

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 mesalazine, the scientific conclusions are as follows:

In view of available data on benign intracranial hypertension from the literature and spontaneous reports, including, in some cases, a close temporal relationship, a positive de-challenge and/or re-challenge, the PRAC considers a causal relationship between mesalazine and benign intracranial hypertension is at least a reasonable possibility. The PRAC concluded that the product information of products containing mesalazine should be amended accordingly. This recommendation is only valid for MAHs who do not already have similar or stricter information included in the product information.

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 mesalazine the CMDh is of the opinion that the benefit-risk balance of the medicinal product(s) containing mesalazine 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~~)

Summary of Product Characteristics

- Section 4.4

A warning should be added as follows:

Idiopathic intracranial hypertension

Idiopathic intracranial hypertension (pseudotumor cerebri) has been reported in patients receiving mesalazine. Patients should be warned for signs and symptoms of idiopathic intracranial hypertension, including severe or recurrent headache, visual disturbances or tinnitus. If idiopathic intracranial hypertension occurs, discontinuation of mesalazine should be considered.

- Section 4.8

The following adverse reaction should be added under the SOC Nervous system disorders with a frequency not known (cannot be estimated from the available data):

Idiopathic intracranial hypertension (see section 4.4)

Package Leaflet

Section 2: Warnings and precautions

Talk to your doctor:

- **If you experience strong or recurrent headache, disturbed vision, or ringing or buzzing in the ears contact your doctor immediately.**

4. Possible side effects

Serious side effects:

Tell your doctor immediately

[Not known (frequency cannot be estimated from the available data)]

- **If you experience strong or recurrent headache, disturbed vision, or ringing or buzzing in the ears. These could be symptoms of increased pressure within your skull (idiopathic intracranial hypertension).**

Annex III

Timetable for the implementation of this position

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Adoption of CMDh position:	October 2024 CMDh meeting
Transmission to National Competent Authorities of the translations of the annexes to the position:	02 December 2024
Implementation of the position by the Member States (submission of the variation by the Marketing Authorisation Holder):	30 January 2025