EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Committee for Medicinal Products for Human Use (CHMP)

Scientific conclusions and grounds for the variation to the terms of the marketing authorisation(s)

Active substance(s): deferiprone

Procedure No. EMEA/H/C/PSUSA/00000940/201608

Period covered by the PSUR: 01/09/2015 - 31/08/2016

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Scientific conclusions

Taking into account the PRAC Assessment Report on the PSUR(s) for deferiprone, the scientific conclusions of the CHMP are as follows:

During the review period of this PSUR (01/09/2015 - 31/08/2016), one relevant case has led to vary the terms of the MA:

Neurological disorders

A relevant case of neurological disorders in the literature (Economou M and al, 20161) has been identified: it concerns a 9 year-old girl with transfusion-dependent thalassaemia experiencing myalgia, arthralgia, behavioural changes, anxiety, hypotonia, inability to walk, hypertonia, dysthymia and loss of appetite during treatment with deferiprone. This girl had been receiving deferiprone at

75 mg/kg/day since the age of 7 years. Concomitantly, she received deferoxamine. The patient recovered after deferiprone discontinuation. She was symptom-free within 7 months under deferoxamine. When deferiprone was restarted due to serum ferritin (SF) increase, hypertonia and walking disability reoccurred within a few weeks. Her condition improved after permanent deferiprone discontinuation. Based on this relevant case and considering that this issue had already been closely monitored since the previous PSUR, an update of the product information has been recommended, adding a statement on the risk of “neurological disorders at recommended doses in children” under the recommended dose in sections 4.4 and 4.8 of the SmPC. The PL was updated accordingly.

Therefore, in view of the data presented in the reviewed PSUR, the PRAC considered that changes to the product information of medicinal products containing deferiprone were warranted.

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

Grounds for the variation to the terms of the Marketing Authorisation(s)

On the basis of the scientific conclusions for deferiprone the CHMP is of the opinion that the benefit- risk balance of the medicinal product(s) containing deferiprone is unchanged subject to the proposed changes to the product information.

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

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