



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): clofarabine

Procedure No. EMEA/H/C/PSUSA/00000805/201912

Period covered by the PSUR: 14 November 2019 – 28 December 2019



Scientific conclusions

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

Several cases reporting non-filtration of Evoltra were identified during the reporting period. No safety signal emerged from these cases, however regarding the theoretical risk of presence of particles that may lead to adverse reactions or product neutralisation when filtration is omitted, and the fact that some cases of omission of filtration during drug preparation have also been reported in the European Union during the review period, the PRAC is of opinion that the product information of clofarabine products should be updated to explicit the need of filtration.

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 clofarabine the CHMP is of the opinion that the benefit-risk balance of the medicinal product(s) containing clofarabine 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.