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PHV-issue: Amlodipin

Sehr geehrte Damen und Herren,

Nach der Fertigstellung des Amlodipin-PSUSAs (PSUSA/00000174/201703) kam das CMDh zu dem Schluss, dass Ergebnisse aus dem PSUR Assessment für alle Arzneimittel, die den Wirkstoff Amlodipin enthalten (auch Kombinationsarzneimittel) relevant sind. (Siehe auch CMDh Press release vom 09.-11. Oktober 2017: <http://www.hma.eu/249.html>)



Auszug aus dem "Report from the CMDh meeting held on 6-8 November 2017"

Fixed dose combination products containing amlodipine

In the framework of the PSUSA on amlodipine, the PRAC considered that the following risks should be reflected in the Product Information of fixed dose combinations containing amlodipine, since they are equally relevant for the combination products as the mono component:

- risk of amlodipine excretion into breast milk
- risk of drug interaction between amlodipine and rifampicin.

The updates should be in line with those proposed in the frame of the PSUSA on amlodipine and the same timelines apply.