

Nexobrid[®] (anacaulase-bcdb) – Expanded indication

- On August 15, 2024, [Vericel Corporation announced](#) the FDA approval of [Nexobrid \(anacaulase-bcdb\)](#), for eschar removal in adults and pediatric patients with deep partial thickness (DPT) and/or full thickness (FT) thermal burns.
 - Nexobrid was previously approved for this indication in adults only.
- The safety and effectiveness of Nexobrid have not been established for treatment of:
 - Chemical or electrical burns
 - Burns on the face, perineum, or genitalia
 - Burns on the feet of patients with diabetes mellitus or on the feet of patients with occlusive vascular disease
 - Circumferential burns
 - Burns in patients with significant cardiopulmonary disease, including inhalation injury.
- Nexobrid is not recommended for:
 - Wounds contaminated with radioactive and other hazardous substances to avoid unforeseeable reactions with the product and an increased risk of spreading the noxious substance
 - Treatment of burn wounds where medical devices (eg, implants, pacemakers, shunts) or vital structures (eg, large vessels) could become exposed during eschar removal.
- The approval of Nexobrid for the expanded indication was based on an open label, randomized, controlled, two arm study comparing Nexobrid to standard of care treatment in 145 patients 7 months to 18 years of age with DPT and/or FT thermal burns.
 - The median time to ≥ 95% eschar removal was 0.99 day (95% CI: 0.88, 1.04) with Nexobrid vs. 5.99 days (95% CI: 2.71, 9.84) with standard of care.
- In pediatric patients 6 years of age and older, Nexobrid is applied as a 3 mm thick layer (approximate thickness of a tongue depressor) to a burn wound area of up to 15% body surface area (BSA) in one application. Nexobrid should be removed after 4 hours. A second application of Nexobrid is not recommended.
- In pediatric patients less than 6 years of age, Nexobrid should be applied as a 3 mm thick layer (approximate thickness of a tongue depressor) to a burn wound area of up to 10% BSA in one application. Nexobrid should be removed after 4 hours. A second application of Nexobrid is not recommended.
- Refer to the Nexobrid drug label for adult dosing.