21 May 2015
EMA/CHMP/303761/2015
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (initial authorisation)

Unituxin

dinutuximab

On 21 May 2015, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Unituxin for the treatment of high-risk neuroblastoma in children. Unituxin was designated an orphan medicinal product on 21 June 2011. The applicant for this medicinal product is United Therapeutics Europe Ltd.

Unituxin will be available as 3.5 mg/ml concentrate for solution for infusion. The active substance of Unituxin is dinutuximab, a monoclonal chimeric antibody (ATC code: L01XC16) which reacts specifically with the ganglioside GD2. GD2 is highly expressed on the surface of neuroblastoma cells but only minimally expressed on the surface of normal human neurons, peripheral pain fibres, and skin melanocytes.

The benefits with Unituxin are an improvement in the 2-year estimates of event free survival and the 3-year estimates of overall survival. The most common side effects are pain, allergic reactions and hypotension.

The full indication is: "Unituxin is indicated for the treatment of high-risk neuroblastoma in patients aged 12 months to 17 years, who have previously received induction chemotherapy and achieved at least a partial response, followed by myeloablative therapy and autologous stem cell transplantation (ASCT). It is administered in combination with granulocyte-macrophage colony-stimulating factor (GM-CSF), interleukin-2 (IL-2), and isotretinoin." Unituxin should be prescribed by physicians experienced in the treatment of cancer.

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

[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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