PHARMACOSMOS
Committed to Quality

13th October 2020

Dear Healthcare professional

Monofer 100mg/ml solution for injection/infusion▼ and Diafer 50mg/ml solution for injection▼: name change from iron isomaltoside to ferric derisomaltose

Pharmacosmos in agreement with the MHRA would like to inform you of the following:

Summary

- We are changing the generic name for Monofer▼ and Diafer▼ from iron isomaltoside 1000 to ferric derisomaltose to align the nomenclature globally and with the International Nonproprietary Name (INN)
- Pharmacosmos has already filed for this change and expect regulatory approval in September 2020
- Newly labelled stock will be available in the UK towards the end of 2020
- Ferric derisomaltose should not be confused with ferric carboxymaltose

Background for the change of generic name:

Monofer and Diafer were initially approved by the Swedish authorities under the generic name ***iron isomaltoside 1000*** in 2009. In the following years many registrations were issued using this generic name. Since then the World Health Organisation (WHO) decided the INN (International Nonproprietary Name) of Monofer and Diafer should be changed to ***ferric derisomaltose.*** The new generic name is already in use in the US, Germany and Australia when the product was launched in these countries. We expect that this generic name will be mandated for use in most new registrations.

Future scientific publications will mainly use the ***ferric derisomaltose*** name and guidelines are likely to do the same. The existence of two different generic names may cause increasing confusion hence our decision to proactively change the generic name to ***ferric derisomaltose*** in all relevant countries in the future, including the UK.

Only the generic name has changed and the medicines remain identical to those available before this action.

Monofer 100mg/ml solution for injection/infusion and Diafer 50mg/ml solution for injection are different formulations of the same active ingredient – ferric derisomaltose (previously **iron isomaltoside 1000**).

Monofer is indicated for the treatment of iron deficiency when oral iron preparations are ineffective or cannot be used and where there is a clinical need to deliver iron rapidly.

Diafer is indicated in adults for the treatment of iron deficiency in patients with chronic kidney disease on dialysis, when oral iron preparations are ineffective or cannot be used.

Call for reporting

Monofer▼ and Diafer▼ are subject to additional monitoring. This will allow quick identification of new safety information.

Please continue to report suspected adverse drug reactions (ADRs) to the MHRA through the Yellow Card Scheme.

It is easiest and quickest to report ADRs online via the Yellow Card website - https://yellowcard.mhra.gov.uk/ or via the Yellow Card app available from the Apple App Store or Google Play Store.

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Alternatively, prepaid Yellow Cards for reporting are available:

- by writing to FREEPOST YELLOW CARD (no other address details necessary)
- by emailing yellowcard@mhra.gov.uk
- at the back of the British National Formulary (BNF)
- by telephoning the Commission on Human Medicines (CHM) free phone line: 0800-731-6789
- by downloading and printing a form from the Yellow Card website (see link above)

When reporting please provide as much information as possible, including information about medical history, any concomitant medication, onset, treatment dates, and product brand name.

If you do have any questions please feel free to contact support@pharmacosmos.co.uk or call customer service at 01844 269007.

Kind regards

Ruth Currie
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