21 July 2011
EMA/CHMP/470877/2011
Committee for medicinal products for human use (CHMP)

Summary of opinion[1] (initial authorisation)

Mercaptopurine Nova Laboratories

mercaptopurine

On 21 July 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 Mercaptopurine Nova Laboratories, 20mg/ml oral suspension, intended for the treatment of acute lymphoblastic leukaemia (ALL) in adults, adolescents and children. Mercaptopurine Nova Laboratories was designated as an orphan medicinal product on 30 April 2009. The applicant for this medicinal product is Nova Laboratories Ltd.

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 Mercaptopurine Nova Laboratories is mercaptopurine, a cytotoxic purine analogue (L01BB02) that interferes with nucleic acid metabolism and inhibits growth of malignant cells.

The benefits with Mercaptopurine Nova Laboratories are its ability to help induce and primarily help maintain remission of disease; these are well established since mercaptopurine in tablet form has been used for many years in the treatment of ALL. The added benefit with Mercaptopurine Nova Laboratories is that, as an oral suspension, it ensures better precision and ease of administration and allows more flexible dosing. The most common side effects are also well known after years of mercaptopurine use and include stomatitis, nausea, vomiting, anorexia, gastro-intestinal ulceration and bleeding, hepatotoxicity, bone marrow toxicity and immune suppression.

A pharmacovigilance plan for Mercaptopurine Nova Laboratories will be implemented as part of the marketing authorisation.

The approved indication is: “Mercaptopurine Nova Laboratories is indicated for the treatment of acute lymphoblastic leukaemia (ALL) in adults, adolescents and children”. It is proposed that Mercaptopurine Nova Laboratories is prescribed by physicians experienced in the treatment of acute lymphoblastic leukaemia.

[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.

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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 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 Mercaptopurine Nova Laboratories and therefore recommends the granting of the marketing authorisation.