

NADA Number: 141-203

Trade Name	Deramaxx® Chewable Tablets
Sponsor	Novartis Animal Health US, Inc.
Ingredients	Deracoxib
Species	DOGS (Dog, no use class stated or implied)
Routes of Administration	ORAL
Dosage Form	CHEWABLE TABLETS
Dispensing Status	RX
Patent Number (Expiration Date)	5,521,207 (05/01/2016) 5,756,529 (09/29/2015) 5,892,053 (05/25/2015) 5,910,597 (05/25/2015)
Exclusivity	Under section 512(c)(2)(F)(iii) of the Federal Food, Drug, and Cosmetic Act, this approval qualifies for three years of marketing exclusivity beginning on the date of the approval. The three years of marketing exclusivity applies only to the postoperative dental pain indication for which this supplement is approved (Exp 11/23/2014).
Specifications	Each chewable tablet contains 12, 25, 50, 75, or 100 milligrams (mg) deracoxib.
Dosage Amount, Indications & Limitations	<p>Dosage: The daily dose of DERAMAXX tablets for the control of pain and inflammation associated with osteoarthritis in dogs is 0.45-0.91 mg/lb/day (1-2 mg/kg/day) as a single daily dose, as needed.</p> <p>The dose for postoperative dental pain is 0.45-0.91 mg/lb/day (1-2 mg/kg/day) as a single daily dose for 3 days. The first dose should be given approximately 1 hour prior to dental surgery and subsequent doses should be given daily for up to two additional treatments.</p> <p>The dose for postoperative orthopedic pain is 1.4-1.8 mg/lb/day (3- 4 mg/kg/day) as a single daily dose, as needed, not to exceed 7 days of administration.</p> <p>Tablets are scored and dosage should be calculated in half-tablet increments.</p> <p>Indications: For the control of pain and inflammation associated with osteoarthritis in dogs, and for the control of postoperative pain and inflammation associated with orthopedic surgery and dental surgery in dogs.</p> <p>Limitations: Federal law restricts this drug to use by or on the order of a licensed veterinarian.</p>