



Datum: 23.04.2019
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Unser Zeichen: PHV-11968232-A-190415-EUIM
Ihr Zeichen:

PHV-issue: 5 Fluorouracil; Tegafur

Sehr geehrte Damen und Herren,

Nach der Fertigstellung des Capecitabin-PSUSAs (C(2019) 2988) kam das CMDh zu dem Schluss, dass Ergebnisse aus dem PSUR Assessment für alle Arzneimittel, die 5 Fluorouracil bzw. Tegafur enthalten relevant sind.

(Siehe auch CMDh Press release meeting held on 28-30 January 2019: <http://www.hma.eu/249.html>)

Auszug aus dem Report from the CMDh meeting held on 28-30 January 2019

Interaction between brivudine and fluoropyrimidines

During the assessment of the PSUSA on capecitabine, the PRAC noted that still cases of the potentially fatal interaction of fluoropyrimidines and brivudine were reported and recommended a revision of the product information of capecitabine-containing products. The PRAC considered that information related to the drug-drug interaction with brivudine is also relevant for other fluoropyrimidines used in oncology (5-fluoruracil, tegafur). Therefore, the PRAC recommends that the MAHs should implement the respective updates also for these products.

Valid for medicinal products containing 5-fluoruracil (i.v.) and tegafur