



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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EMA/CHMP/390286/2012
Committee for Medicinal Products for Human Use (CHMP)

Summary of opinion¹ (initial authorisation)

NexoBrid

Concentrate of proteolytic enzymes enriched in bromelain

On 20 September 2012, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product NexoBrid, 2g/20g, 5g/50g, cutaneous powder and gel intended for the removal of eschar in adults with deep partial- and full-thickness thermal burns. NexoBrid was designated as an orphan medicinal product on 30 July 2002. The applicant for this medicinal product is Teva Pharma GmbH. They may request a re-examination of any CHMP opinion, provided they notify the European Medicines Agency in writing of their intention within 15 days of receipt of the opinion.

The active substance of NexoBrid is concentrate of proteolytic enzymes enriched in bromelain (ATC Code: Not yet assigned). The mixture of enzymes in NexoBrid dissolves burn wound eschar. The specific components responsible for this effect have not been identified. The major constituent is stem bromelain.

The benefits of NexoBrid are its ability to debride eschar from burn wounds. The most common side effects are local pain and pyrexia/hyperthermia.

A pharmacovigilance plan for NexoBrid will be implemented as part of the marketing authorisation.

The approved indication is: "NexoBrid is indicated for removal of eschar in adults with deep partial- and full-thickness thermal burns." NexoBrid should be only be applied by trained healthcare professionals in specialist burn centres.

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

The CHMP, on the basis of quality, safety and efficacy data submitted, considers there to be a favourable benefit-to-risk balance for NexoBrid and therefore recommends the granting of the marketing authorisation.

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.

