16 December 2010
EMA/CHMP/806039/2010
Committee for medicinal products for human use (CHMP)

Summary of opinion[1] (initial authorisation)

Teysuno

tegafur/gimeracil/oteracil

On 16 December 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 Teysuno, 15 mg and 20 mg, hard capsule, intended for the treatment of advanced gastric cancer in adults when given in combination with cisplatin. Teysuno was designated as an orphan medicinal product on 20 December 2007. The applicant for this medicinal product is Taiho Pharma Europe 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 Teysuno is tegafur, a prodrug of 5-FU which is a Pyrimidine analogue (L01BC53) together with the two modulators of 5-FU metabolism, gimeracil and oteracil. Tegafur is an orally bioavailable fluoropyrimidine that is converted into 5-FU, which causes death of proliferating cells by inhibiting DNA synthesis and by affecting RNA function.

The benefits with Teysuno are its daily oral dosing without the requirement of a central venous catheter and hospital admission (as necessary for 5-FU continuous i.v. infusion). Teysuno in combination with cisplatin has been shown to be non-inferior to 5-FU+cisplatin in patients with advanced gastric cancer in terms of overall survival, response rate and progression free survival. The most common side effects are anaemia, neutropenia, vomiting, diarrhoea, abdominal pain, weight decrease, anorexia and fatigue.

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

The approved indication is: "Teysuno is indicated in adults for the treatment of advanced gastric cancer when given in combination with cisplatin".

Teysuno should only be prescribed by a qualified physician experienced in treating cancer patients with anti-neoplastic medicinal products.

[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 Teysuno and therefore recommends the granting of the marketing authorisation.