Bundesamt für Sicherheit
im Gesundheitswesen

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PHV-issue: Vitamin K Antagonisten

Sehr geehrte Damen und Herren,

Nach der Fertigstellung des Glucosamin-PSUSAs (PSUSA/00001539/201703) kam das CMDh zu dem Schluss, dass Ergebnisse aus dem PSUR Assessment für alle Vitamin K Antagonisten (auch Kombinationsarzneimitttel) relevant sind. (Siehe auch CMDh Press release vom 11.-13. Dezember: http://www.hma.eu/249.html)

Auszug aus dem "Report from the CMDh meeting held on 11-13 December 2017"

Interaction between glucosamine and oral vitamin K antagonists

In the framework of the PSUSA for glucosamine, the PRAC considered that the interaction between glucosamine and oral vitamin K antagonists would also be relevant to be included in the product information of oral vitamin K antagonists, as the interaction is applicable to both substances interacting. The PRAC therefore recommends the inclusion of the below wording, in all product information of products containing oral vitamin K antagonists, either as a single agent or in fixed dose combinations, that do not already include a warning on their interaction with glucosamine. The same timelines as for the present PSUSA apply (i.e.105 calendar days after adoption of the CMDh position) The following wording on the interaction should be used in the product information of oral vitamin K antagonists:

Summary of Product Characteristics

• Section 4.5
A warning should be added as follows:
Increased INR has been reported in patients taking glucosamine and oral vitamin K antagonists. Patients treated with oral vitamin K antagonists should therefore be closely monitored at the time of initiation or termination of glucosamine therapy.

Package Leaflet

2. What you need to know before you <take> <use> X
Other medicines and X
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines:
– Glucosamine (for osteoarthritis) may increase the effect of X.

Valid for all medicinal products containing oral vitamin K antagonists