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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): deferasirox

Procedure No. EMEA/H/C/PSUSA/00000939/201510

Period covered by the PSUR: 01 Nov 2014 - 31 Oct 2015

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Scientific conclusions

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

Acute pancreatitis
A total of 78 cases of acute pancreatitis in children with Exjade have been retrieved during the clinical review cumulatively. A total of 40 cases were excluded from analysis as they contained only hepatic events or non-specific abdominal pain, without a diagnosis of pancreatitis or elevated serum lipase and/or amylase. Out of the remaining 38 cases, the PRAC observed that deferasirox could not be excluded from potential causality in 3 cases.
Toxic Epidermal Necrolysis (TEN)
During the reporting period, one (1) case report which concerned a 71 year-old male patient with myelodysplastic syndromes (MDS), who developed progressive erythematous, blistering rash with pustular component on the trunk four (4) weeks after commencing Exjade therapy, has been identified in the literature. Given the reviewed literature, causal association with deferasirox could not be ruled out.
Therefore, in view of the data presented in the reviewed PSUR, the PRAC considered that changes to the product information of medicinal products containing deferasirox were warranted.
The risk of TEN has been classified as an important identified risk Exjade EU RMP (V12).
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 deferasirox the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing deferasirox 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.