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EPAR summary for the public

NexoBrid

concentrate of proteolytic enzymes enriched in bromelain

This is a summary of the European public assessment report (EPAR) for NexoBrid. It explains how the Committee for Medicinal Products for Human Use (CHMP) assessed the medicine to reach its opinion in favour of granting a marketing authorisation and its recommendations on the conditions of use for NexoBrid.

What is NexoBrid?

NexoBrid is a medicine that contains the active substance 'concentrate of proteolytic enzymes enriched in bromelain'. It is available as a powder and gel, which are mixed together to make a gel (2 g/22 g or 5 g/55 g).

What is NexoBrid used for?

NexoBrid is used in adults to remove eschar (dead tissue which is dried-out, thick, leathery and black) from deep partial thickness and full thickness burns of the skin caused by heat or fire. Deep partial thickness burns (sometimes called 'second degree' burns) extend into a deep region of an inner layer of the skin called the dermis, while full thickness burns (sometimes called 'third degree' burns) extend even deeper, through the whole dermis.

Because the number of patients with deep partial thickness and full thickness thermal burn wounds is low, the disease is considered 'rare', and NexoBrid was designated an 'orphan medicine' (a medicine used in rare diseases) on 30 July 2002.

The medicine can only be obtained with a prescription.

How is NexoBrid used?

NexoBrid is applied to the area of burnt skin after the wound has been appropriately prepared. It should only be used in specialised burns centres, and should not be applied to more than 15% of the

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patient's total body surface area. For a burn wound area of 100 cm^2, NexoBrid 2 g/20 g gel is used. For a burn wound area of 250 cm^2, NexoBrid 5 g/50 g gel is used. NexoBrid should be used within 15 minutes after mixing and should be left in contact with the skin for four hours. A second application is not recommended.

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.

How has NexoBrid been studied?

The effects of NexoBrid were first tested in experimental models before being studied in humans.

NexoBrid was studied in one main study involving 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 treatments to remove the eschar) before receiving further treatment if required, such as surgery or a skin graft. The main measure of effectiveness was the proportion of deep partial thickness wounds that needed surgery to remove further skin tissue or that required a skin graft from another area of the patient's body. The results were also considered for burn wounds of all thicknesses, including full thickness wounds.

What benefit has NexoBrid shown during the studies?

The study showed that NexoBrid was more effective than standard of care treatment (surgical and non-surgical) at reducing the proportion of the deep partial thickness burn wounds that needed surgery to remove skin tissue or required a skin graft. In patients receiving NexoBrid, in around 15% (16 out of 106) of the wounds the eschar needed to be removed by surgery and around 18% (19 out of 106) 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.

What is the risk associated with NexoBrid?

The most commonly reported side effects with NexoBrid are local pain, and pyrexia (fever) or hyperthermia (high body temperature). For the full list of all side effects reported with NexoBrid, see the package leaflet.

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

Why has NexoBrid been approved?

The CHMP concluded that NexoBrid effectively removes eschar from deep partial thickness and full thickness wounds and reduces the need for surgery to remove further skin tissue in deep partial thickness wounds. The Committee considered that NexoBrid was shown to be an effective debridement treatment with an acceptable safety profile which complements available surgical techniques. Since

some of the side effects seen, including delay in complete wound healing, may have been related to wound care procedures, the Committee decided that NexoBrid should only be used in specialised burns centres by healthcare professionals who have been trained to use it. The CHMP noted the importance of prompt skin grafting of areas of full thickness and deep burn directly after debridement with NexoBrid, in line with the standard of care in European burns centres. The CHMP decided that NexoBrid's benefits are greater than its risks and recommended that it be given marketing authorisation.

What measures are being taken to ensure the safe use of NexoBrid?

The company that markets NexoBrid must ensure that healthcare professionals in specialised burns centres who are expected to use NexoBrid receive appropriate training and an educational pack including a step-by-step guide to NexoBrid treatment, covering important safety considerations before and after using NexoBrid. The company will also carry out a long-term study in adults and children comparing NexoBrid with standard debridement treatment to investigate the outcome of patients including cosmetic considerations.

Other information about NexoBrid

The European Commission granted a marketing authorisation valid throughout the European Union for NexoBrid on 18 December 2012.

The full EPAR for NexoBrid can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/European public assessment reports. For more information about treatment with NexoBrid, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

The summary of the opinion of the Committee for Orphan Medicinal Products for NexoBrid can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/Rare disease designation.

This summary was last updated in 12/2012.