

Discover enzymatic surgery



NexoBrid® (formerly Debrase) is a new class of non-surgical eschar removal agent for deep partial- and full-thickness thermal burns in adults. NexoBrid® can significantly reduce the extent of surgery required and the time to successful eschar removal compared with Standard of Care. NexoBrid® can remove the eschar without harming healthy tissue.

NexoBrid®
Debride and Protect

Abbreviated prescribing information: NexoBrid powder and gel for gel. Each pack contains 2g powder per vial and 20g gel per bottle or 5g powder per vial and 50g gel per bottle. **Posology and method of administration:** NexoBrid should only be applied by trained healthcare professionals in specialist burn centres. NexoBrid should not be applied to more than 15% Total Body Surface Area (TBSA). NexoBrid should be left in contact with the burn for duration of 4 hours. There is very limited information on the use of NexoBrid on areas where eschar remained after the first application. A second and subsequent application is not recommended. **Qualitative and quantitative composition:** One vial contains 2g or 5g of concentrate of proteolytic enzymes enriched in bromelain, corresponding to 0.09 g/g concentrate of proteolytic enzymes enriched in bromelain after mixing (2g/22g gel or 5g/55g gel). The proteolytic enzymes are a mixture of enzymes from the stem of *Ananas comosus* (pineapple plant). **Indication:** NexoBrid is indicated for removal of eschar in adults with deep partial- and full-thickness thermal burns. **Method of administration:** Cutaneous use. Before use, the powder must be mixed with the gel producing a uniform gel. NexoBrid should

be applied to a clean, keratin-free (blisters removed), and moist wound area. Topically applied medicinal products (such as silver sulfadiazine or povidone-iodine) at the wound site must be removed and the wound must be cleansed prior to NexoBrid application. **Contraindication:** Hypersensitivity to the active substance, to pineapples or papain, or to any of the excipients. **List of excipients:** NexoBrid powder: Ammonium sulphate, Acetic acid. Gel: Carbomer 980; disodium phosphate anhydrous; Sodium hydroxide; Water for injections. **Special precautions:** Concentrate of proteolytic enzymes enriched in bromelain is systemically absorbed from burn wound areas. NexoBrid is not recommended for use on penetrating burn wounds, chemical burn wounds, wounds contaminated with radioactive and other hazardous substances. NexoBrid should be used with caution in patients with cardiopulmonary and pulmonary disease. There is no experience of the use of NexoBrid on perineal and genital burns and electrical burns. There is limited information on the use of NexoBrid on facial burn wounds. NexoBrid should be used with caution in patients with disorders of coagulation, low platelet counts and increased risk of bleeding from other causes e.g.

peptic ulcers and sepsis. **Summary of the safety profile:** The frequencies of the adverse reactions presented below reflect the use of NexoBrid in a regimen with local antibacterial prophylaxis, recommended analgesia, as well as coverage of the wound area after application of NexoBrid for 4 hours with an occlusive dressing for containment of NexoBrid on the wound. **Very common adverse reactions:** Pyrexia/hyperthermia. **Common adverse reactions:** Local pain, wound infection, wound complication. **Marketing Authorisation Holder:** MediWound GmbH, Germany. **Authorisation number:** EU/1/12/803/001 NexoBrid - 2g - Powder and gel for gel; EU/1/12/803/002 NexoBrid - 5g - Powder and gel for gel. For additional information relating to the use of the product, precautions, special warnings, interactions with other medicinal products, as well as undesirable and addictive effects of the product, please refer to the EMA approved wording of the SmPC.

▼ This medicine is subject to additional monitoring.

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MediWound