



15 December 2011
EMA/796457/2011
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion¹ (post authorisation)

Teysuno

tegafur / gimeracil / oteracil

On 15 December 2011, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion recommending a variation to the terms of the marketing authorisation for the medicinal product Teysuno. The marketing authorisation holder for this medicinal product is Nordic Group B.V. They may request a re examination of the CHMP opinion, provided that they notify the European Medicines Agency in writing of their intention within 15 days of receipt of the opinion.

The CHMP adopted a change to a contraindication as follows:

- ~~“Severe renal impairment (CrCl below 30 ml/min). End stage renal disease patients requiring dialysis.”~~

Detailed conditions for the use of this product will be described in the updated summary of product characteristics (SmPC), which will be published in the revised European public assessment report (EPAR), and will be available in all official European Union languages after the variation to the marketing authorisation has been granted by the European Commission.

For information, the full contraindications for Teysuno will be as follows²:

- Hypersensitivity to any of the active substances (tegafur, gimeracil, and oteracil) or to any of the excipients (see sections 4.4 and 6.1).
- History of severe and unexpected reactions to fluoropyrimidine therapy.
- Known dihydropyrimidine dehydrogenase (DPD) deficiency.
- Pregnancy and breastfeeding.
- Severe bone marrow suppression (severe leucopenia, neutropaenia, or thrombocytopenia; see section 4.2, Table 5).
- **End stage renal disease patients requiring dialysis.**
- Co-administration of other fluoropyrimidines with Teysuno.
- Treatment within 4 weeks with DPD inhibitors, including sorivudine or its chemically related analogues such as brivudine.
- Contraindications for cisplatin; refer to the cisplatin SmPC.

¹ Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued within 44 days (Type II variations) and 67 days (Annex II applications) from adoption of the opinion.

² The text in bold represents the new or the amended contraindication.

