



Bundesamt für
Sicherheit im
Gesundheitswesen
BASG

Unternehmen/Frau/Herr
Organisationseinheit (optional)
(z. H.) Vorname Nachname
Straße
PLZ Ort

Datum: 06.07.2026
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Unser Zeichen: PHV-105640330 -A-260706

PHV-issue: Acetylsalicylsäure

Sehr geehrte Damen und Herren,

Bitte beachten Sie die Coordination Group for Mutual Recognition and Decentralised Procedures - Human (CMDh) Minutes for the meeting on 19-20 May 2026 bezüglich Acetylsalicylsäure.

Bei Unklarheiten bezüglich der Implementierung oder wenn die Änderungen bereits aufgenommen worden sind, kontaktieren Sie uns bitte per E-Mail (pv-implementation@basg.gv.at).

Beachten Sie auch die aktuellen sicherheitsrelevanten Änderungen der Produktinformation unter: www.basg.gv.at/fuer-unternehmen/pharmakovigilanz/mustertexte

In der Begründung ist „**PHV-Issue: „Acetylsalicylsäure“**“ sowie die **Geschäftszahl (PHV-105640330 - A-260706)** anzugeben.

Mit freundlichen Grüßen
Für das Bundesamt

Ing. Veronika Heimlich BSc



Auszug aus den Coordination Group for Mutual Recognition and Decentralised Procedures - Human (CMDh) Minutes for the meeting on 19-20 May 2026

6.6.1. Acetylsalicylic acid - FI/H/XXXX/WS/190 / FI

The CMDh was informed about the outcome of the worksharing procedure FI/H/XXXX/WS/190 for acetylsalicylic acid-containing medicinal products. PRAC advice was sought during the procedure, which confirmed the updates to SmPC section 4.4 and 4.8 and the PL sections 2 and 4 to add Kounis syndrome as ADR.

MAHs of products containing acetylsalicylic acid (all strengths and pharmaceutical forms, including combination products) are requested to implement the below wording, if a similar wording is not yet present, via a type IB variation C.3.b. (new text in **bold underlined italics**):

SmPC section 4.4

Rare cases of acute myocardial ischemia with or without myocardial infarction as part of a hypersensitivity reaction (Kounis syndrome) have been reported in patients treated with acetylsalicylic acid. In the event of confirmed Kounis syndrome due to acetylsalicylic acid, [product name] should be discontinued immediately.

SPC section 4.8

Alternative a)

4.8.2 Tabulated list of Adverse reactions

System Organ Class	Common	Uncommon	Rare	Not Known
Cardiac Disorders				Cardio-respiratory distress ^d <u>Kounis syndrome*</u>

^d In the context of severe allergic reactions

***Acute myocardial ischemia with or without myocardial infarction as part of a hypersensitivity reaction, see section 4.4.**

Alternative b) (in case the national SmPC does not have a tabular ADR overview (SOC and frequency))

Kounis syndrome (acute myocardial ischemia with or without myocardial infarction as part of a hypersensitivity reaction), with frequency not known (see section 4.4).

PL section 2

When taking acetylsalicylic acid, serious allergic reactions which may include chest pain and even heart attack (Kounis syndrome) have been reported (see section 4). Seek medical care immediately when you notice chest pain with allergic reactions (such as skin rashes, shortness of breath).

PL section 4

Frequency not known:

Acute myocardial ischemia (painful heart condition caused by lack of blood flow to the heart) with or without myocardial infarction (heart attack) occurring as part of an allergic reaction (Kounis syndrome).

Heimlich Veronika
am 6.7.2026