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Kontakt: Ing. Veronika Iro, B.Sc.
Abteilung: REGA
Tel. / Fax: +43 (0) 505 55 – 36247
E-Mail: pv-implementation@ages.at
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PHV-issue: Rifampicin

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 Rifampicin enthalten 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"

Rifampicin containing products

In the framework of the PSUSA on amlodipine, the PRAC also considered that section 4.5 of the SmPC of products containing rifampicin as a single agent or in fixed dose combination with ethambutol, isoniazid, pyrazinamide should be updated in order to include amlodipine to the list of drugs affected by the rifampicin CYP inducing effect. The Package Leaflets should be updated accordingly. The same timelines as for the implementation of the PSUSA on amlodipine apply.