

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 beta-alanine, the scientific conclusions are as follows:

In view of available data on **anaphylactic reaction** from spontaneous reports, including in 5 cases a positive de-challenge and 3 cases with a positive re-challenge and in view of a plausible mechanism of action, the PRAC considers a causal relationship between beta-alanine and anaphylactic reaction is at least a reasonable possibility. The PRAC concluded that the product information of products containing beta-alanine 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 beta-alanine the CMDh is of the opinion that the benefit-risk balance of the medicinal product(s) containing beta-alanine 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 4.8

The following adverse reaction should be added under the SOC Immune system disorders with a frequency not known: **Anaphylactic reaction**

Package Leaflet

Section 4

Tell your doctor straight away if you notice:

Signs of a serious allergic reaction (anaphylactic reaction) such as swelling of the face, lips, throat or tongue which makes it difficult to swallow or breathe, shortness of breath, feeling of loss of consciousness.

....

Not known

Allergic reactions:

- **swelling of the face, lips, throat, or tongue which makes it difficult to swallow or breathe, shortness of breath**
- **pale skin, a weak and rapid pulse, or a feeling of loss of consciousness**

Annex III

Timetable for the implementation of this position>

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Adoption of CMDh position:	October 2023 CMDh meeting
Transmission to National Competent Authorities of the translations of the annexes to the position:	27 November 2023
Implementation of the position by the Member States (submission of the variation by the Marketing Authorisation Holder):	26 January 2024