فرع شركة أمجن أوروبا جي أم بي إتش
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Direct Health Care Professional Communication

Date: June 2017

Title: Aranesp® (darbepoetin alfa) – New Safety Information: Risk of Severe Skin Reactions: Stevens - Johnson syndrome and Toxic Epidermal Necrolysis

Dear Healthcare Professional,

Amgen would like to inform you about the risk of severe cutaneous reactions in patients receiving Aranesp.

Summary of the safety issue

Blistering and skin exfoliation including Erythema multiforme and Stevens-Johnson syndrome (SJS)/Toxic Epidermal Necrolysis (TEN), have been reported very rarely in patients treated with Aranesp in the post-marketing environment.

Summary of Recommendations for Healthcare Professionals

Due to the potential severity of this reaction, healthcare professionals are advised to discontinue Aranesp therapy immediately if a severe cutaneous reaction, such as SJS/TEN, is suspected. Because severe cutaneous adverse reactions have been seen with other ESAs and are not easily predictable, switching to another ESA is not recommended.

Further Information About the safety issue

Since Aranesp was first commercially available in May 2001, it is estimated there is over 6.1 million patient-years of exposure to Aranesp. During this time, there have been a small number of cases reported in the post-marketing setting.

For detailed information regarding Aranesp, it is essential that you read the Aranesp prescribing information and patient information leaflet.

Action being taken by Amgen

Amgen is proposing to include severe cutaneous reactions in the Warnings and Precautions and Undesirable Effects sections of the Aranesp prescribing information and patient information leaflet.

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The information in this letter has been approved by the Saudi Food and Drug Authority (SFDA).

Contact details for adverse event reporting or to request further information

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

Amgen Local QPPV in Saudi Arabia is Yasser Al Ahmary,

Tel #: +966 112 799328
E-mail: ymohamma@amgen.com

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 Aranesp, please contact Medical Information by e-mail at: meamedinfo@amgen.com

Sincerely,

Nasser Alrajhi
Regulatory Affairs Senior Manager
Amgen Saudi Arabia

Yasser Al Ahmary
Senior Associate Global Safety
Amgen Saudi Arabia

Tarek Nassar
Medical Director
GCC,Egypt Cluster