



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Committee for Medicinal Products for Human Use (CHMP)

Siklos

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

International non-proprietary name: hydroxycarbamide

Procedure No. EMEA/H/C/000689/PSUV/0020

Period covered by the PSUR: 29.06.2012 to 28.06.2013



Scientific conclusions

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

“Preliminary results of the HYDREP study were provided in March 2013. Sperm results were available for the majority of patients: 63% of the trial population, corresponding to 31 patients of the 49 patients included, for whom follow-up sperm results after 6 months of hydroxycarbamide treatment were available. The preliminary results show that there is a statistically significant impairment in all sperm parameters after a 6 months HU therapy. The rapporteur acknowledges that these results may vary with the final analysis. However they are evocative of a risk of male fertility impairment after 6 months of treatment with SIKLOS. In view of available data, the PRAC considers that the changes to the product information proposed by the MAH should be amended. The frequency of azoospermia and oligospermia in the SmPC/PL should be changed from “very rare” to “very common”. The proposed changes to sections 4.6 and 4.8 of the SmPC and the leaflet are detailed in Annex 1 of this assessment report. However, a further update to the SmPC might be needed, if final study results become available in 2014.”

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