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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: Magnesiumhydroxid

Sehr geehrte Damen und Herren,

Nach der Fertigstellung des Magnesiumhydroxid-PSUSAs (PSUSA/00001926/201610) kam das CMDh zu dem Schluss, dass Ergebnisse aus dem PSUR Assessment für alle Arzneimittel zum Einnehmen (auch Kombinationsarzneimittel), die den Wirkstoff Magnesiumhydroxid enthalten relevant sind. (Siehe auch CMDh Press release vom 17-19 Juli 2017: <http://www.hma.eu/249.html>)



For the PSUSA for magnesium hydroxide the PRAC noted that the conclusions and recommendations resulting from the assessment of PSURs for products containing the active substance magnesium hydroxide only should also be taken into account for combination products containing magnesium hydroxide as the safety issues of hypermagnesemia and DDI with salicylates are considered substance related and are therefore relevant for all medicinal products for oral use which contain the active substance magnesium hydroxide. The risk of abdominal pain, hypermagnesemia, DDI with salicylates and the safety concerns recommended by the PRAC could be of relevance for other combination products containing the active substance magnesium hydroxide, if the posology is comparable.