NOVARTIS

Our ref :

Date : 29/05/2018

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التاريخ : ١٨-٠٥-١٥٠٠
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Direct Healthcare Professional Communication

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

Dear Healthcare Professional,

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

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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 BINOCRIT (epoetin alfa) will be updated to reflect the risk of severe cutaneous adverse reactions.

Call for reporting
Please report any suspected adverse reactions associated with the use of epoetins in accordance with the national requirements via the national spontaneous reporting system, to:

Novartis Consulting AG, Patient Safety Department:
Saudi Arabia: P.O. Box 16032, Riyadh 11464, Tel: +966114658882
Phone: +996112658100
Mobile: 0545544426 or 0508035430
Fax: +966112658107
Email: adverse.events@novartis.com

National Pharmacovigilance and Drug Safety Center:
Toll free phone: 8002490000
Fax: +966112057662
E-mail: npc.drug@sfda.gov.sa
Or by online: https://ade.sfda.gov.sa

Yours faithfully,

29/05/2018

Malak Alowais
Patient Safety Head Deputy (QPPV)
Sandoz Saudi Arabia

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