10 April 2014
EMA/394323/2014
Committee for Medicinal Products for Human Use (CHMP)

Cayston

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

International non-proprietary name: aztreonam

Procedure No.: EMEA/H/C/PSUSA/00000283/201309

Period covered by the PSUR: 12.03.2013 to 11.09.2013

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Scientific conclusions

Taking into account the PRAC Assessment Report on the PSUR for aztreonam lysine nebuliser solution (Cayston), the scientific conclusions of the CHMP are as follows:

- The sections 4.4 and 4.8 of the SmPC of Cayston state: "The following rare and severe adverse reactions have not been observed to date with Cayston, but have been reported after parenteral use of other aztreonam containing products: toxic epidermal necrolysis, anaphylaxis, purpura, erythema multiforme, exfoliative dermatitis, urticaria, petechiae, pruritus, diaphoresis."

  In the periods covered by this as well as previous PSURs, several reports of pruritus, urticaria, and erythema have been received in relation to Cayston. Therefore, the MAH is requested to amend the aforementioned statement in the sections 4.4 and 4.8 as follows:

  "The following rare and severe adverse reactions ~~have not been observed to date with Cayston, but~~ have been reported after parenteral use of other aztreonam containing products: toxic epidermal necrolysis, anaphylaxis, purpura, erythema multiforme, exfoliative dermatitis, urticaria, petechiae, pruritus, diaphoresis."

In the next PSUR:

- The MAH is requested to provide a brief clinical evaluation of new cases regarding hypersensitivity reactions (pruritus, urticaria, erythema nodosum, etc.) that are not listed in the EU-SmPC, under the PSUR section "new information on important potential risks" to assist the assessment process.
- The MAH is requested to continue to report on fatal cases and the reporting trend for fatal outcomes in the future PSUR periods.
- The MAH is requested to regard the dizziness as an on-going signal and to re-evaluate it in the next PSUR.

The next PSUR (covering one year period) for Cayston should be submitted in accordance with the requirements set out in the list of Union reference dates (EURD list) provided for under Article 107c(7) of Directive 2001/83/EC and published on the European medicines web-portal.

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

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