EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

20 January 2011
EMA/31145/2011
Committee for medicinal products for human use (CHMP)

Summary of opinion[1] (initial authorisation)

Trobalt

retigabine

On 20 January 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 Trobalt, 50 mg, 100 mg, 200 mg, 300 mg and 400 mg film-coated tablets, intended as adjunctive treatment of partial onset seizures with or without secondary generalisation in adults aged 18 years and above with epilepsy. The applicant for this medicinal product is Glaxo Group 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 Trobalt is retigabine, an other antiepileptic, (ATC code: N03AX21), with mechanism of action through activation of specific KCNQ2-5 voltage-gated potassium channels.

The benefits with Trobalt are its ability to be effective in partial onset epilepsy as add-on therapy. In addition, there is a high medical need in the partial epilepsy patient population. The most common side effects are CNS related adverse events, renal and urinary tract symptoms and cardiac effects.

A pharmacovigilance plan for Trobalt will be implemented as part of the marketing authorisation.

The approved indication is: "as adjunctive treatment of partial onset seizures with or without secondary generalisation in adults aged 18 years and above with epilepsy".

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 Trobalt and therefore recommends the granting of the marketing authorisation.

[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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