

**BRAND NAME:** VECTIBIX**PROPER NAME:** Panitumumab**MANUFACTURER:** Amgen Incorporated

**INDICATION:** Vectibix is an epidermal growth factor receptor antagonist indicated as a single agent for the treatment of metastatic colorectal carcinoma with disease progression on or following fluoropyrimidine, oxaliplatin, and irinotecan chemotherapy regimens. Approval is based on progression-free survival; no data demonstrate an improvement in disease-related symptoms or increased survival with Vectibix.

**DESCRIPTION:** Vectibix (panitumumab) is a recombinant, human IgG2 kappa monoclonal antibody that binds specifically to the human epidermal growth factor receptor (EGFR). Panitumumab has an approximate molecular weight of 147 kDa.

**BLA NO:****REGULATORY MILESTONES:**

<b>US pre-BLA</b>	May 12, 2005
<b>US Approval</b>	September 27, 2006
<b>EU Approval</b>	December 3, 2007
<b>Health Canada Approval</b>	December 12, 2008
<b>TGA</b>	May 7, 2012

**ADVISORY COMMITTEE:****MANUFACTURING:**

PARAMETER	DATA	REFERENCE
<b>Manufacturer</b>	Amgen Incorporated	
<b>Indication</b>	Vectibix is an epidermal growth factor receptor antagonist indicated as a single agent for the treatment of metastatic colorectal carcinoma with disease progression on or following fluoropyrimidine, oxaliplatin, and irinotecan chemotherapy regimens. Approval is based on progression-free survival; no data demonstrate an improvement in disease-related symptoms or increased survival with Vectibix.	1
<b>Cell Substrate</b>	Genetically engineered mammalian (Chinese Hamster Ovary) cells.	3
<b>Manufacturing platform</b>	Panitumumab is produced from Chinese Hamster Ovary (CHO) cells and purified by a series of chromatography steps, viral inactivation step, viral filtration step and ultrafiltration/diafiltration steps. The expression plasmid containing the genes for the heavy and light chains was transfected into CHO cells. Following cloning and subcloning steps, one clone producing panitumumab at high levels was selected as lead cell line. A two-tiered cell banking system of Master Cell bank (MCB) and Working Cell Bank (WCB) has been developed and maintained in accordance to cGMP and ICH guidelines.	3
<b>Dose in vial/final container</b>	Single-use vials (20 mg/mL): 100 mg/5 mL, 200 mg/10 mL, 400 mg/20 mL.	1
<b>Dose to patient</b>	6 mg/kg every 14 days as an intravenous infusion over 60 minutes ( $\leq$ 1000 mg) or 90 minutes ( $>$ 1000 mg)	1

1. Package insert - [Vectibix](#)
2. EPAR full - [Vectibix](#)
3. EPAR quality - [Vectibix: EPAR - Scientific Discussion](#)
4. FDA Review - [Vectibix Panitumumab Injectable](#)

#### CLINICAL TRIALS:

NCT	TRIAL PHASE	NO OF PATIENTS ENROLLED	STUDY TITLE	COUNTRIES
<b><i>Monotherapy (Metastatic Colorectal Cancer (mCRC))</i></b>				
NCT00113763	3	463	<a href="#">Evaluating Panitumumab (ABX-EGF) Plus Best Supportive Care Versus Best Supportive Care in Patients with Metastatic Colorectal Cancer</a>	
NCT00113776	2	-	<a href="#">Evaluating ABX-EGF Extended Therapy in Subjects with Metastatic Colorectal Cancer</a>	
NCT00083616	2	185	<a href="#">Evaluating Panitumumab (ABX-EGF) Monotherapy in Patients with Metastatic Colorectal Cancer Following Treatment with Fluoropyrimidine, Irinotecan, and Oxaliplatin Chemotherapy</a>	
NCT00089635	2	203	<a href="#">Panitumumab (ABX-EGF) Monotherapy in Patients with Metastatic Colorectal Cancer</a>	
NCT00111774	2	150	<a href="#">Evaluating ABX-EGF in Patients with Metastatic Colorectal Carcinoma</a>	
<b><i>Solid Tumors</i></b>				
NCT00425204	2	31	<a href="#">Study for Patients Who Have Benefited and Tolerated Prior Panitumumab Treatment</a>	
NCT00091806	1	86	<a href="#">Two Dose Schedules of Panitumumab in Subjects with Advanced Solid Tumors</a>	
NCT00101920	2	50	<a href="#">ABX-EGF as Second Line Treatment of Advanced Non-Small-Cell Lung Cancer (NSCLC)</a>	
NCT00425035	2	115	<a href="#">Safety and Efficacy Study of ABX-EGF in Patients with Renal Cancer, Part 2</a>	
<b><i>Combination Therapy</i></b>				
NCT00111761	2	43	<a href="#">Evaluating Panitumumab (ABX-EGF) in Patients with Metastatic Colorectal Cancer</a>	

NCT00034346	2	194	<a href="#">ABX-EGF in Combination with Paclitaxel and Carboplatin for the Treatment of Advanced Non-Small-Cell Lung Cancer (NSCLC)</a>	
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**POST APPROVAL CHANGES**

<b>DATE</b>	<b>TYPE OF CHANGE</b>	<b>DESCRIPTION</b>	<b>LINK</b>