

Public Summary SwissPAR dated 6 September 2022

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

First authorisation in Switzerland: 21 April 2022

Medicinal product (powder and gel for gel) to remove eschar from deep partial and full-thickness burns (second (2b) and third-degree burns) in adults

About the medicine

The medicinal product NexoBrid contains a concentrate of proteolytic enzymes¹ enriched in bromelain. Bromelain is extracted from pineapple plant stems. The proteolytic enzymes it contains can split proteins and thus break down the dead tissue. NexoBrid is used in adults to remove dead skin and the wound eschar that forms after severe burns.

Burns are classified into different degrees of severity. NexoBrid is used for burns that affect an inner layer of the skin called the dermis (second-degree (2b): deep partial thickness and third-degree: full thickness burns)

NexoBrid should only be applied by trained healthcare professionals in specialist burns centres.

Mode of action

Deep partial thickness skin burns lead to dead tissue and wound eschar. This tissue must be removed, i.e. the wound must be cleaned (debridement) to accelerate the healing process and avoid infection. This

cleaning is carried out surgically as standard. The proteolytic enzymes in NexoBrid enable the removal of the dead tissue from burn wounds by dissolving the wound eschar.

Use

NexoBrid, which contains the active substance concentrate of proteolytic enzymes enriched in bromelain, is a prescription-only

medicine. NexoBrid is available in a pack containing 5 g concentrate and 50 g gel. Both components, the concentrate and the

¹ Proteolytic enzymes: Proteolytic enzymes or peptidases are enzymes that can split and break down proteins.

gel, are mixed to form a gel shortly before use. A 1.5 to 3 mm thick layer of NexoBrid gel is applied to the burn wound. NexoBrid should not be applied to more than 15% of the total body surface of an adult. NexoBrid

must be applied within 15 minutes of mixing the powder into the gel and be left in contact with the skin for four hours. A second application is not recommended.

Efficacy

Second (2b) and third-degree burns require early removal of the dead tissue. This tissue is surgically removed as standard. An autologous (from own body) skin graft may then be necessary if the surviving skin is unable to close the wound (re-epithelisation).

The efficacy of NexoBrid has been demonstrated in two Phase 3 studies (MW 2010-03-02 and MW 2004-11-02). The data from study MW 2004-11-02 have already been evaluated by the European Medicines Agency (EMA). The second, more recent efficacy study MW 2010-03-02 (DETECT) investigated 175 patients with deep (second-

degree (2b)) and very deep (third-degree) burn wounds. The patients received either NexoBrid, surgical debridement (corresponds to standard treatment) or the gel from NexoBrid without addition of the active substance. The efficacy of NexoBrid in dissolving the wound eschar and the reduction in further necessary surgical measures were demonstrated.

The need for a subsequent autologous skin graft decreased demonstrably compared to standard treatment only in second-degree (2b) patients in the NexoBrid group, but not in the third-degree NexoBrid group.

Precautions, undesirable effects & risks

NexoBrid must not be used in those who are hypersensitive to pineapple, the active substance concentrate or any of the excipients.

The most frequent undesirable effects are fever, local pain and tachycardia (increased heart rate).

All precautions, risks and other possible side effects are listed in the Information for patients (package leaflet) and the Information for healthcare professionals.

Why the medicinal product has been authorised

The studies showed that patients with deep and very deep burns (second (2b) and third-degree) benefit from treatment with NexoBrid. NexoBrid is an effective alternative to surgical debridement.

Taking all the risks and precautions into account, and based on the available data, the

benefits of NexoBrid outweigh the risks. Swissmedic has therefore authorised the medicinal product NexoBrid with the active substance concentrate of proteolytic enzymes enriched in bromelain for use in Switzerland.

Further information on the medicinal product

Information for healthcare professionals: [Information for healthcare professionals NexoBrid®](#)

Information for patients (package leaflet): [Information for patients 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 Public Summary SwissPAR.

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