swissmedic

Summary report on authorisation dated 21 November 2025

NexoBrid® (active substance: concentrate of proteolytic enzymes enriched in bromelain)

Indication extension in Switzerland: 24 July 2025

Powder and gel for gel to remove eschar from deep partial and full-thickness burns

About the medicinal product

The medicinal product NexoBrid contains a concentrate of proteolytic enzymes enriched in bromelain. Bromelain is extracted from pineapple plant stems. The proteolytic enzymes it contains can split proteins and thus break down dead tissue.

NexoBrid is used in patients in all age groups to remove dead skin and the eschar that forms with deep partial and full-thickness burns.

NexoBrid was first authorised by Swissmedic on 21 April 2022 to remove eschar from deep partial and full-thickness burns in adults. This indication extension authorises NexoBrid for the treatment of patients in all age groups.

In deciding whether to authorise the indication extension for NexoBrid, Swissmedic took into account the assessment of the European Medicines Agency (EMA) and the corresponding medicinal product information texts.

As deep partial and full-thickness burns are rare, life-threatening health conditions, the medicinal product has been authorised as an orphan drug. The term "orphan drug" is used to refer to medicines for rare diseases.

Since the assessment of the clinical data was based on the assessment reports of this foreign authority, the preconditions for a full SwissPAR (Swiss Public Assessment Report – a detailed report for professionals) and a resulting Summary report on authorisation are not met. Swissmedic refers to the authorisation of the foreign reference authority (EMEA/H/C/002246/II/0058).

www.ema.europa.eu

Further information on the medicinal product

Information for healthcare professionals: Information for healthcare professionals NexoBrid®

Healthcare professionals can answer any further questions.

The date of revision of this text corresponds to that of the SwissPAR. New information concerning the authorised medicinal product in question will not be incorporated into the Summary report on authorisation.

Swissmedic monitors medicinal products authorised in Switzerland. Swissmedic initiates the necessary action in the event of newly discovered adverse drug reactions or other safety-relevant signals. New findings that could impair the quality, efficacy, or safety of this medicinal product are recorded and published by Swissmedic. If necessary, the medicinal product information is adapted.