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): dexamethasone (centrally authorised product indicated in symptomatic multiple myeloma)

Procedure No. EMEA/H/C/PSUSA/00010480/201809

Period covered by the PSUR: 17 September 2017 – 16 September 2018

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Scientific conclusions

Taking into account the PRAC Assessment Report on the PSUR(s) for dexamethasone (centrally authorised product indicated in symptomatic multiple myeloma), the scientific conclusions of CHMP are as follows:

In the previous PSUR reporting period, a relevant publication describing a case of tumour lysis syndrome (TLS) that occurred under dexamethasone monotherapy, with suggestive time to onset and without confounding factor or concomitant treatment, was reported. During this PSUR reporting (17 September 2017 to 16 September 2018), 3 poorly documented cases of TLS have been identified by the MAH following a search in the global safety database. In addition, the MAH identified 2 case reports and 4 studies in the literature. In the 2 case reports, the timing of TLS coincided with administration of new therapeutic agents. In the 4 studies there was little information regarding the TLS and dexamethasone was used along with other chemotherapeutic agents known to be associated with the risk of TLS.

The PRAC has already recommended for all oral and parenteral formulations of dexamethasone, the addition of a warning regarding the risk of TLS in patients with haematological malignancies following the use of dexamethasone alone or in combination with other chemotherapeutic agents.

Based on the above considerations, it is recommended to update section 4.4 of the Neofordex SmPC with addition of a warning regarding the risk of tumour lysis syndrome, in line with changes introduced for other dexamethasone products in systemic formulations. The PL should be updated accordingly.

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 dexamethasone (centrally authorised product indicated in symptomatic multiple myeloma) the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing dexamethasone (centrally authorised product indicated in symptomatic multiple myeloma) 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.