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**Kontakt:** Ing. Veronika Heimlich, B.Sc.  
**T:** +43 505 55-36247  
**E-Mail:** pv-implementation@basg.gv.at  
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### **PHV-issue: Acetylsalicylsäure**

Sehr geehrte Damen und Herren,

Nach der Fertigstellung des Metamizol-PSUSAs kam das CMDh zu dem Schluss, dass Ergebnisse aus dem PSUR Assessment für alle niedrig dosierten Arzneimittel, die Acetylsalicylsäure zur sekundären Prävention kardiovaskulärer Erkrankungen enthalten relevant sind.  
(Siehe auch CMDh Press release meeting held on 10-12 December 2018: <http://www.hma.eu/249.html>)

## Auszug aus dem Report from the CMDh meeting held on 10-12 December 2018

### Interaction between metamizole and acetylsalicylic acid (ASA)

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During the assessment of the PSUSA on metamizole, the PRAC noted the following:

According to Section 4.5 of metamizole SmPCs: '*Metamizole may reduce the effect of acetylsalicylic acid (aspirin) on platelet aggregation, when taken concomitantly. Therefore, this combination should be used with caution in patients taking low dose aspirin for cardioprotection.*' This interaction is not included in the SmPCs of low-dose ASA indicated for secondary cardiovascular prevention. Similar pharmacodynamic interaction resulting in the inhibition of platelet activity has been proposed for certain NSAIDs, including ibuprofen and naproxen. Contrary to the information on the potential interaction with metamizole, reduction of antiplatelet effect of low-dose ASA when co-administered with naproxen or ibuprofen, is flagged in the SmPC of low-dose ASA (originator). For consistency reasons, the pharmacodynamic interaction of ASA and metamizole resulting in high on-treatment platelet reactivity in patients should also be included in the product information of low-dose ASA products indicated for the secondary prevention of cardiovascular events.

**Valid for medicinal products containing low-dose acetylsalicylic acid indicated for secondary cardiovascular prevention**