janssen

IMPORTANT MEDICINE SAFETY INFORMATION

26 April 2018

Dear Healthcare Professional

Re: EPREX® (EPOETIN ALFA): New warnings on severe cutaneous adverse reactions

In collaboration with the South African Health Products Regulatory Authority (SAHPRA), JANSSEN PHARMACEUTICA (PTY) LTD, would like to inform you of the risk of severe cutaneous adverse reactions in patients treated with Eprex®.

Summary

- Severe cutaneous adverse reactions (SCARs) have been reported in patients treated with Eprex®. 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; including Eprex®.
- The frequency of these severe cutaneous reactions could not be calculated, as they occur rarely.
- Patients should be advised of the following signs and symptoms of severe skin reactions when starting treatment with Eprex®:
    - 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, including Eprex® again.

JANSSEN PHARMACEUTICA (PTY) LTD.
(Reg. No. 1980/011122/07)
Building 6
Country Club Estate
21 Woodlands Drive
Woodmead 2191, South Africa
785939
Sandton
2146
South Africa
(011) 518-7000
Orders: PHD 0860-655-600
Telefax: (011) 518-7104
www.janssen.co.za

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, including Eprex® a detailed analysis of all cases (including data from the EudraVigilance database and data from the Marketing Authorisation Holders) 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, including Eprex®. The more severe reactions were reported with long-acting epoetins and included cases with positive dechallenge and positive rechallenge.

The local package insert of Eprex® (epoetin alfa) has been updated to reflect the risk of severe cutaneous adverse reactions.

Additional Information for Healthcare Professionals

If you have any questions or require further information, please contact Janssen Medical Information Centre on 011 518 7169 or 0860 111 117 or email RA-JACZA-MedInfo@its.jnj.com.

Any suspected adverse reactions associated with the use of epoetin can be reported to Janssen Pharmaceutica (Pty) Ltd or alternatively to the NADEMC (National Adverse Drug Event Monitoring Centre) or SAHPRA Pretoria Office, indicated below:

COMPANY	CONTACT DETAILS
Janssen Pharmaceutica (Pty) Ltd	**Tel:** 011 518 7000 **Fax:** 011 518 7104 E-mail: AdverseEventZA@its.jnj.com
National Adverse Event Monitoring Centre (NADEMC):	**Tel:** 021 447 1618 **Fax:** 021 448 6181
SAHPRA Pretoria Office, Pharmacovigilance Unit	**Tel:** 011 385 8176 **Fax:** 012 395 8775

Yours sincerely

ABEDA WILLIAMS

Technical and Medical Director