ZELBORAF® (vemurafenib) tablets | ACCESS SOLUTIONS®

ZELBORAF Sample Coding

Malignant Melanoma

TYPE	CODE		DESCRIPTION
Diagnosis: ICD-10-CM	C43.0*–C43.9		Malignant melanoma of skin, by site
Drug: NDC Note: Payer requirements regarding use of a 10-digit or 11-digit NDC may vary. Both formats are listed here for your reference.	**10-digit**	**11-digit**	
	50242-090-02	50242-0090-02	240 mg (112 film-coated tablets)

ICD-10-CM=International Classification of Diseases, 10th Revision, Clinical Modification.
NDC=National Drug Code.

Important Safety Information & Indication

Indication

Unresectable or Metastatic Melanoma

ZELBORAF® (vemurafenib) is indicated for the treatment of patients with unresectable or metastatic melanoma with BRAF V600E mutation as detected by an FDA-approved test.

Limitation of Use: ZELBORAF is not indicated for treatment of patients with wild-type BRAF melanoma.

Erdheim-Chester Disease

ZELBORAF® is indicated for the treatment of patients with Erdheim-Chester Disease (ECD) with BRAF V600 mutation.

Important Safety Information

WARNINGS AND PRECAUTIONS

The following can occur in patients treated with ZELBORAF:

- New primary malignancies including cutaneous squamous cell carcinoma, noncutaneous squamous cell carcinoma, new primary melanoma, and other malignancies
- Tumor promotion in BRAF wild-type melanomas
- Serious hypersensitivity reactions including anaphylaxis
- Severe dermatologic reactions including Stevens-Johnson syndrome and toxic epidermal necrolysis
- QT prolongation
- Hepatotoxicity including liver injury leading to functional hepatic impairment (including coagulopathy or other organ dysfunction); increases in transaminases and bilirubin when concurrently administered with ipilimumab
- Photosensitivity
- Ophthalmologic reactions
- Embryo-fetal toxicity
- Radiation sensitization and radiation recall, including fatal cases in patients with visceral involvement
- Renal failure, including acute interstitial nephritis and acute tubular necrosis
- Dupuytren's contracture and plantar fascial fibromatosis

DRUG INTERACTIONS

Avoid concurrent use of ZELBORAF with strong CYP3A4 inhibitors, strong CYP3A4 inducers, and CYP1A2 and P-glycoprotein substrates with a narrow therapeutic window.

USE IN SPECIFIC POPULATIONS

Lactation: Advise women not to breastfeed while taking ZELBORAF and for 2 weeks after the final dose.

Most Common Adverse Reactions

The most common adverse reactions of any grade (≥30%) reported were arthralgia (53%), rash (37%), alopecia (45%), fatigue (38%), photosensitivity reaction (33%), nausea (35%), pruritus (23%), and skin papilloma (21%).

You may report side effects to the FDA at (800) FDA-1088 or www.fda.gov/medwatch. You may also report side effects to Genentech at (888) 835-2555.

Please see accompanying Full Prescribing Information for additional Important Safety Information.