Bundesamt für
Sicherheit im
Gesundheitswesen
BASG

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PHV-issue: Ranitidin

Sehr geehrte Damen und Herren,

Nach der Fertigstellung des Ranitidin-PSUSAs (PSUSA/00002610/201805) kam das CMDh zu dem Schluss, dass Ergebnisse aus dem PSUR Assessment für alle Arzneimittel, die Ranitidin 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 ranitidine and erlotinib

During the assessment of the PSUSA on ranitidine, the PRAC noted that information on interactions between ranitidine and erlotinib stated in the product information for erlotinib containing-products is not reflected in the product information of all ranitidine containing-products (including combination products). The following wording should be included, if not yet present:

SmPC – Section 4.5

Erlotinib and medicinal products altering pH

...

"Concomitant administration of 300 mg ranitidine and erlotinib decreased erlotinib exposure [AUC] and maximum concentrations [Cmax] by 33% and 54%, respectively. However, when erlotinib was dosed in a staggered manner 2 hours before or 10 hours after ranitidine 150 mg b.i.d., erlotinib exposure [AUC] and maximum concentrations [Cmax] decreased only by 15% and 17%, respectively."

PL – Section 2

"2. What you need to know before you take [product name]

Other medicines and [product name]

If you are taking erlotinib, a drug used for the treatment of certain types of cancer, talk to your doctor before you take [product name]. Ranitidine contained in [product name] may decrease the amount of erlotinib in your blood and your doctor may need to adjust your treatment if it is used while you are receiving erlotinib."

Valid for all ranitidine containing medicinal products (including combination products)