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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 57 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 Pain Scale (mGCPS) to assess pain.¹ 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:

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 No dogs were withdrawn from the study due to the occurrence of an adverse reaction.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

¹Dogs may have experienced more than one adverse reaction during the study.
²Included animals with results over 2x the high normal.

Post-Approval 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: anorexia, 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 report 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, incoordination, 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:

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.

Use within 90 days of splitting.

How Supplied:

Deracoxib 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

References:

- 1 Data on file under NADA 141-203
- 2 Data on file under NADA 141-203
- 3 Smith, et al.: "Pharmacological Analysis of Cyclo-oxygenase-1 in Inflammation," Proc. Natl. Acad. Sci. USA (October 1998) 95: 13313-13318, Pharmacology.
- 4 Zhang, et al.: "Inhibition of Cyclo-oxygenase-2 Rapidly Reverses Inflammatory Hyperalgesia and Prostaglandin E2 Production," *JPET*, (1997) 283: 1069-1075.
- 5 Verburg, KM et al.: "Cox-2 Specific Inhibitors: Definition of a New Therapeutic Concept." Amer J of Therapeutics 8, 49-64, 2001.
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- 7 Holton, L., Reid, J., Scott, E.M., Pawson, P. and Nolan, A. (2001). Development of a behaviour-based scale to measure acute pain in dogs. Veterinary Record, 148, 525-53.

Approved by FDA under ANADA # 200-704

Distributed by: Felixvet Inc.,
1300 NW Briarcliff Parkway,
Suite 100, Kansas City, Missouri. 64116

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Neutral Code No. MP/DRUGS/25/90/2020

Rev. September 2023

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Deracoxib
Chewable Tablets

For Oral Use in Dogs Only
Do Not Use in Cats

Information for Dog Owners

Deracoxib Chewable Tablets are for the control of pain and inflammation due to osteoarthritis or following orthopedic and dental surgery.

This summary contains important information about Deracoxib Chewable Tablets. You should read this information before starting your dog on Deracoxib Chewable Tablets. This sheet is provided only as a summary and does not take the place of instructions from your veterinarian. Talk to your veterinarian if you do not understand any of this information or you want to know more about Deracoxib Chewable Tablets.

What is Deracoxib Chewable Tablets?

Deracoxib Chewable Tablets are a prescription non-steroidal anti-inflammatory drug (NSAID) of the coxib class. They are indicated for the control of postoperative pain and inflammation associated with orthopedic (bone) and dental surgery in dogs and for the control of pain and inflammation (soreness) associated with osteoarthritis in dogs. The tablets are flavored to make administration more convenient.

What kind of results can I expect when my dog takes Deracoxib Chewable Tablets for postoperative orthopedic and dental pain and inflammation?

Deracoxib Chewable Tablets allow your dog to recover more comfortably by controlling pain and inflammation that follow orthopedic and dental surgery.

- The postoperative orthopedic pain dose is a higher dose; administration at this dose **should not exceed 7 days total, including the days the patient is administered Deracoxib Chewable Tablets while in the hospital.**
- Control of pain and inflammation may vary from dog to dog.
- If Deracoxib Chewable Tablets are not given according to your veterinarian's directions, your dog's pain may return.
- Consult your veterinarian if your dog appears to be uncomfortable.

What kind of results can I expect when my dog takes Deracoxib Chewable Tablets for pain and inflammation due to osteoarthritis?

Osteoarthritis is a painful condition caused by damage to cartilage and other parts of the joint that may result in the following changes or signs in your dog:

- Limping or lameness
- Decreased activity or exercise (reluctance to stand, climb stairs, jump or run, or difficulty in performing these activities)
- Stiffness or decreased movement of joints

While Deracoxib Chewable Tablets is not a cure for osteoarthritis, it can control the pain and inflammation of osteoarthritis and improve your dog's mobility. Response may vary from dog to dog but can be quite dramatic. **Deracoxib Chewable Tablets may need to be given on a periodic basis for the animal's lifetime. Use the lowest dose to provide adequate relief. Always consult with your veterinarian before altering the dose.**

What dogs should not take Deracoxib Chewable Tablets?

Your dog should not be given Deracoxib Chewable Tablets if s/he:

- Has had an allergic reaction to deracoxib, the active ingredient in Deracoxib Chewable Tablets
- Has had an allergic reaction (such as hives, facial swelling, or red or itchy skin) to aspirin or other NSAIDs
- Is presently taking aspirin, other NSAIDs, or corticosteroids (unless directed by your veterinarian)
- Has bloody stool or vomit
- Has a pre-existing kidney or liver condition
- Has any condition predisposing to dehydration
- Is anorexic (loss of appetite)

Deracoxib Chewable Tablets should only be given to dogs. Do not use in cats.

People should not take Deracoxib Chewable Tablets. Keep Deracoxib Chewable Tablets and all medication out of reach of children. Call your physician immediately if you accidentally take Deracoxib Chewable Tablets.

What to discuss with your veterinarian before giving Deracoxib Chewable Tablets?

Tell your veterinarian about:

- Any side effects your dog has experienced from Deracoxib Chewable Tablets or other NSAIDs
- Any digestive upset (vomiting or diarrhea) your dog has had
- Any kidney disease your dog has had
- Any other medical problems or allergies that your dog has now or has had in the past
- All medications that you are giving your dog or plan to give your dog, including those you can get without prescription and any dietary supplements
- If you plan to breed your dog, or if your dog is pregnant or nursing

Talk to your veterinarian about:

- The orthopedic or dental surgery your dog will undergo
- What tests might be done before surgery is performed or Deracoxib Chewable Tablets are prescribed
- The signs of pain or inflammation that may occur after surgery
- Normal events that can be expected after your dog undergoes surgery
- The proper amount of exercise after surgery to aid recovery
- The signs of osteoarthritis you have observed (for example, limping or stiffness)
- The importance of weight control, physical therapy and exercise in the management of osteoarthritis
- How often your dog may need to be examined by your veterinarian
- The risks and benefits of using Deracoxib Chewable Tablets

How to give Deracoxib Chewable Tablets to your dog.

Deracoxib Chewable Tablets should be given according to your veterinarian's instructions. Your veterinarian will tell you what amount of Deracoxib Chewable Tablets is right for your dog and for how long they should be given. Do not change the way you give Deracoxib Chewable Tablets to your dog without first speaking with your veterinarian. Deracoxib Chewable Tablets should be given by mouth and may be given with or without food, although with food is preferable.

What are the possible side effects that may occur in my dog during therapy with Deracoxib Chewable Tablets?

Deracoxib Chewable Tablets may cause some side effects in individual dogs. Serious side effects associated with this drug can occur with or without warning and, in some cases, result in death. The most common side effects associated with Deracoxib Chewable Tablets therapy involve the digestive tract (vomiting, decreased appetite and diarrhea). Liver and kidney problems have also been reported. It is important to stop the medication and contact your veterinarian immediately if you think your dog may have a medical problem or side effect while on Deracoxib Chewable Tablets. If you have additional questions about possible side effects, talk with your veterinarian or call Felix Pharmaceuticals Private Limited at 1-833-571-1525.

Look for the following side effects that may indicate that your dog is having a problem with Deracoxib Chewable Tablets or may have another medical problem:

- Vomiting
- Decrease in appetite
- Change in behavior, such as depression, restlessness, aggression or apprehension
- Change in bowel movements such as diarrhea or change in stool color (black, tarry or bloody stool)
- Change in drinking or urination
- Yellowing of gums, skin or whites of the eyes (jaundice)

Can Deracoxib Chewable Tablets be given with other medications?

Deracoxib Chewable Tablets should not be given with other non-steroidal anti-inflammatory drugs (NSAIDs) or corticosteroids (for example, aspirin, carprofen, etodolac, prednisone).

Tell your veterinarian about all medications that you have given your dog in the past, and any medications that you are planning to give with Deracoxib Chewable Tablets. This should include any medications that you can get without a prescription and any dietary supplements. Your veterinarian may want to evaluate the potential for any drug interactions and to assure drug compatibility.

What can I do in case my dog eats more than the prescribed amount of Deracoxib Chewable Tablets?

Contact your veterinarian immediately if your dog eats more than the prescribed amount of Deracoxib Chewable Tablets.

What else should I know about Deracoxib Chewable Tablets?

This sheet provides a summary of information about Deracoxib Chewable Tablets. If you have any questions or concerns about Deracoxib Chewable Tablets, postoperative orthopedic and dental pain and inflammation, or osteoarthritis, talk to your veterinarian.

As with all prescribed medications, Deracoxib Chewable Tablets should only be given to the dog for which they are prescribed. They should be given to your dog only for the condition for which they were prescribed, at the prescribed dose, as directed by your veterinarian. It is important to periodically discuss your dog's response to Deracoxib Chewable Tablets at regular checkups. Your veterinarian will best determine if your dog is responding as expected and if your dog should continue receiving Deracoxib Chewable Tablets.

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

Use within 90 days of splitting.

Approved by FDA under ANADA # 200-704

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1300 NW Briarcliff Parkway,
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Neutral Code No. MP/DRUGS/25/90/2020
Rev. September 2023

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Folding Size: 33 x 33 mm

425.00 mm

Folding Size: 33 x 33 mm

DESCRIPTION: Deracoxib Chew. Tablets

BLACK

280.00 mm

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Rev. September 2023

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What kind of results can I expect when my dog takes Deracoxib Chewable Tablets for postoperative orthopedic and dental pain and inflammation?

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What kind of results can I expect when my dog takes Deracoxib Chewable Tablets for pain and inflammation due to osteoarthritis?

Osteoarthritis is a painful condition caused by damage to cartilage and other parts of the joint that may result in the following changes or signs in your dog:

- Limping or lameness
- Decreased activity or exercise (reluctance to stand, climb stairs, jump or run, or difficulty in performing these activities)
- Stiffness or decreased movement of joints

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- Change in behavior, such as depression, restlessness, aggression or apprehension
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Can Deracoxib Chewable Tablets be given with other medications?

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Tell your veterinarian about all medications that you have given your dog in the past, and any medications that you are planning to give with Deracoxib Chewable Tablets. This should include any medications that you can get without a prescription and any dietary supplements. Your veterinarian may want to evaluate the potential for any drug interactions and to assure drug compatibility.

What can I do in case my dog eats more than the prescribed amount of Deracoxib Chewable Tablets?

Contact your veterinarian immediately if your dog eats more than the prescribed amount of Deracoxib Chewable Tablets.

What else should I know about Deracoxib Chewable Tablets?

This sheet provides a summary of information about Deracoxib Chewable Tablets. If you have any questions or concerns about Deracoxib Chewable Tablets, postoperative orthopedic and dental pain and inflammation, or osteoarthritis, talk to your veterinarian.

As with all prescribed medications, Deracoxib Chewable Tablets should only be given to the dog for which they are prescribed. They should be given to your dog only for the condition for which they were prescribed, at the prescribed dose, as directed by your veterinarian. It is important to periodically discuss your dog's response to Deracoxib Chewable Tablets at regular checkups. Your veterinarian will best determine if your dog is responding as expected and if your dog should continue receiving Deracoxib Chewable Tablets.

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

Use within 90 days of splitting.

Approved by FDA under ANADA # 200-704

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DESCRIPTION: Deracoxib Chew. Tablets

BLACK

280.00 mm

Folding Size: 33 x 33 mm

425.00 mm

Folding Size: 33 x 33 mm