26 January 2023
EMA/CHMP/27760/2023
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

Byfavo

remimazolam

On 26 January 2023, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion recommending a change to the terms of the marketing authorisation for the medicinal product Byfavo. The marketing authorisation holder for this medicinal product is Paion Deutschland GmbH.

The CHMP adopted the addition of a new pharmaceutical form associated with a new strength (50 mg powder for concentrate for solution for injection/infusion). The new pharmaceutical form is introduced with an extension to the existing indication to include intravenous induction and maintenance of general anesthesia in adults. For information, the indication for Byfavo 50 mg powder for solution for infusion/injection will be as follows: [2]

> **Remimazolam 50 mg is indicated in adults for intravenous induction and maintenance of general anaesthesia**

For information, the indication for other pharmaceutical forms is provided in the Summary of Product Characteristics for Byfavo.

Detailed recommendations for the use of this product will be described in the updated summary of product characteristics (SmPC), which will be published in the revised European public assessment report (EPAR), and will be available in all official European Union languages after a decision on this change to the marketing authorisation has been granted by the European Commission.

[1] Summaries of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion
[2] New text in **bold**

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