



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

20 February 2014  
EMA/383579/2014  
Committee for Medicinal Products for Human Use (CHMP)

## Elaprase

International non-proprietary name: idursulfase

Procedure No. EMEA/H/C/000700/PSUV/0047

Period covered by the PSUR: 24 July 2012 to 23 July 2013

### **Scientific conclusions and grounds recommending the variation to the terms of the Marketing Authorisation**



## **Scientific conclusions**

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

During the previous PSUR period updates were made to the CCDS and SmPC regarding the relationship between antibody status and clinical efficacy and safety. In particular, a warning was included in section 4.4 of the SmPC regarding that patients with the complete deletion/large rearrangement genotype tend to show a muted response to treatment. On review of the information in the current CCDS it is noted there is further information included regarding this subgroup of patients, in particular that patients with this genotype also have a higher probability of developing infusion-related adverse events. This increased risk is also acknowledged in the information included in the present PSUR. To bring the EU product information in-line with the known safety profile of IV Idursulfase, the MAH is requested to update the warning in section 4.4 of the SmPC to include this point. This additional information should also be added under the "Description of selected adverse reactions in section 4.8 of the SmPC with a cross reference to section 4.4. The package leaflet should be updated accordingly.

In view of available data regarding IV Idursulfase, the PRAC considered that these changes to the product information were warranted.

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

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