

Brand Name: Bridion

Generic: sugammadex

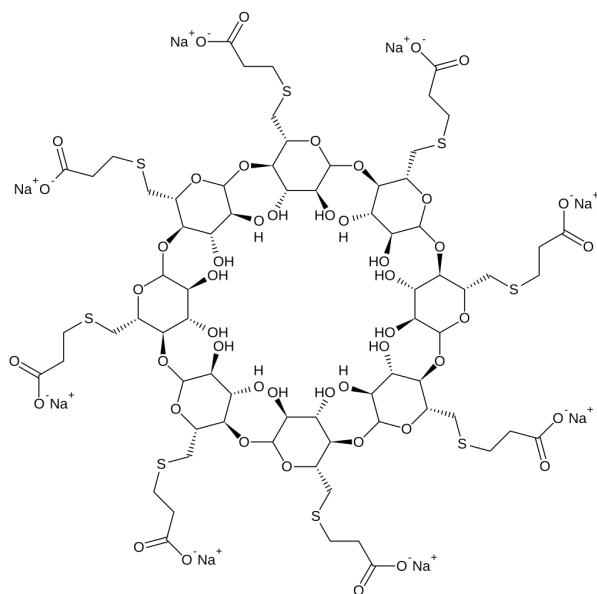
Type: small molecule

Year Accepted/Phase: 2015

Mechanism:

Sugammadex is a selective relaxant binding agent (SRBA) that works by encapsulating and forming a complex with aminosteroid non-depolarizing neuromuscular blocking agents, specifically rocuronium and vecuronium. By binding to these muscle relaxants, sugammadex effectively reduces their concentration in the plasma and reverses neuromuscular blockade, allowing for the rapid recovery of muscle function.

Chemical Structure:



Indication:

Bridion is indicated for the reversal of neuromuscular blockade induced by rocuronium or vecuronium in adults undergoing surgery.

Clinical trials:

Phase II Trials

Purpose: Evaluate the efficacy and safety of sugammadex in reversing neuromuscular blockade induced by rocuronium and vecuronium.

Dates: Conducted in the early 2000s.

Results: Phase II studies demonstrated that sugammadex rapidly and effectively reversed the effects of rocuronium and vecuronium, with a favorable safety profile. Patients experienced a quicker return to spontaneous breathing and muscle function compared to traditional reversal agents.

Impact: These results provided the basis for further large-scale studies in Phase III trials.

Phase III Trial (Study 19.4.301)

Purpose: Compare the efficacy of sugammadex with neostigmine for the reversal of rocuronium-induced neuromuscular blockade.

Dates: Conducted from 2004 to 2006.

Results: The study found that sugammadex provided significantly faster recovery from neuromuscular blockade than neostigmine. The median time to recovery to a train-of-four (TOF) ratio of 0.9 was significantly shorter with sugammadex.

Impact: These findings supported the use of sugammadex as a superior alternative to traditional reversal agents like neostigmine.

Phase III Trial (Study 19.4.304)

Purpose: Assess the safety and efficacy of sugammadex in reversing deep neuromuscular blockade induced by rocuronium.

Dates: Conducted from 2005 to 2007.

Results: The trial demonstrated that sugammadex rapidly and effectively reversed deep neuromuscular blockade, with patients recovering much faster than those who received placebo. The safety profile of sugammadex was comparable to placebo.

Impact: This trial confirmed the effectiveness of sugammadex in rapidly reversing deep neuromuscular blockade, leading to its approval for clinical use.