09 November 2023
EMA/CHMP/480164/2023
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion[1] (post authorisation)

NexoBrid

concentrate of proteolytic enzymes enriched in bromelain

On 09 November 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 NexoBrid. The marketing authorisation holder for this medicinal product is MediWound Germany GmbH.

The CHMP adopted an extension to the existing indication. The full indication will be as follows:[2]

> NexoBrid is indicated **in all age groups** for removal of eschar in ~~adults~~ **patients** with deep partial- and full-thickness thermal burns.

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, removed text as strikethrough

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