'ן אירופה בי וי, בעלת הרישום, מבקשת להודיעך על עדכונים בעלון לרופא לתכשיר וקטיביקס.

בהודעה זו מצוינים השינויים המהווים החמרה בלבד.

ההתוויות המאושרות:

In combination with chemotherapy for the treatment of unresectable, advanced or recurrent colorectal cancer (mCRC) with wild-type RAS.

Monotherapy for the treatment of patients with metastatic colorectal carcinoma with wild-type RAS after failure of fluoropyrimidine-, oxaliplatin-, and irinotecan-containing chemotherapy regimens.

החמרות בעלון לרופא:

4.8 Undesirable effects

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Tabulated summary of adverse reactions

The data in the table below describe adverse reactions reported from clinical studies in patients with mCRC who received panitumumab as a single agent or in combination with chemotherapy (n = 2,224) and spontaneous reporting. Within each frequency grouping, undesirable effects are presented in order of decreasing seriousness.

	Adverse reactions		
MedDRA system organ class	**Very common (≥ 1/10)**	**Common (≥ 1/100 to < 1/10)**	**Uncommon (≥ 1/1,000 to< 1/100)**
Infections and infestations	Conjunctivitis Paronychia[1]	Rash pustular Cellulitis[1] Urinary tract infection Folliculitis Localized infection	Eye infection Eyelid infection
Blood and lymphatic system disorders	Anemia	Leukopenia	
Immune system disorders		Hypersensitivity[1]	Anaphylactic reaction[2]
Metabolism and nutrition disorders	Hypokalemia Hypomagnesemia Decreased appetite	Hypocalcemia Dehydration Hyperglycemia Hypophosphatemia	
Psychiatric disorders	Insomnia	Anxiety	

	Adverse reactions		
MedDRA system organ class	**Very common (≥ 1/10)**	**Common (≥ 1/100 to < 1/10)**	**Uncommon (≥ 1/1,000 to< 1/100)**
Nervous system disorders		Headache Dizziness	
Eye disorders		Blepharitis Growth of eyelashes Lacrimation increased Ocular hyperemia Dry eye Eye pruritus Eye irritation	Ulcerative keratitis[1,4] Keratitis[1] Eyelid irritation
Cardiac disorders		Tachycardia	Cyanosis
Vascular disorders		Deep vein thrombosis Hypotension Hypertension Flushing	
Respiratory, thoracic and mediastinal disorders	Dyspnea Cough	Pulmonary embolism Epistaxis	Interstitial lung disease[3] Bronchospasm Nasal dryness
Gastrointestinal disorders	Diarrhea[1] Nausea Vomiting Abdominal pain Stomatitis Constipation	Rectal hemorrhage Dry mouth Dyspepsia Aphthous ulcer Cheilitis Gastroesophageal reflux disease	Chapped lips Dry lips
Skin and subcutaneous tissue disorders[1]	Dermatitis acneiform Rash Erythema Pruritus Dry skin Skin fissures Acne Alopecia	Skin ulcer Skin exfoliation Exfoliative rash Dermatitis Rash papular Rash pruritic Rash erythematous Rash generalized Rash macular Rash maculo-papular Skin lesion Skin toxicity Scab Hypertrichosis Onychoclasis Nail disorder Hyperhidrosis Palmar-plantar erythrodysesthesia syndrome	Toxic epidermal necrolysis[4] Stevens-Johnson syndrome[4] Skin necrosis[4] Angioedema[1] Hirsutism Ingrowing nail Onycholysis

	Adverse reactions		
MedDRA system organ class	**Very common (≥ 1/10)**	**Common (≥ 1/100 to < 1/10)**	**Uncommon (≥ 1/1,000 to< 1/100)**
Musculoskeletal and connective tissue disorders	Back pain	Pain in extremity	
General disorders and administration site conditions	Fatigue Pyrexia Asthenia Mucosal inflammation Edema peripheral	Chest pain Pain Chills	
Injury, poisoning and procedural complications			Infusion-related reaction[1]
Investigations	Weight decreased	Blood magnesium decreased	

[1] See section "Description of selected adverse reactions" below
[2] See section 4.4 Infusion-related reactions
[3] See section 4.4 Pulmonary complications
[4] Ulcerative keratitis, skin necrosis, Stevens-Johnson syndrome and toxic epidermal necrolysis are panitumumab ADRs that were reported in the post-marketing setting. For these ADRs the maximum frequency category was estimated from the upper limit of 95% confidence interval for the point estimate based on regulatory guidelines for estimation of the frequency of adverse reactions from spontaneous reporting. The maximum frequency estimated from the upper limit of 95% confidence interval for the point estimate, i.e., 3/2244 (or 0.13%).

העלון לרופא המעודכן נשלח לפרסום במאגר התרופות שאתר משרד הבריאות, וניתן לקבלו גם על-ידי פניה למפיץ המקומי של התרופה, חברת מדיסון פארמה.
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בברכה,

סיגל בן דור

רוקחת ממונה