

Annex I

Scientific conclusions and grounds for the variation to the terms of the Marketing Authorisation(s)

Scientific conclusions

Taking into account the PRAC Assessment Report on the PSUR(s) for ioversol, the scientific conclusions are as follows:

In view of available data on Kounis syndrome from the literature and in view of a plausible mechanism of action, the PRAC Lead Member State considers a causal relationship between ioversol and Kounis syndrome is at least a reasonable possibility. The PRAC concluded that the product information of products containing ioversol should be amended accordingly.

Having reviewed the PRAC recommendation, the CMDh agrees with the PRAC overall conclusions and grounds for recommendation.

Grounds for the variation to the terms of the marketing authorisation(s)

On the basis of the scientific conclusions for ioversol the CMDh is of the opinion that the benefit-risk balance of the medicinal product(s) containing ioversol is unchanged subject to the proposed changes to the product information

The CMDh recommends that the terms of the marketing authorisation(s) should be varied.

Annex II

Amendments to the product information of the nationally authorised medicinal product(s)

<Amendments to be included in the relevant sections of the Product Information (new text underlined and in bold, deleted text ~~strike through~~)>

- Section 4.4

A warning should be added as follows:

Cardiovascular ~~diseases~~-disorders

Cases of Kounis syndrome have been reported in patients treated with ioversol. Kounis syndrome has been defined as cardiovascular symptoms secondary to an allergic or hypersensitive reaction associated with constriction of coronary arteries and potentially leading to myocardial infarction.

- Section 4.8

The following adverse reaction should be added under the SOC Cardiac disorders with a frequency not known:

Kounis syndrome

Package Leaflet

Section 2: What you need to know before you use <product name>

...

Warnings and precautions

...

Signs of an allergic reaction to this medicine, including breathing problems and chest pain, have been reported with <product name>. Tell your doctor immediately if you notice any of these signs.

Annex III

Timetable for the implementation of this position

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Adoption of CMDh position:	January 2026 CMDh meeting
Transmission to National Competent Authorities of the translations of the annexes to the position:	15 March 2026
Implementation of the position by the Member States (submission of the variation by the Marketing Authorisation Holder):	14 May 2026