26 June 2014
EMA/CHMP/610925/2014
Committee for Medicinal Products for Human Use (CHMP)

Exjade

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

International non-proprietary name: deferasirox

Procedure No.: EMEA/H/C/000670/PSUV/0037

Period covered by the PSUR: 01 November 2012 – 31 October 2013

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Scientific conclusions

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

The PRAC continues to be strongly concerned by the renal safety profile of Exjade, particularly in paediatric patients. This risk is already addressed in the risk management plan with wording in the SmPC; the PRAC however considers that the SmPC wording should be further strengthened with the specific term “renal tubular necrosis” added to section 4.8. In addition, based on the data provided, the risk of “nephrolithiasis” should also be added to the section 4.8 of the SmPC.

In order to ensure that physicians follow the recommendations regarding the risk of gastric ulcer and digestive haemorrhage, a warning on the risk of gastrointestinal perforation should be added to section 4.4 the SmPC.

The risk of “metabolic acidosis” should be added to section 4.4 and 4.8 of the SmPC with a frequency of unknown.

Section 4.4 of the SmPC should be updated to include information on the risk of severe skin reactions in light of these being added to the RMP as an important potential risk.

During the reporting period, one new case of optic neuritis was reported. This risk is listed as an identified risk in the RMP and should be added to section 4.8 with a frequency of rare.

The PRAC recommends the addition of “neutropenia” to section 4.8 of the SmPC with a frequency of “not known” due to the significant number of cumulative events.

Therefore, in view of available data regarding deferasirox, 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 Exjade, the CHMP is of the opinion that the benefit-risk balance of the medicinal product containing the active substance 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.

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