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16 May 2011

Vectibix®: DHPC EU

Direct Healthcare Professional Communication on the association of Vectibix® (panitumumab) with keratitis and ulcerative keratitis.

Dear Healthcare Professional

Summary

- **Serious cases of keratitis and ulcerative keratitis have been rarely reported in the post-marketing setting.**
- **Keratitis and ulcerative keratitis can lead to permanent visual impairment. Ulcerative keratitis is an ophthalmological emergency.**
- **Patients presenting with acute or worsening signs and symptoms suggestive of keratitis such as:**
  - **eye inflammation**
  - **increased lacrimation**
  - **light sensitivity**
  - **blurred vision**
  - **eye pain**
  - **red eye**

  while receiving Vectibix® should be referred promptly to an ophthalmology specialist.
- **If a diagnosis of ulcerative keratitis is confirmed, treatment with Vectibix® should be interrupted or discontinued.**
- **If keratitis is diagnosed, the benefits and risks of continuing treatment should be carefully considered.**
- **Vectibix® should be used with caution in patients with a history of keratitis, ulcerative keratitis or severe dry eye. Contact lens use is also a risk factor for keratitis and ulceration.**

The information in this communication has been agreed with the European Medicines Agency and the Irish Medicines Board.

Further Information on the Safety Concern

Vectibix® is indicated as monotherapy for the treatment of patients with EGFR expressing metastatic colorectal carcinoma with non-mutated (wild-type) *KRAS* after

failure of fluoropyrimidine-, oxaliplatin-, and irinotecan-containing chemotherapy regimens.

Since Vectibix® was licensed in 2007, one serious case of keratitis and three serious cases of ulcerative keratitis have been identified in patients treated with Vectibix® monotherapy. In one case, ulcerative keratitis led to blindness in one eye and severe loss of vision in the other eye. There have been reports of keratitis and ulcerative keratitis with other EGFR inhibitors.

In clinical trials, seven non-serious cases of keratitis were reported in patients receiving Vectibix® with an incidence rate between 0.2% and 0.7%.

Keratitis may cause corneal scarring and permanent visual loss and is a known risk factor for ulcerative keratitis. Ulcerative keratitis (corneal ulcer) may lead to corneal perforation and permanent visual impairment.

The product information for Vectibix® has been updated with information on keratitis and ulcerative keratitis (see Annex).

Reporting of suspected adverse reactions with the use of Vectibix®

Any suspected adverse reactions should be reported to the Pharmacovigilance section of the Irish Medicines Board (via post or using the on-line form available at www.imb.ie) or alternatively to Amgen Europe B.V. by contacting Amgen UK/Ireland Drug Safety Department directly on 00 44 1223 436712.

Communication Information

Should you have any questions or require additional information regarding the use of Vectibix®, please contact Amgen UK/Ireland Medical Information on 00 44 1223 436441 or by email to gbinfoline@amgen.com.

Yours sincerely,

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