21 October 20010
EMA/643392/2010
Committee for medicinal products for human use (CHMP)

Summary of opinion[1] (initial authorisation)

Potactasol

topotecan

On 21 October 2010 the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product Potactasol, 1 mg and 4 mg, powder for concentrate for solution for infusion intended for the treatment of patients with metastatic carcinoma of the ovary after failure of first-line or subsequent therapy or with relapsed small cell lung cancer for whom re-treatment with the first-line regimen is not considered appropriate; and in combination with cisplatin Potactasol is intended for the treatment of patients with carcinoma of the cervix recurrent after radiotherapy and for patients with Stage IVB disease. Patients with prior exposure to cisplatin require a sustained treatment free interval to justify treatment with the combination. The applicant for this medicinal product is Actavis Group PTC ehf. 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 topotecan (as hydrochloride), is an antineoplastic and immunomodulating agent (L01XX17). Topotecan is a cytotoxic anti-cancer agent and acts by inhibition of the nuclear enzyme topoisomerase I that is involved in DNA replication. As a result, DNA damage induces apoptotic cell death predominantly in replicating cells such as tumour cells.

Potactasol is a generic of Hycamtin, which has been authorised in the EU since 12 November 1996. Studies have demonstrated the satisfactory quality of Potactasol. Potactasol is administrated intravenously and is 100% bioavailable. Therefore, a bioequivalence study versus the reference medicinal product was not required. A question-and-answer document on generic medicines can be found here.

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

The approved indication is:

"Topotecan monotherapy is indicated for the treatment of:

[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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- patients with metastatic carcinoma of the ovary after failure of first-line or subsequent therapy
- patients with relapsed small cell lung cancer [SCLC] for whom re-treatment with the first-line regimen is not considered appropriate.

Topotecan in combination with cisplatin is indicated for patients with carcinoma of the cervix recurrent after radiotherapy and for patients with Stage IVB disease. Patients with prior exposure to cisplatin require a sustained treatment free interval to justify treatment with the combination."

When used in combination with cisplatin, the full prescribing information for cisplatin should be consulted.

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 Potactasol and therefore recommends the granting of the marketing authorisation.