15 December 2021

Amgen Canada Inc. would like to inform you of a recent update to the Vectibix® (panitumumab for injection) Product Monograph to include keratorhexis (corneal perforation) as a post-market adverse reaction.

It is biologically plausible and has been long recognized that panitumumab, as an epidermal growth factor receptor (EGFR) inhibitor, may increase the risk of corneal pathology. Keratorhexis (corneal perforation) is a more severe manifestation of the known risks of keratitis and ulcerative keratitis but may develop in the absence of these conditions. The Product Monograph describes the risk of keratitis and ulcerative keratitis with panitumumab use. Cases of corneal perforation with panitumumab use have been reported so keratorhexis (corneal perforation) has been added as a post-market adverse reaction.

Patients who develop ocular toxicities while receiving VECTIBIX should be monitored for evidence of keratitis, ulcerative keratitis, or corneal perforation. Depending on the severity and/or persistence of the event, interrupt or discontinue VECTIBIX. VECTIBIX should be used with caution in patients with a history of keratitis, ulcerative keratitis or severe dry eye. It is important to note that contact lens use is a risk factor for corneal inflammation and ulceration.

VECTIBIX, a recombinant, fully human IgG2 monoclonal antibody that binds specifically to the human EGFR, is indicated:

- for the treatment of previously untreated patients with non-mutated (wild-type) *RAS* metastatic colorectal carcinoma (mCRC) in combination with FOLFOX (infusional 5-fluorouracil, leucovorin, and oxaliplatin).
- as monotherapy for the treatment of patients with non-mutated (wild-type) *RAS* mCRC after failure of fluoropyrimidine-, oxaliplatin-, and irinotecan-containing chemotherapy regimens.

The benefit-risk profile remains favourable in the approved indications and serious adverse events of corneal perforation will continue to be monitored through routine pharmacovigilance.

For additional questions, please contact Amgen Medical Information at 1-866-502-6436.

Report health or safety concerns
Managing marketed health product-related side effects depends on healthcare professionals and consumers reporting them. Any case of keratorhexis (corneal perforation) or other serious or unexpected side effects in patients receiving VECTIBIX should be reported to Amgen Canada Inc. or Health Canada. [E-mail: CanadaVigilance@hc-sc.gc.ca].

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Safety e-mail: safetycanada@amgen.com

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Sincerely,

Suna Avcil, MD
Executive Medical Director
AMGEN Canada Inc.