Confusion, weakness, hyperactivity, tremor, paresis, head tilt, nystagmus, mydriasis, aggression, uveitis

Depression/lethargy, ataxia, seizures, nervousness,

Elevated BUN, elevated creatinine, polydypsia, polyuria, hematuria, urinary incontinence, hematachezia, weight loss, gastrointestinal ulceration, peritonitis, abdominal pain, hypersalivation, nausea


In a target animal safety study, firocoxib was administered orally to healthy adult Beagle dogs (68.5%) by owners in multi-center field studies involving client-owned dogs of various breeds and sizes.

The safe use of PREVICOX Chewable Tablets in pregnant, lactating or breeding dogs has not been evaluated.

Adverse Reactions Seen in the Soft-tissue Surgery Postoperative Pain Field Study

Laboratory:

Orthopedic Surgery:

A multi-center field study with 226 client-owned dogs of various breeds, and ranging in age from 1 to 11 years has been conducted to determine the effectiveness of PREVICOX Chewable Tablets at a dose of 2.27 mg/kg (5.0 mg/kg) for prevention of pain in client-owned dogs undergoing soft-tissue surgery.

If additional pain medication is needed after the daily dose of PREVICOX, a non-NSAID class of analgesic may be considered. Consideration should always be given to the role of concomitant corticosteroid use to NSAID use.

Cardiovascular / Respiratory:

Elevated ALP, elevated ALT, elevated bilirubin, decreased albumin, elevated AST, icterus, decreased or increased total protein and globulin, pancreatitis, ascites, liver failure, decreased BUN

In a separate dose tolerance safety study involving a total of six dogs (two control dogs and four treated dogs), firocoxib was administered as a 5 mg/kg oral dose to fasted adult dogs. Firocoxib is rapidly cleared from the blood via hepatic metabolism with hepatic clearance of approximately 3 L/hr/kg (range: 2.1 - 4.3 L/hr/kg). The small volume of distribution (Vdss) of firocoxib is ~0.4 L/hr/kg. Despite a high level of plasma protein binding (96%), firocoxib exhibits a large volume of distribution (Vd), of 0.2 L/kg and a terminal elimination half-life of 17 hours (11.5 - 22.7 hours). The drug distributes passively in highly variable amounts on serum proteins. On administration of PREVICOX with food decreased drug absorption (Table 191) is found to 14% and 46% in dogs and humans, respectively. However, food does not affect the overall bioavailability at the recommended dose.

As a class, cyclooxygenase inhibitors (NSAIDs) may be associated with renal, gastrointestinal and hepatic adverse reactions.

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Two hundred and forty-nine dogs of various breeds, ranging in age from 11 months to 12 years were included in this study. Dogs were randomly assigned to receive either placebo (n=72) or firocoxib (n=177) for 30 days.

All dogs were solicited by a thorough history, physical examination before the initiation of the NSAID therapy. Appropriate monitoring of laboratory, clinical chemistry and hematology parameters is recommended prior to and periodically during administration of an NSAID.

Owners should be advised to observe for signs of potential drug toxicity and to report Adverse Reactions and Animal Safety and to give a Client Information Sheet about PREVICOX Chewable Tablets.

For technical assistance or to report suspected adverse events, call 1-877-217-3543.

Post Approval Experience (Rev. 2009):

In a target animal safety study, firocoxib was administered orally to fasted adult dogs (68.5%) by owners in multi-center field studies involving client-owned dogs of various breeds and sizes.

Appropriate monitoring procedures should be employed during all surgical procedures. Anesthetic drugs may interact adversely with PREVICOX at the surgical site. If additional pain medication is needed after the daily dose of PREVICOX, a non-NSAID class of analgesic may be considered. Consideration should always be given to the role of concomitant corticosteroid use to NSAID use.

In a separate safety study, firocoxib was administered orally to healthy puppies (10.7 to 12 weeks of age) for 30 days and to healthy adult dogs (68.5%) by owners in multi-center field studies involving client-owned dogs of various breeds and sizes.

Two hundred and fifty-eight client-owned dogs of various breeds, ranging in age from 1 to 11 years has been conducted to determine the effectiveness of PREVICOX Chewable Tablets at a dose of 2.27 mg/kg (5.0 mg/kg) for prevention of pain in client-owned dogs undergoing orthopedic surgery.

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