19 May 2011
EMA/CHMP/373819/2011
Committee for medicinal products for human use (CHMP)

Summary of opinion[1] (initial authorisation)

Temozolomide Sun

temozolomide

On 19 May 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 Temozolomide Sun 5 mg, 20 mg, 100 mg, 140 mg, 180 mg, 250 mg hard capsules intended for oncology treatment. The applicant for this medicinal product is Sun Pharmaceutical Industries Europe B.V. 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 Temozolomide Sun is temozolomide an antineoplastic and immunomodulating agent (ATC code: L01AX03). Temozolomide (TMZ) is a triazene, which undergoes rapid chemical conversion at physiologic pH to the active monomethyl triazenoimidazole carboxamide (MTIC). The cytotoxicity of MTIC is thought to be due primarily to alkylation at the O6 position of guanine with additional alkylation also occurring at the N7 position. Cytotoxic lesions that develop subsequently are thought to involve aberrant repair of the methyl adduct.

Temozolomide Sun is a generic of Temodal, which has been authorised in the EU since 26 January 1999. Studies have demonstrated the satisfactory quality of Temozolomide Sun and its bioequivalence with Temodal. A question-and-answer document on generic medicines can be found here.

The approved indication is:

- "For the treatment of adult patients with newly-diagnosed glioblastoma multiforme concomitantly with radiotherapy (RT) and subsequently as monotherapy treatment.
- For the treatment of children from the age of three years, adolescents and adult patients with malignant glioma, such as glioblastoma multiforme or anaplastic astrocytoma, showing recurrence or progression after standard therapy".

Medicinal product subject to special and restricted medical prescription.

[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 data submitted, considers there to be a favourable benefit to risk balance for Temozolomide Sun and therefore recommends the granting of the marketing authorisation.