

## **Deramaxx® Chewable Tablets**

Common Drug Name - Deracoxib

**How Supplied by SmartPak** – Deramaxx is available as 25 mg, 75 mg and 100 mg tablets in daily dose SmartPaks and in 30 or 90 count bottles.

Category – Deramaxx is a non-narcotic, non-steroidal anti-inflammatory drug (NSAID) of the coxib class.

**Caution** - Federal law restricts this drug to use by or on the order of a licensed veterinarian.

Indications (Uses) – Deramaxx is indicated 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 in dogs  $\geq 4$  lbs (1.8kg).

## Dosage and Administration -

Osteoarthritis: 0.45 - 0.91 mg/lb/day (1 - 2 mg/kg/day) as a single daily dose as needed) Postoperative Othropedic Surgery: 1.4 - 1.8 mg/lb/day (3 - 4mg/kg/day) as a single daily dose, as needed, not to exceed 7 days of administration.

Since Deramaxx Tablet bioavailability is greatest when taken with food, postprandial administration is preferable. However, Deramaxx Tablets have been shown to be effective under both fed and fasted conditions; therefore, they may be administered in the fasted state if necessary.

Contraindications – Dogs with known hypersensitivity to Deramaxx or other NSAIDS should not receive Deramaxx.

**Human Warning** – Not for human use. Keep out of reach of children. Consult a physician in case of accidental ingestion by humans.

**Warning** – For use in dogs only. All dogs should undergo a thorough history and physical examination before the initiation of NSAID therapy. Appropriate laboratory tests to establish hematological and serum biochemical baseline data prior to, and periodically during administration of any NSAID is recommended. Sensitivity to drug-associated adverse events varies with the individual patient. As a class, NSAIDs may be associated with GI, renal and hepatic toxicity. Patients at greatest risk for NSAID toxicity are those that are dehydrated, on concomitant diuretic therapy, or those with existing renal, cardiovascular, and/or hepatic dysfunction. Since many NSAIDs possess the potential to produce GI ulceration and/or perforation, concomitant use of Deramaxx Tablets with other anti-inflammatory drugs, such as NSAIDs or corticosteroids, should be avoided. Owners should observe for signs of potential drug toxicity.

**Precautions** – The safe use of Deramaxx in dogs younger than 4 months of age, dogs used for breeding, or in pregnant or lactating dogs has not been evaluated. NSAIDs may inhibit the prostaglandins which maintain normal homeostatic function. Such antiprostaglandin effects may result in clinically significant disease I patients with underlying or pre-existing disease that has not been previously diagnosed. Appropriate monitoring procedures should be employed during all surgical procedures. The use of parenteral fluids during surgery should be considered to decrease potential renal complications when using NSAIDs perioperatively. Concurrent administration of potentially nephrotoxic drugs should be carefully approached. Consider appropriate

washout times when switching from one NSAID to another or when switching from corticosteroid use to NSAID use.

Adverse Reactions (Side Effects) – The most common adverse reaction observed in dogs dosed with Deramaxx or placebo was vomiting.

**Storage Conditions**: Deramaxx should be stored at controlled room temperatures, between 59 – 86F.

## Manufactured for:

Novartis Animal Health US, Inc. Greensboro, NC 27408

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SmartPak<sup>TM</sup>
40 Grissom Road, Suite 500
Plymouth, MA 02360
Phone: 1-800-431-4194
Fax: 1-800-431-4179

www.SmartPak.com