Felixvet Inc.

Deracoxib Chewable Tablets

For Oral Use in Dogs Only Do Not Use in Cats

Deracoxib Chewable Tablets are indicated for the control of pain and inflammation associated with osteoarthritis in dogs, as well as control of postoperative pain and inflammation associated with orthopedic/dental surgery in dogs.

Product	Strength	Pack Size
	12 MG	30 Chewable Tablets
	12 MG	90 Chewable Tablets
Deracoxib	25 MG	30 Chewable Tablets
Chewable	25 MG	90 Chewable Tablets
\ Tablets	75 MG	30 Chewable Tablets
\	75 MG	90 Chewable Tablets
	100 MG	30 Chewable Tablets
	100 MG	90 Chewable Tablets

Features and benefits

- Therapeutically equivalent to the pioneer drug, the same safety and efficacy
- Tablets are available in four strengths 12, 25, 75 and 100 mg
- Palatable beef flavor
- Chewable for best compliance & each chewable tablet is scored for easy/accurate dosing.



Deracoxib **Chewable Tablets**

For Oral Use in Dogs Only Do Not Use in Cats

Caution:

Federal Law (U.S.) restricts this drug to use by or on the order of a licensed veterinarian

Description

Description:

Deracoxib Chewable Tablets is a non-narcotic, non-steroidal anti-inflammatory drug (NSAID) of the coxib class. Deracoxib Chewable Tablets are round, light brown colored, chewable tablets that contain deracoxib formulated with beefy finding. The molecular weight of deracoxib is 397.38. The empirical formula is cir-Hu-F≻-№-O⊳-S. Deracoxib is 4/3-(diffuoromethyl)-5/3-fluoro-4-methoxyphenyl)-1H-pyrazole-1-yl] benzenesullionamide, and can be termed a diarryl substituted pyrazole. The structural formulais:



Clinical Pharmacology

Clinical Pharmacology
Mode of Action:

Deracoxib Chewable Tablets are a member of the coxib class of non-narcotic, nonsteroidal, cyclooxygenase-inhibiting antiinflammatory drugs for the control of postoperative pain and inflammation associated with orthopedic and dental surgery and
for the control of pain and inflammation associated with osteoarthritis in dogs.

Data indicate that deracoxib inhibits the production of PGE1 and 6-keto PGF1 by its inhibitory effects on prostaglandin
biosynthesis. Deracoxib inhibited COX-2 mediated PGE2 production in LPS-stimulated human whole blood.

Cyclooxygenase-1 (COX-1) is the enzyme responsible for facilitating constitutive physiological processes (e.g., platelet
aggregation, gastric mucosal protection, renal perfusion). Cyclooxygenase-2 (COX-2) is responsible for the synthesis of
inflammatory mediators. Both COX isoforms are constitutively expressed in the canine kidney. At doses of 2-4 mg/kg/day,
deracoxib tablets do not inhibit COX-1 based on in vitro studies using cloned canine cyclooxygenase. The clinical relevance of
this in vitro data has not been shown.

Although the plasma terminal elimination half-life for deracoxib tablets is approximately 3 hours, a longer duration of clinical
effectiveness is observed.

Summary pharmacokinetics of Deracoxib tablets are listed in Table 1.

Table 1: Pharmacokinetics of Deracoxib

Parameter	Value	
Tmax ^a	2 hours	
Oral Bioavailability (F)	> 90% at 2 mg/kg	
Terminal elimination half-life ^b	3 hours at 2-3 mg/kg 19 hours at 20 mg/kg	
Systemic Clearance ^b	~ 5 ml/kg/min at 2 mg/kg ~1.7 ml/kg/min at 20 mg/kg	
Volume of Distribution ^c	~ 1.5 L/kg	
Protein binding ^d	> 90%	

Values obtained following a single 2.35 mg/kg dose
"Estimates following IV administration of deracoxib as an aqueous solution
"Based upon a dose of 2 mg/kg of deracoxib
"Based upon in vitro plasma concentrations of 0.1, 0.3, 1.0, 3.0, 10.0 µg/ml
Non-linear elimination kinetics are exhibited at doses above 8 mg/kg/day, at which competitive inhibition of constitutive COX-1

Non-linear elimination kinetics are exhibited at doses above 5 mg/kg/day, at which competitive inhibition of constitutive COX-1 may occur.

Deracoxib is not excreted as parent drug in the urine. The major route of elimination of deracoxib is by hepatic biotransformation producing four major metabolites, two of which are characterized as products of oxidation and odemethylation. The majority of deracoxib is excreted in feces as parent drug or metabolite.

Large intersubject variability was observed in drug metabolite profiles of urine and feces. No statistically significant differences between genders were observed.

Indications and Usage:
Always provide "Information for Dog Owners" Sheet with prescription. Carefully consider the potential benefits and risk of Deracoxib Chewable Tablets and other treatment options before deciding to use Deracoxib Chewable Tablets. Use the lowest effective dose for the shortest duration consistent with individual response.

Osteoarthritis Pain and Inflammation:

Deracoxib Chewable Tablets are indicated for the control of pain and Inflammation associated with osteoarthritis in dogs.

Dosage and Administration:

Osteoarthritis Pain and Inflammation: 0.45 – 0.91 mg/lb/day (1 to 2 mg/kg/ day) as a single daily dose, as needed.

Dogs needing a dose of less than 12.5 mg can only be accurately dosed through use of the 12 mg tablet, which can be broken in half to provide 6 mg. Do not attempt to accurately dose smaller dogs through the use of breaking larger tablets. Inaccurate dosing may result in adverse drug events (see Adverse Reactions, Animal Safety, and Post-Approval Experience). Postoperative Orthopedic Pain and Inflammation:
Deracoxib Chewable Tablets are indicated for the control of postoperative pain and inflammation associated with orthopedic

Detactors to leave to the control of possibility of the use of the control of possibility of the use of the control of possibility of the use of the control of the control of the use of the 12 mg daily dose, as needed, not to exceed 7 days of administration.

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Destonarship Dental Pain and Inflammation:

Postoperative Dental Pain and Inflammation:

Deracoxib Chewable Tablets are indicated for the control of postoperative pain and inflammation associated with dental

surgery in dogs. **Dosage and Administration:**

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Postoperative Dental Pain and Inflammation: 0.45 – 0.91 mg/lb/day (1 to 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.

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Dogs needing a dose of less than 12.5 mg can only be accurately dosed through use of the 12 mg tablet, which can be broken in half to provide 6 mg. Do not attempt to accurately dose smaller dogs through the use of breaking larger tablets. Inaccurate dosing may result in adverse drug events (see Adverse Reactions, Animal Safety, and Post-Approval Experience). Since deracoxib tablet bioavailability is greatest when taken with food, postprandial administration is preferable. However, claracoxib tablets have been shown to be effective under both fed and fasted conditions; therefore, when you be administered in the fasted state if necessary. For postoperative orthopedic and dental pain, administer Deracoxib Chewable Tablets prior to the procedure. Tablets are scored and dosage should be calculated in half-tablet increments. In clinical practice it is recommended to adjust the individual patient dose while continuing to monitor the dog's status until a minimum effective dose has been reached.

Contraindications:

Dogs with known hypersensitivity to deracoxib should not receive Deracoxib Chewable Tablets.

Warnings:
Not for use in humans. Keep this and all medications out of reach of children. Consult a physician in case of accidental ingestion

Not for use in humans. Keep this and all medications out of reach of children. Consult a physician in case of accidental ingestion by humans. For use in dogs only. Do not use in cats.

Dogs needing a dose of less than 12.5 mg can only be accurately dosed through use of the 12 mg tablet, which can be broken in half to provide 6 mg. Do not attempt to accurately dose smaller dogs through the use of breaking larger tablets. Inaccurate dosing may result in adverse drug events (see Adverse Reactions, Animal Safety, and Post-Approval Experience). 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. Owners should be advised to observe for signs of potential drug toxicity (see Adverse Reactions, Animal Safety and Post-Approval Experience) and be given an "Information for Dog Owners" Sheet.

Keep Deracoxib in a secure location out of reach of dogs, cats, and other animals to prevent accidental ingestion or

Precautions

Precautions:

Dogs needing a dose of less than 12.5 mg can only be accurately dosed through use of the 12 mg tablet, which can be broken in half to provide 6 mg. Do not attempt to accurately dose smaller dogs through the use of breaking larger tablets. Inaccurate dosing may result in adverse drug events (see Adverse Reactions, Animal Safety, and Post-Approval Experience). Since NSAIDs possess the potential to produce gastrointestinal ulceration and/or perforation, concomitant use of Deracoxib Chewable Tablets with other anti-inflammatory drugs, such as NSAIDs or corticosteroids, should be avoided. As a class, NSAIDs may be associated with gastrointestinal, renal and hepatic toxicity. The following collective group of clinical signs has been reported with some serious gastrointestinal events, in decreasing order of reported frequency: anorexia, tachycardia, tachypnea, pyrexia, ascites, pale mucous membranes, dyspnea. In some cases, circulatory shock, collapse and cardiac arrest have also been reported. Sensitivity to drug-associated adverse events varies with the individual patient. Dogs that have experienced adverse reactions from one NSAID may experience adverse reactions from anternational patients at greatest risk for adverse events are those that are dehydrated, on concomitant diuretic therapy, or those with existing renal, cardiovascular, and/ or hepatic dysfunction. Plasma levels of deracoxib may increase in a greater han dose-proportional fashion above 8 mg/kg/day. Deracoxib tablets have been safely used during field studies in conjunction with other common medications, including heartworm preventatives, anthelminitics, anesthetics, pre-anesthetic medications, and antibiotics. If additional pain medication is needed after a daily dose of Deracoxib Chewable Tablets, a non-NSAID/non-corticosteroid class of analgesic may be necessary. It is not known whether dogs wi

bound drugs include cardiac, anticonvulsaria and behavioral medications. The influence of concentrating that may inhibit metabolism of deracoxib tablets has not been evaluated. Drug compatibility should be monitored in patients requiring adjunctive therapy. Consider appropriate washout times when switching from one NSAID to another or when switching from corticosteroid use to NSAID use.

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Animal Safety:
In a 6-month study, dogs were dosed with deracoxib at 0, 2, 4, 6, 8 and 10 mg/kg with food once daily for 6 consecutive months. There were no abnormal feeces, and no abnormal findings on clinical observations, food and water consumption, body weights, physical examinations, ophthalmoscopic evaluations, macroscopic pathological examinations, hematology, or buccal bleeding time. Unnalysis results showed hyposthenuria (specific gravity <1.005) and polyuria in one male and one female in 6 mg/kg group after 6 months of treatment, the mean BUIN values for dogs treated with 6, 8, or 10 mg/kg/day were 30.0, 35.3, and 48.2 mg/dL respectively. No effects were seen on any other clinical chemistry parameters, including other variables associated with renal physiology (serum creatinine, serum electrolytes, and urine sediment evaluation). Dose dependent focal renal tubular degeneration/regeneration was seen in some dogs treated at 6, 8, and 10 mg/kg/day. Focal renal papillary necrosis was seen in 3 dogs dosed at 10 mg/kg/day and in one dog dosed at 8 mg/kg/day. No renal lesions were seen at the label doses of 2 and 4 mg/kg/day. There was no evidence of gastrointestinal, hepatic, or hematopoietic pathology at any of the doses tested.

In a laboratory study, healthy young dogs were dosed with deracoxib tablets once daily, within 30 minutes of feeding, at doses of 0, 4, 6, 8, and 10 mg/kg body weight for 21 consecutive days. No adverse drug events were reported. There were no abnormal findings reported for clinical observations, food and water consumption, body weights, physical examinations, ophthalmic evaluations, organ weights, macroscopic pathologic evaluation, hematology, urinalyses, or buccal mucosal bleeding time. In the clinical chemistry results there was a statistically significant (p<0.0009) dose-dependent trend toward increased levels of blood urea ni

Effectiveness:

Deracoxib tablets were evaluated in masked, placebo-controlled multi-site field studies involving client-owned animals to

determine effectiveness

Osteoarthritis Pain and Inflammation Field Study:

Two hundred and nine (209) client-owned dogs with clinical and radiographic signs of osteoarthritis of at least one appendicular joint were enrolled in this study. A total of 194 dogs were included in the safety evaluation and a total of 181 dogs were included in the effectiveness evaluation. The effectiveness of deracoxib tablets in the control of pain and inflammation associated with osteoarthritis was demonstrated in a placebo-controlled, masked study evaluating the anti-inflammatory and analgesic effects of deracoxib tablets. Tablets were administered by the owner at approximately 1-2 mg/kg/day for forty-three (43) consecutive days. In general, statistically significant (p≤ 0.05) differences in favor of deracoxib were seen for force plate parameters (vertical impulse area, peak vertical force) and owner evaluations (quality of life, lameness and overall level of activity). The results of this field study demonstrate that deracoxib tablets, when administered at 1-2 mg/kg/day for 43 days, are effective for the control of pain and inflammation associated with osteoarthritis.

Adverse Reactions:

Deracoxib was well tolerated and the incidence of clinical adverse reactions was comparable in deracoxib and placebo-treated animals. A total of 209 dogs of 41 breeds, 1-14 years old, weighing 17-177 lbs were included in the field safety analysis. The following table shows the number of dogs displaying each adverse reaction.

Clinical Observation	Deracoxib tablets N = 105	Placebo N = 104
/omiting	3	4
Diarrhea/soft stool	3	2
Weight loss	1	0
Abdominal pain (splinting)	0	1
Seizure	1	0
Lethargy	0	1
Pyoderma/Dermatitis	2	0
Unilateral conjunctivitis	1	0
Scleral injection	0	1
Hematuria/UTI	1	0
Splenomegaly*	1	0
Grade II murmur systolic	1	0

Dogs may have experienced more than one adverse reaction during the study.

*This dog was less active and eating less on enrollment, with elevated WBC, amylase, and AST and died 1 month after exiting the study. The dog was withdrawn from the study on Day 17 with anorexia, lethargy and a suspicion of diarrhea. Follow-up laboratory analyses revealed hyposalbuminemia, hyperphosphatemia, elevated AST and decreased BUN. Follow-up treatment included other anti-inflammatories and antibiotics.

Complete blood count, serum chemistry, and buccal bleeding time analysis were conducted at the beginning and end of the trial. Mean values of all CBC and chemistry results for both deracoxib and placebo-treated dogs were within normal limits. There was no statistically significant difference in the buccal bleeding time between deracoxib and placebo-treated dogs before or after the study, and all results remained within normal limits (less than 5 minutes). The results of this field study demonstrate that deracoxib is safe and effective for the control of pain and inflammation associated with osteoarthritis in dogs. During this trial, dogs were safely treated with a variety of commonly used medications, including antibiotics, anti-parasiticides, topical flea adulticides and thyroid supplements.

The results of this field study demonstrate that deracoxib tablets are well tolerated when administered at 1-2 mg/kg/day for up to 43 days for the control for ain and inflammation associated with osteoarthritis.

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To stoperative Orthopedic Pain and Inflammation resociated with osteodrimus.

Postoperative Orthopedic Pain and Inflammation Field Study:
In this study, 207 dogs admitted to veterinary hospitals for repair of a cranial cruciate injury were randomly administered deracoxib tablets or a placebo. Drug administration started the evening before surgery and continued once daily for 6 days postoperatively. Effectiveness was evaluated in 119 dogs and safety was evaluated in 207 dogs. Statistically significant differences in favor of deracoxib tablets were found for lameness at walk and trot, and pain on palpation values at all post-surgical time points. The results of this field study demonstrate that deracoxib tablets, when administered daily for 7 days are effective for the control of postoperative pain and inflammation associated with orthopedic surgery.

Adverse Reactions:

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A total of 207 dogs of forty-three (43) different breeds, 1-15 years old, weighing 7-141 lbs were included in the field safety analysis. The following table shows the number of dogs displaying each adverse reaction.

Clinical Observation	Deracoxib tablets N = 105	Placebo N = 102
Vomiting	11	6
Diarrhea	6	7
Hematochezia	4	0
Melena	0	1
Anorexia	0	4
Incision site lesion (drainage, oozing)	11	6
Non-incision skin lesions (moist dermatitis, pyoderma)	2	0
Otitis externa	2	0
Positive joint culture	1	0
Phlebitis	1	0
Hematuria	2	0
Conjunctivitis	1	2
Splenomegaly	1	0
Hepatomegaly	1	0
Death	0	1

This table does not include one dog that was dosed at 16.92 mg/kg/day for the study duration. Beginning on the last day of treatment, this dog experienced vomitting, diarrhea, increased water intake and decreased appetite. Hematology and clinical chemistry values were unremarkable. The dog recovered uneventfully within 3 days of cessation of dosing. Incisional drainage was most prevalent in dogs enrolled at a single study site. There were no statistically significant changes in the mean values for hepatic or renal clinical pathology indices between deracoxib tablet and placebo treated dogs. Four deracoxib tablet-treated dogs and two placebo-treated dogs exhibited elevated billrubin during the dosing phase. One deracoxib tablet-treated dog exhibited elevated ALT, BUN and total billrubin and a single vomiting event. None of the changes in clinical pathology values were considered clinically significant. The results of this clinical study demonstrate that deracoxib tablets, when administered daily for 7 days to control postoperative orthopedic pain and inflammation in dogs, are well tolerated.

orthopedic pain and inflammation in dogs, are well tolerated.

Postoperative Dental Pain and Inflammation Field Study:

In this study, 62 dogs admitted to veterinary hospitals for dental extractions were randomly administered deracoxib tablets or a placebo. Drug administration started approximately 1 hour before surgery and continued once daily for 2 days postoperatively. Effectiveness was evaluated in 67 dogs and safety was evaluated in 62 dogs. There was a statistically significant reduction (p=0.0338) in the proportion of dogs that required rescue therapy to control post-surgical pain in the deracoxib treated group compared to the placebo control group. Pain assessors used a modification of the Glasgow Composite an Scale (mcGCPS) to assess pain. A dog was rescued if it scored ≥ 4 on the combined mGCPS variables of Posture/Activity, Demeanor, Response to Touch, and Vocalization, or if the investigator determined at any time that pain intervention was needed. The results of this field study demonstrate that deracoxib, when administered once daily for 3 days, is effective for the control of postoperative pain and inflammation associated with dental surgery.

Adverse Reactions:

Adverse Reactions:

A total of 62 male and female dogs of various breeds, 1.5-16 years old, were included in the field safety analysis. The following table shows the number of dogs displaying each adverse reaction. Digestive tract disorders (diarrhea and vomiting) and systemic disorders (abnormal clinical chemistry results) were the most frequently reported findings. There were no distinct breed, age, or sex predilections for adverse reactions that were reported. No dogs were withdrawn from the study due to the occurrence of an adverse reaction.

Abnormal Health Findings in the Dental Pain Field Study ¹			
Clinical Observation	Deracoxib tablets N = 31	Placebo N = 31	
Vomiting	4	1	
Diarrhea/soft stool	3	1	
Regurgitation	0	2	
Increased AST ²	3	0	
Increased ALT ²	1	0	
Hematuria	1	0	
Leukocytosis	1	1	
Neutrophilia	1	1	
Lameness	1	0	
Facial swelling	0	1	
Tachycardia	0	1	

Dogs may have experienced more than one adverse reaction during the study. Included animals with results over 2x the high normal.

PostApproval Experience (Rev. 2010):
The following adverse events are based on post-approval adverse drug experience reporting. Not all adverse reactions are reported to FDA CVM. It is not always possible to reliably estimate the adverse event frequency or establish a causal relationship to product exposure using this data. The following adverse events are grouped by body system and are presented in decreasing order of reporting frequency.

Gastrointestinal: vomiting, diarrhea, hypoalbuminemia, melena, hematochezia, elevated amylase/lipase, hematemesis, abdominal pain, peritonitis, decreased or increased total protein and globulin, gastrointestinal perforation, gastrointestinal ulceration, hypersalivation.

General: an or exia, depression/lethargy, weight loss, weakness, fever, dehydration

Hepatic: elevated liver enzymes, hyperbilirubinemia, icterus, ascites, decreased BUN Hematologic: anemia, leukocytosis, leukocytopenia, thrombocytopenia

Neurologic: seizures, ataxia, recumbency, trembling, confusion, collapse, hind limb paresis, nystagmus, proprioceptive disorder, vestibular signs
Behavioral: nervousness, hyperactivity, aggression, apprehension

Urologic: elevated BUN/creatinine, polydipsia, polyuria, hyper-phosphatemia, hematuria, low urine specific gravity, urinary incontinence, renal failure, urinary tract infection

 $Dermatologic: pruritus, erythema, urticaria, moist dermatitis, facial/muzzle\,edema, dermal\,ulceration/necrosis$ Respiratory: panting, dyspnea, epistaxis, coughing

Cardiovascular: tachycardia, heart murmur, bradycardia, arrest Sensory: Vestibular signs, glazed eyes, uveitis.

Ophthalmic: blindness, mydriasis, conjunctivitis, keratoconjunctivitis sicca, uveitis.

In some cases, death has been reported as an outcome of the adverse events listed above.

To eport suspected adverse drug events, for technical assistance or to obtain a copy of the Safety Data Sheet, contact Felix
Pharmaceuticals Private Limited at 1-833-571-1525. For additional information about adverse drug experience reporting for animal drugs, contact FDA at 1-888-FDA-VETS or http://www.fda.gov/reportanimalae

Chewable Tablets
Information for Dog Owners:
Deracoxib Chewable Tablets, like other drugs of its class, is not free from adverse reactions. Owners should be advised of the potential for adverse reactions and be informed of the clinical signs associated with drug intolerance. Adverse reactions may include vomiting, diarrhea, decreased appetite, dark or tarry stools, increased water consumption, increased urination, anemia, yellowing of gums, skin or white of the eye due to jaundice, lethargy, inccordination, seizure, or behavioral changes. Serious adverse reactions associated with this drug class can occur without warning and in some cases result in death (see Warnings, Post-Approval Experience and Adverse Reactions). Owners should be advised to discontinue Deracoxib Chewable Tablets therapy and contact their veterinarian immediately if signs of intolerance are observed. The vast majority of patients with drug related adverse reactions have recovered when the signs are recognized, the drug is withdrawn, and veterinary care, if appropriate, is initiated. Owners should be advised of the importance of periodic follow up for all dogs during administration of any NSAID.

Storage Conditions:

Storage Conditions:
Deracoxib Chewable Tablets should be Store at 20° to 25°C (68° to 77°F), excursions permitted between 15° and 30°C (between 59° and 86°F) [see USP Controlled Room Temperature].
Keep this and all medications out of reach of children.

ithin 90 days of splitting.

How Supplied: Deracoxib Chew

Chewable Tablets are available as 12 mg, 25 mg, 75 mg and 100 mg round, brownish, half-scored tablets in 30 and 90 count bottles.

NDC Number	Tablet Size	Tablets/Bottle
86101-004-31	12 mg	30
86101-004-91	12 mg	90
86101-005-31	25 mg	30
86101-005-91	25 mg	90
86101-006-31	75 mg	30
86101-006-91	75 mg	90
86101-007-31	100 mg	30
86101-007-91	100 mg	90

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Approved by FDA under ANADA # 200-704 **Distributed by:** Felixvet Inc., 1300 NW Briarcliff Parkway, Suite 100, Kansas City, Missouri. 64116

Made in India

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Felix