17 February 2011
EMA/CHMP/82326/2011
Committee for medicinal products for human use (CHMP)

Summary of opinion[1] (initial authorisation)

Methylthioninium chloride Proveblue

methylthioninium chloride

On 17 February 2011 the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Methylthioninium chloride Proveblue 5 mg/ml solution for injection intended for the treatment of medicinal and chemical products- induced methaemoglobinaemia. The applicant for this medicinal product is Provepharm S.A.S. They may request a re-examination of any CHMP opinion, provided they notify the European Medicines Agency in writing of their intention within 15 days of receipt of the opinion.

The active substance of Methylthioninium chloride Proveblue is methylthioninium chloride (also called methylene blue), a substance belonging to the group of antidotes (ATC code: V03AB17*),* it speeds up the conversion of methaemoglobin to haemoglobin.

The benefits with Methylthioninium chloride Proveblue are that it is a single most documented and clinically used substance to treat drug- and chemical induced methaemoglobinaemia. The clinical experience of methylthioninium chloride has demonstrated its efficacy to reverse most cases of induced methaemoglobinaemia. The most common side effects are nausea, abdominal and chest pain, headache, dizziness, tremors, anxiety, confusional state, dyspnoea, tachycardia, hypertension, the formation of methaemoglobinaemia and hyperhidrosis.

A pharmacovigilance plan for Methylthioninium chloride Proveblue will be implemented as part of the marketing authorisation.

The approved indication is: "Acute symptomatic treatment of medicinal and chemical products- induced methaemoglobinaemia. Methylthioninium chloride Proveblue is indicated in adults, children and adolescents (aged 0 to 17 years)." It is proposed that Methylthioninium chloride Proveblue is prescribed by a healthcare professional.

Detailed recommendations for the use of this product will be described in the summary of product characteristics (SmPC), which will be published in the European public assessment report (EPAR), and

[1] Summaries of positive opinion are published without prejudice to the commission decision, which will normally be issued 67 days from adoption of the opinion.

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7523 7455
E-mail info@ema.europa.eu **Website** www.ema.europa.eu

will be available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

The CHMP, on the basis of quality, safety and efficacy data submitted, considers there to be a favourable benefit to risk balance for Methylthioninium chloride Proveblue and therefore recommends the granting of the marketing authorisation.