



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

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## NexoBrid (*concentrate of proteolytic enzymes enriched in bromelain*)

An overview of NexoBrid and why it is authorised in the EU

### What is NexoBrid and what is it used for?

NexoBrid is a medicine used for removing eschar (dead tissue which is dried out, thick, leathery and black) due to skin burns caused by heat or fire. It can be used both for deep partial-thickness burns (sometimes called 'second degree' burns) which extend into a deep region of an inner layer of the skin called the dermis, and full-thickness burns (sometimes called 'third degree' burns) which extend even deeper, through the whole dermis.

The active substance in NexoBrid is a concentrate of proteolytic enzymes enriched in bromelain.

### How is NexoBrid used?

NexoBrid can only be obtained with a prescription. It should only be applied by trained healthcare professionals in specialised burn centres.

NexoBrid is available as a powder and a gel, which are mixed together to make a gel. The medicine should not be applied to more than 10% (for children up to 3 years of age) or 15% (for older people) of the body surface area. NexoBrid should be left in contact with the skin for 4 hours. A second application is not recommended.

For more information about using NexoBrid, see the package leaflet or contact your doctor or pharmacist.

### How does NexoBrid work?

The active substance in NexoBrid is a mixture of enzymes extracted from the stem of the pineapple plant. This mixture of enzymes acts as a debriding agent, a substance used to remove dead tissue from areas of the skin such as burn wounds, by dissolving the burn wound eschar. Removing the eschar helps to allow the living skin tissue to be treated and to heal.

### What benefits of NexoBrid have been shown in studies?

NexoBrid was shown to be effective at removing eschar in two main studies.

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One main study involved 156 patients who were hospitalised with deep partial-thickness or full-thickness burn wounds. The patients received either NexoBrid or standard debridement treatment (surgical or non-surgical) before receiving further treatment if required, such as surgery or a skin graft.

In patients receiving NexoBrid, around 15% (16 out of 106) of the wounds required surgery to remove the eschar and around 18% (19 out of 106) of the wounds required a skin graft, compared with around 63% (55 out of 88) and around 34% (30 out of 88), respectively, in patients receiving standard debridement treatment. NexoBrid was also seen to be an effective debridement treatment for burn wounds of all thicknesses, including full thickness wounds. In addition, it was found that NexoBrid removed eschar from wounds faster than standard treatments.

Another main study involved 145 patients from birth to 18 years old with deep partial- or full-thickness burn wounds who received either NexoBrid or standard-of-care treatment.

Complete eschar removal took an average of 1 day with NexoBrid compared with an average of 6 days with standard treatment. In patients who received NexoBrid, about 1.5% of the wound area needed to be removed by surgery compared with 48% in patients receiving standard treatment. About a year after the closure of the wounds, improvement in skin appearance and function was measured using a standard scar assessment scale called MVSS (modified Vancouver Scar Scale); the scale ranges from 0 to 18, with 0 indicating normal appearance and function. The average MVSS score in patients who received NexoBrid was 3.83 compared with 4.86 for patients who received standard treatment.

### **What are the risks associated with NexoBrid?**

For the full list of side effects and restrictions with NexoBrid, see the package leaflet.

The most common side effects with NexoBrid include fever (which may affect more than 1 in 10 people) and pain (which may affect up to 1 in 10 people).

NexoBrid must not be used in people who are hypersensitive (allergic) to the active substance, pineapple, papaya fruit or papain (an enzyme found in papaya fruit) or any of the other ingredients.

### **Why is NexoBrid authorised in the EU?**

NexoBrid has been shown to effectively remove eschar from deep partial-thickness and full-thickness wounds and to reduce the need for surgery to remove further skin tissue in deep partial-thickness wounds. The eschar was removed faster than with standard treatment. In children and adolescents, treatment with NexoBrid was shown to have no negative effect on skin appearance and function about 1 year after treatment compared with standard of care treatment. The safety profile of NexoBrid was considered acceptable.

Since some of the side effects seen, including delay in complete wound healing, may have been related to wound care procedures, the European Medicines Agency decided that NexoBrid should only be used in specialised burn centres by healthcare professionals who have been trained to use it. The Agency decided that NexoBrid's benefits are greater than its risks and it can be authorised for use in the EU.

### **What measures are being taken to ensure the safe and effective use of NexoBrid?**

The company marketing NexoBrid must provide educational materials to all healthcare professionals in specialised burn centres with information about how the medicine should be used, including a step-by-

step guide covering important safety considerations before and after using NexoBrid. In addition, the company must ensure that NexoBrid is only available at centres where at least one surgeon has received formal training in how to use the medicine.

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of NexoBrid have also been included in the summary of product characteristics and the package leaflet.

As for all medicines, data on the use of NexoBrid are continuously monitored. Suspected side effects reported with NexoBrid are carefully evaluated and any necessary action taken to protect patients.

## **Other information about NexoBrid**

NexoBrid received a marketing authorisation valid throughout the European Union on 18 December 2012.

Further information on NexoBrid can be found on the Agency's website:  
[ema.europa.eu/en/medicines/human/EPAR/nexobrid](http://ema.europa.eu/en/medicines/human/EPAR/nexobrid).

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