Amgen Middle East FZ LLC
P.O. Box 502607
Office 2007
Business Central Tower A
Dubai Media City
Dubai, United Arab Emirates
www.amgen.com

Date: 27th May 2014

Dear Health Care Professional,

Title: Rare cases of Stevens-Johnson syndrome and toxic epidermal necrolysis have been reported in patients treated with Vectibix®/TM (panitumumab)

Summary

The purpose of this communication is to inform you that as part of Amgen's regular safety review, rare (≥1/10,000 patients and <1/1000 patients) cases of Stevens-Johnson syndrome (SJS) and toxic epidermal necrolysis (TEN) have been reported in patients treated with Vectibix.

Action being taken by Amgen

To communicate the risk of SJS and TEN, Amgen is proposing to update the Vectibix prescribing information to include SJS and TEN within the Special Warnings and Precautions for use section as well as Undesirable effects section.

Recommendation

Withhold or discontinue Vectibix if SJS or TEN are suspected.

Further Information

Panitumumab is a fully human IgG2 monoclonal antibody that is directed against the human epidermal growth factor receptor (EGFR). Cutaneous events such as skin exfoliation, exfoliative rash, erythema, skin necrosis and mucosal events such as stomatitis and mucosal inflammation have previously been reported with the administration of panitumumab. Serious complications that have been observed include events of cellulitis, necrotizing fasciitis (some with a fatal outcome), and other soft tissue complications.

Healthcare professionals should monitor their patients for dermatologic and soft tissue signs or symptoms and consider withholding or discontinuing VECTIBIX in patients with severe or life-threatening and inflammatory or infectious complications.

This letter is being sent with the agreement of Saudi Food and Drug Authority (SFDA).

Amgen Middle East FZ LLC
P.O. Box 502607
Office 2007
Business Central Tower A
Dubai Media City
Dubai, United Arab Emirates
www.amgen.com

Call for Reporting:

Any suspected adverse reactions should be reported immediately to local Amgen representative or the National Pharmacovigilance and Drug Safety Center

Amgen Local Representative in Saudi Arabia is Cigalah Group, Fax: 00966126578861
or email: drug-safety@cigalah.com.sa

The National Pharmacovigilance & Drug safety Centre (NPC)
Saudi Food and Drug Authority (SFDA)
Fax: +966-11-2057662
Email: npc.drug@sfda.gov.sa
Online: http://ade.sfda.gov.sa/

Should you have any questions or require additional information regarding the use of Vectibix, please contact Amgen Medical Information on 00971 4 4396800 or by e-mail at meamedinfo@amgen.com

Sincerely,

Adel Djalal
Director Regulatory Affairs & Safety
Amgen Middle East & North Africa

Tamer Saad
Medical Director
Amgen Middle East & North Africa