16 December 2021
EMA/CHMP/714788/2021
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Teysuno

tegafur / gimeracil / oteracil

On 16 December 2021, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion recommending a change 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.

The CHMP adopted a new indication as follows:[2]

Teysuno is indicated in adults:

- for the treatment of advanced gastric cancer when given in combination with cisplatin (see section 5.1).
- **as monotherapy or in combination with oxaliplatin or irinotecan, with or without bevacizumab, for the treatment of patients with metastatic colorectal cancer for whom it is not possible to continue treatment with another fluoropyrimidine due to hand-foot syndrome or cardiovascular toxicity that developed in the adjuvant or metastatic setting.**

Detailed recommendations 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 a decision on this change to the marketing authorisation has been granted by the European Commission.

[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
[2] New text as bold

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