



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

21 September 2012
EMA/CHMP/406865/2012
Press Office

Press release

European Medicines Agency recommends first medical treatment for removal of eschar from severe burn wounds

Pineapple enzyme-based debriding agent adds new treatment option for burn wounds care management

The European Medicines Agency has recommended approval of NexoBrid (concentrate of proteolytic enzymes enriched in bromelain), an orphan-designated medicine, for removal of eschar in adult patients with deep partial- and/or full-thickness thermal burn. Eschar is the dried-out, thick, leathery, black necrotic tissue that covers severe burn wounds. Its removal is essential to initiate the wound healing process and prevent further complications such as infections in burn victims.

Treatment of severe burn wounds today rests mainly on surgical intervention. NexoBrid is the first pharmacological, enzyme-based debriding agent for the removal of necrotic tissue from severe burn wounds recommended for approval in the European Union.

The medicine consists of a mixture of enzymes which are extracted from the stem of the pineapple plant. It should be applied topically to a clean burn wound by a trained healthcare professional in a specialised burns centre.

Data from clinical studies assessed as part of the marketing authorisation application have shown that, compared to standard of care, NexoBrid reduces the time to successful eschar removal and the need for excisional surgery in patients with severe burn wounds.

The studies have also shown that wounds not treated optimally after debridement with NexoBrid can be associated with longer time to complete wound closure. In clinical practice and in the literature it is known that delays of two weeks or more in wound closure may be associated with an increased risk of wound-related and general adverse effects. The Agency's Committee for Medicinal Products for Human Use (CHMP) has therefore required the company to roll out a training programme and provide educational materials to healthcare professionals in specialist burns centres to ensure they have all the information they need for use of NexoBrid in the management of burn wounds.

NexoBrid was designated as an orphan medicine in 2002. The Agency gave free scientific advice to the applicant during the development of the medicine. Orphan designation and the associated incentives such as free scientific advice or 'protocol assistance' are among the Agency's most important



instruments to encourage the development of medicines for patients suffering from life-threatening or debilitating diseases or conditions that affect less than 5 in 10,000 Europeans.

Notes

1. This press release, together with all related documents, is available on the Agency's website.
2. More information on the orphan designation for NexoBrid can be found here:
http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/orphans/2009/11/human_orphan_000295.jsp&mid=WC0b01ac058001d12b&murl=menus/medicines/medicines.jsp
3. More information on the work of the European Medicines Agency can be found on its website:
www.ema.europa.eu

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