



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

28 February 2019
EMA/258063/2019
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): asparaginase (centrally authorised product)

Procedure No. EMEA/H/C/PSUSA/00010445/201807

Period covered by the PSUR: 15 January 2018 – 14 July 2018



Scientific conclusions

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

To aid traceability of rASNase batches and distinction between different ASNase and rASNase products, the product information should include in section 4.4 of the SmPC and relevant section of the PL a prominent statement that the name and batch number of the administered product should be clearly recorded in the patient records.

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