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Committee for Medicinal Products for Human Use (CHMP)

Methylthioninium chloride Proveblue

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

Active substance(s): methylthioninium chloride

Procedure No.: EMEA/H/C/PSUSA/00002029/201505

Period covered by the PSUR: 06 May 2014 to 05 May 2015

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Scientific conclusions

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

Injection site pain

In an MAH sponsored phase I clinical study a total of 12/70 subjects experienced 'infusion site pain' after receiving an intravenous infusion of methylthioninium chloride.

'Infusion site pain' has also been observed post-marketing including two reports identified in the scientific literature.

Overall, in this study a total of 17/117 subjects experienced 'injection site reactions (including discomfort and pain)' after receiving an intravenous infusion of methylthioninium chloride.

Pain in extremity

Across two MAH sponsored clinical trials, a total of 94/117 subjects experienced 'pain in extremity' after receiving an intravenous infusion of methylthioninium chloride.

There have been no reports of 'pain in extremity' from post-marketing data sources, however the MAH has identified a literature article where 4/10 patients who were infused methylthioninium chloride experienced pain in the infused arm.

Therefore, in view of the data presented in the reviewed PSUR(s), the PRAC considered that changes to the product information of medicinal products containing methylthioninium chloride were warranted.

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