25 April 2014
Committee for Medicinal Products for Human Use (CHMP)

Javlor

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

International non-proprietary name: vinflunine

Procedure No. EMEA/H/C/000983/PSUV/0015

Period covered by the PSUR: 22.09.12 – 21.09.13

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Scientific conclusions

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

The safety information that became available in this reporting period is generally consistent with the known safety profile of vinflunine. Although no new safety concerns have been identified, the MAH proposed two changes to the product information.

The MAH has proposed to add a warning to section 4.4 of the SmPC regarding the risk of hyponatraemia, including cases that are due to syndrome of inappropriate antidiuretic hormone secretion, which was identified as a risk in the previous PSUR and included in the SmPC as a listed adverse reaction. Given the high frequency of grade 3 or 4 events of hyponatraemia (11.7 %), which includes a fatal outcome, the adverse impact of hyponatraemia on survival in cancer patients and the potential for it to cause serious CNS sequelae (e.g. confusion, seizures), this proposal was endorsed.

Finally, the MAH has proposed minor amendments to the list of adverse reactions in section 4.8 of the SmPC in order to ensure consistency in how these reactions are coded. The changes do not impact on the frequency categories for the listed ADRs apart from “peripheral sensory neuropathy” which is upgraded from common to very common and “tumour pain”, which is now categorised as uncommon (previously its frequency was not known). No new ADRs have been added and no ADRs have been removed, other than “anorexia” which has been re-classified as “decreased appetite”. These changes are considered acceptable.

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 Javlor, the CHMP is of the opinion that the benefit-risk balance of the medicinal product containing the active substance VINFLUNINE DITARTRATE is favourable subject to the proposed changes to the product information.

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