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Committee for Medicinal Products for Human Use (CHMP)

Scientific conclusions and grounds recommending the variation to the terms of the marketing authorisation

International non-proprietary name: deferasirox

Procedure No. EMEA/H/C/PSUSA/00000939/201410

Period covered by the PSUR: 01 November 2013 – 31 October 2014

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Scientific conclusions

Taking into account the PRAC Assessment Report on the PSUR for deferasirox, the scientific conclusions of CHMP are as follows:

During the reporting period the Marketing Authorisation Holder (MAH) detected cases of anaphylactic shock which were further investigated due to their potential seriousness.

Twenty-one (21) cases (excluding 2 duplicate cases) were reported with anaphylactic shock (n=5), anaphylaxis (n=12) and hypersensitivity reactions (n=4). Among the 5 cases of anaphylactic shock identified by the MAH, the role of Exjade could be excluded in 2 cases. Among the 3 remaining cases, 2 had history of hypersensitivity of deferasirox. For the last case, anaphylactic shock and chronology are not clearly detailed. Lastly, another case was reported in a 12 year-old child with positive rechallenge.

Anaphylactic reactions and hypersensitivity are already mentioned in the summary of product characteristics (SmPC). Given these 3 cases of anaphylactic shock which occurred after reintroduction of deferasirox, despite a first hypersensitivity reaction, and given the potential seriousness of anaphylactic shock, section 4.4 of the SmPC should be amended to reinforce that Exjade should not be reintroduced in patients who have experienced previous hypersensitivity reactions as anaphylactic shock can occur.

Therefore, in view of available data regarding anaphylactic shock, the PRAC considered that changes to the product information were warranted.

The CHMP agrees with the scientific conclusions made by the PRAC.

Grounds recommending the variation to the terms of the Marketing Authorisation

On the basis of the scientific conclusions for deferasirox the CHMP is of the opinion that the benefit-risk balance of the medicinal product containing deferasirox is favourable subject to the proposed changes to the product information.

The CHMP recommends that the terms of the Marketing Authorisation should be varied.