فرع شركة جونسون أند جونسون ميدل إيست

Direct Healthcare Professional Communication

4-Feb-2018

Eprex (epoetin alfa): new warnings on severe cutaneous adverse reactions

Dear Healthcare Professional,

Janssen Pharmaceutical company, the Marketing Authorization Holder (MAH) of Eprex (epoetin alfa), in agreement with the Saudi Food and Drug Authority would like to inform you of the risk of severe cutaneous adverse reactions in patients treated with **epoetin alfa**.

Summary

- Severe cutaneous adverse reactions (SCARs) have been reported in patients treated with epoetins. These included cases of Stevens-Johnson syndrome (SJS) and toxic epidermal necrolysis (TEN) some of which have been fatal.
- Severe cutaneous adverse reactions are considered to be a class effect of all epoetins.
- The reactions have been more severe with long-acting epoetins.
- The frequency of these severe cutaneous reactions could not be calculated, but they occur very rarely.
- Patients should be advised of the following signs and symptoms of severe skin reactions when starting treatment with an epoetin product:
    - widespread rash with reddening and blistering of the skin and oral mucosa, eyes, nose, throat, or genital area, which follow flu-like symptoms including fever, tiredness, muscle and joint pain. This often leads to peeling and shedding of the affected skin which looks like a severe burn
- **Patients who develop these signs and symptoms should be instructed to contact their doctor immediately and stop epoetin treatment.**
- If the patient has developed a severe cutaneous adverse reaction such as SJS or TEN, which is considered to be related to the use of an epoetin, the patient **must never** be given an epoetin again.

Background of the safety concern

Following post-marketing reports of severe cutaneous adverse reactions, in particular SJS, TEN and blistering and exfoliative reactions with some epoetins, a detailed analysis of all cases has been performed by the European Medicines Agency's Pharmacovigilance Risk Assessment Committee (PRAC) for all epoetin-containing medicines.

This analysis has revealed that severe cutaneous reactions including SJS and TEN can be considered a class risk for all epoetins. The more severe reactions were reported with long-acting epoetins and included cases with positive dechallenge and positive rechallenge.

The frequency of these severe cutaneous reactions could not be calculated, but they occur very rarely.

The product information of Eprex (epoetin alfa) will be updated to reflect the risk of severe cutaneous adverse reactions.

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رقم السجل التجاري: ١٠١٠٦٠٩٥٦٧ ـ رقم العضوية: ٤١٥٠٠٤
مركز موهبة ـ الطابق الثالث ـ شارع العليا ـ حي الورود
الرياض المملكة العربية السعودية ص. ب ٥٥٠٣١ الرياض ١١٥٣٣
هاتف: ٤١٩٧٩٦٦ ١١ ٩٦٦+ فاكس: ٢١٥٣١٩٠ ١١ ٩٦٦+

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Call for reporting

Health Care professionals are reminded to continue to report suspected adverse reactions associated with this product in accordance with the national spontaneous reporting system.

SFDA (National Pharmacovigilance and Drug Safety Department)
Email to: npc.drug@sfda.gov.sa
Fax: +966-11-2057662
Online: http://ade.sfda.gov.sa

If you have further questions or require additional information, please contact our Local Safety Department at:
Email: GCC-PV2@its.jnj.com
Fax: +966-11-2153190

Yours faithfully,

4 Feb 2018

Hesham Atef
Medical Affairs Director-GCC

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