FIROCOXIB (Veterinary—Systemic)†

Some commonly used *brand names* for veterinary-labeled products are *Equioxx* and *Previcox*.

Note: For a listing of dosage forms and brand names by country availability, see the *Dosage Forms* section(s).

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†Not commercially available in Canada.

Category: Analgesic; anti-inflammatory (nonsteroidal); antipyretic.

Indications

Note: The text between [EL][US] and [EL] describes uses that are not included in U.S. product labeling. Text between [EL][CAN] and [EL] describes uses that are not included in Canadian product labeling.

The [EL][US] or [EL][CAN] designation can signify a lack of product availability in the country indicated. See the *Dosage Forms* section of this monograph to confirm availability.

Accepted

[EL][CAN]Inflammation, osteoarthritis-associated (treatment)[EL]; or [EL][CAN]Pain, osteoarthritis-associated (treatment)[EL]—*Dogs* and [EL][US]*horses*[EL]: Firocoxib tablets are indicated for dogs and firocoxib oral paste is indicated for horses in the control of pain and inflammation associated with osteoarthritis.{R-1; 11}

Regulatory Considerations

U.S.—Firocoxib oral paste is not labeled for use in horses intended for human consumption.{R-11}

Chemistry

Chemical group: Coxib nonsteroidal anti-inflammatory.{R-1}

Chemical name: 3-(cyclopropylmethoxy)-4-(4-(methylsulfonyl) phenyl)-5,5-dimethylfuranone.{R-1; 5}

Molecular formula: $C_{17}H_{20}O_5S$.{R-1}

Molecular weight: 336.40.{R-1; 5}

Description: White crystalline compound.{R-1; 5}

Pharmacology/Pharmacokinetics

Note: All feline pharmacokinetic data in this monograph are from a study of two cats, each given a single dose; the results for each animal is reported separately.

Mechanism of action/Effect: Like other coxib anti-inflammatories, firoxocib is a cyclooxygenase inhibitor. *In vitro* studies have shown it to be highly selective for cyclooxygenase-2 (COX-2), which is responsible for the production of inflammatory mediators, and very sparing of cyclooxygenase-1 (COX-1), which is involved in production of prostaglandins for maintenance of physiologic functions, including gastric cytoprotection, renal homeostasis, and normal platelet function.{R-1; 4} However, the relationship between these *in vitro* results and the clinical effects and safety of nonsteroidal anti-inflammatories has not been completely defined.{R-1}

Absorption: Oral—

Cats: When a suspension of firocoxib was administered to two fasted cats by orogastric gavage, F (absolute bioavailability) was found to be—
Cat 1: 54.5%.{R-8}
Cat 2: 69.8%.{R-8}

Dogs: Absorption of tablets is highly variable among subjects.{R-1} Although administration of firocoxib with food will delay absorption and decrease peak serum concentration, overall bioavailability is not affected.{R-1}
F (in fasted dogs)—
With chewable tablets: 38%.{R-1}
With an oral suspension of firocoxib: 101.0 ± 19.0%.{R-4}

Horses: F = 79%, with oral paste at a dose of 0.1 mg per kg of body weight (mg/kg).{R-5}

Distribution: Volume of distribution—

Cats: Vd_{ss}—
Cat 1: 2.8 liters per kilogram (L/kg).{R-8}
Cat 2: 2.1 L/kg.{R-8}

Dogs: Vd_{ss}—2.9 ± 0.3 L/kg.{R-4}

Horses: Vd_{ss}—1.7 L/kg.{R-5; 11}

Biotransformation: *Horses*—Firocoxib is primarily metabolized by decyclopropylmethylation followed by glucuronidation.{R-5}

Protein binding:

Dogs—96%.{R-1}

Horses—98%.{R-5; 11}

Half-life: Elimination (terminal)—

Cats:
Cat 1—12.2 hours.{R-8}
Cat 2—8.7 hours.{R-8}

Dogs: 7.8 ± 2.3 hours;{R-1} 5.9 ± 1.1 hours.{R-4}

Horses: 30 to 40 hours, with either intravenous or oral administration. Firocoxib accumulates and steady state concentrations are reached with six to eight daily oral doses.{R-5; 11}

Concentrations: Peak serum concentration—

Cats: With orogastric administration of a firocoxib suspension—
Cat 1: 1.4 micromoles in 1 hour.{R-8}
Cat 2: 1.1 micromoles in 4 hours.{R-8}

Dogs: With chewable tablets administered at a dose of 5 mg/kg—{R-1}
Fed: 0.9 mcg/mL at 5 hours.
Fasted: 1.3 mcg/mL at 1 hour.

Horses: Firocoxib has peaked at 0.08 mcg/mL, 4 hours after oral administration of paste at a dose of 0.1 mg/kg; however, in some animals, significant plasma concentration may not be measured for twelve hours after adminstration.{R-5; 11}

Elimination: *Horses*—Primarily eliminated in the urine, as decyclopropylmethylated metabolite.{R-5; 11}

Clearance—

Cats:
Cat 1—5.8 mL/min/kg.{R-8}
Cat 2—4.7 mL/min/kg.{R-8}

Dogs: 6.7 mL/min/kg;{R-1} 7.7 ± 0.7 mL/min/kg.{R-4}

Precautions to Consider

Reproduction/Pregnancy/Lactation

Dogs and *horses:* There is no information on the safety of firocoxib in the treatment of breeding, pregnant, or lactating animals.{R-1; 11}

Pediatrics

Foals: The safety of firocoxib administration to horses less than one year of age has not been evaluated.{R-11}

Puppies: Administration of the labeled dose for dogs (5 mg per kg of body weight [mg/kg] a day) to 10-to-13-week-old puppies for six months caused subclinical periportal hepatic fatty changes. Administration of higher doses (15 to 25 mg/kg a day) has been fatal (see also the *Overdose* section in this monograph).{R-1; 2}

Drug interactions and/or related problems

The following drug interactions and/or related problems have been selected on the basis of their potential clinical significance (possible mechanism in parentheses where appropriate)—not necessarily inclusive (» = major clinical significance):

Note: Combinations containing any of the following medications, depending on the amount present, may also interact with this medication.

» Anti-inflammatory medications,[{R-1}] such as
Corticosteroids
Other nonsteroidal anti-inflammatory drugs (NSAIDs)
(concurrent use of two or more NSAIDs or an NSAID and a corticosteroid is not recommended; concurrent therapy may increase the risk of gastrointestinal toxicity, including ulceration or hemorrhage, without providing additional symptomatic relief)

Diuretics[{R-1}]
(animals on diuretic therapy may be at a higher risk for renal toxicity with firocoxib administration)

» Nephrotoxic medications, other[{R-1}]
(such medications may compound the risk of renal toxicity from NSAID administration)

Protein-bound medications, other[{R-1}]
(the effect of administering firocoxib, a highly protein-bound drug, with other protein-bound medications, including some anticonvulsant, behavioral, and cardiovascular drugs, has not been studied; monitoring patients receiving concomitant therapy is recommended)

Human drug interactions and/or related problems:[{R-9}]

In addition to the above drug interactions reported in animals, the following drug interactions have been reported in humans, and are included in the human monograph *Anti-inflammatory Drugs, Nonsteroidal (Systemic)* in *USP DI Volume I;* these drug interactions are intended for informational purposes only and may or may not be applicable to the use of firocoxib in the treatment of animals:

Note: There are no firocoxib products labeled for use in human beings; the following are those listed for all nonsteroidal anti-inflammatory drugs (NSAIDs).

Not all of the following interactions have been documented with every NSAID; however, each has been reported in humans with several NSAIDs.

Antidiabetic agents, oral or
Insulin
(NSAIDs may increase the hypoglycemic effect of these medications because prostaglandins are directly involved in regulatory mechanisms of glucose metabolism)

Bone marrow depressants
(leukopenic and/or thrombocytopenic effects of these medications may be increased with concurrent or recent therapy if an NSAID causes the same effects)

Digitalis glycosides
(diclofenac and ibuprofen have been shown to increase serum digoxin concentrations, and indomethacin has increased digitalis concentrations in neonates being treated for patent ductus arteriosus; however, studies have failed to show that flurbiprofen, ketoprofen, piroxicam, or tenoxicam increase digoxin concentrations, and phenylbutazone may decrease digitalis concentrations)

Medications affecting hemostasis, including
Anticoagulants, coumarin- or indandione-derivative, or heparin, or thrombolytic agents
Hypoprothrombinemia-inducing agents, such as certain cephalosporins, plicamycin or valproic acid
Platelet aggregation inhibitors, other
(inhibition of platelet aggregation by NSAIDs, and the possibility of NSAID-induced gastrointestinal ulceration or bleeding, may be hazardous to patients receiving anticoagulant or thrombolytic therapy)
(additive interferences with platelet function from concurrent administration of an NSAID with other aggregation inhibitors may increase the risk of bleeding and/or the potential occurrence of NSAID-induced gastrointestinal ulceration or hemorrhage)

Methotrexate
(NSAIDs may decrease protein binding and/or renal elimination of methotrexate, resulting in increased and prolonged methotrexate plasma concentrations and an increased risk of toxicity; severe, sometimes fatal, methotrexate toxicity has been reported)

Photosensitizing medications, other
(concurrent use with photosensitizing NSAIDs may cause additive photosensitizing effects)

Probenecid
(probenecid may decrease excretion and increase serum concentrations of NSAIDs)

Medical considerations/Contraindications

The medical considerations/contraindications included have been selected on the basis of their potential clinical significance (reasons given in parentheses where appropriate)—not necessarily inclusive.

Except under special circumstances, this medication should not be used when the following medical problems exist:

Gastrointestinal ulceration
(many nonsteroidal anti-inflammatory drugs are known to increase the risk of gastrointestinal disease, particularly ulceration; therefore, the presence of lesions before treatment may put an animal at risk of exacerbation or perforation)

Hypersensitivity to firocoxib[{R-1; 11}] or
Hypersensitivity to other nonsteroidal anti-inflammatory drugs[{R-1; 11}]
(animals previously found to be hypersensitive should not receive firocoxib)

Risk-benefit should be considered when the following medical problems exist:

Cardiovascular disorders or
Dehydration or
Hepatic dysfunction or
Renal dysfunction
(animals with the above medical problems can be at higher risk for renal toxicity)[{R-1}]
(cardiovascular disorders, gastrointestinal disorders, or hepatic dysfunction may be exacerbated)[{R-1}]

Patient monitoring

The following may be especially important in patient monitoring (other tests may be warranted in some patients, depending on condition; » = major clinical significance):

Blood chemistry and
Complete blood count (CBC) and
Urinalysis
(particularly in older dogs, dogs with a history of liver or renal disease, or dogs expected to receive long-term therapy, baseline CBC, blood chemistry, and urinalysis testing before initiation of firocoxib administration, as well as regular follow-up blood chemistry testing, should be considered)[{R-1}]
(in horses, appropriate laboratory tests are recommended before treatment and periodically during therapy)[{R-11}]

Physical examinations
(pretreatment history and physical exam and periodic check-ups are recommended)

Side/Adverse Effects

The following side/adverse effects have been selected on the basis of their potential clinical significance (possible signs in parentheses where appropriate)—not necessarily inclusive:

Note: The following were reported during preapproval controlled field trials.

Those indicating need for medical attention

Incidence unknown

Dogs[R-1]

Gastrointestinal effects (anorexia or decreased appetite was reported in about 2%, diarrhea in <1%, and vomiting in about 4% of 128 dogs given 5 mg/kg a day for 30 days in clinical trials); ***neurologic/behavioral effects*** (hyperactivity, lethargy, or somnolence were reported in <1% of 128 dogs); ***pain—***in about 1.6% of 128 dogs

Horses[R-5; 11]

Gastrointestinal effects—(diarrhea was reported in about 1.6% and loose stool in <1% of 127 horses given 0.1 mg/kg a day for 14 days in clinical trials); ***neurologic/behavioral effects*** (excitation)—in <1% of 127 horses

Human side/adverse effects[R-9]

In addition to the above side/adverse effects reported in animals, the following side/adverse effects have been reported in humans, and are included in the human monograph *Anti-inflammatory Drugs, Nonsteroidal (Systemic)* in *USP DI Volume I;* these side/adverse effects are intended for informational purposes only and may or may not be applicable to the use of firocoxib in the treatment of animals:

Note: There are no firocoxib products labeled for use in human beings; the following are those listed for all nonsteroidal anti-inflammatory drugs (NSAIDs).

Cardiovascular effects *(cardiac arrhythmias; congestive heart failure; hemoptysis; increased blood pressure; nosebleeds, unexplained; pericarditis; pulmonary edema),* ***dermatologic effects*** *(dermatitis, allergic; dermatitis, exfoliative; erythema or other skin discoloration; erythema multiforme; erythema nodosum; peeling skin; photoallergic or photosensitive dermatologic reaction; toxic epidermal necrolysis),* ***gastrointestinal effects*** *(colitis, enterocolitis, or regional enteritis; constipation; decreased appetite or loss of appetite; diarrhea; esophagitis; gastritis; gastrointestinal bleeding, ulceration, or perforation; pancreatitis; vomiting; weight loss),* ***genitourinary effects*** *(bleeding from vagina; blood in urine; crystalluria, renal calculi, or ureteral obstruction; dysuria; incontinence; urinary tract infection),* ***hematologic effects*** *(agranulocytosis [granulocytopenia]; anemia; anemia, aplastic [pancytopenia]; anemia, hemolytic; bone marrow depression; disseminated intravascular coagulation; ecchymosis/bruising; eosinophilia; hypocoagulability; leukopenia [neutropenia]; petechia; thrombocytopenia with or without purpura),* ***hepatic effects*** *(cholistatic hepatitis or jaundice; toxic hepatitis or jaundice),* ***hypersensitivity reactions*** *(anaphylaxis or anaphylactoid reactions; angioedema; bronchospastic allergic reactions; fever, with or without chills; laryngeal edema; loosening or splitting of fingernails or other nail disorders; lymphadenopathy; rhinitis, allergic; serum sickness-like reaction; systemic lupus erythematosus [SLE]-like syndrome; vasculitis),* ***neurologic effects*** *(anxiety; convulsions; meningitis, aseptic; neuropathy, peripheral; syncope),* ***ocular effects*** *(conjunctivitis; corneal deposits or opacity; dry, irritated, or swollen eyes; palpebral edema; photophobia; retinal hemorrhage; retinal or macular disturbances),* ***oral effects*** *(glossitis; irritation, dryness, sores, ulcers, or white spots in mouth; swelling of lips and tongue),* ***renal effects*** *(fluid retention and edema; glomerulitis or glomerulonephritis; hyperkalemia; interstitial nephritis; nephrotic syndrome; oliguria/anuria; polyuria; proteinuria; renal impairment or failure; renal papillary or tubular necrosis; thirst, continuing)*

Overdose

For more information in cases of overdose or unintentional ingestion, **contact the American Society for the Prevention of Cruelty to Animals (ASPCA) National Animal Poison Control Center** (888-426-4435 or 900-443-0000; a fee may be required for consultation) **and/or the drug manufacturer**.

Lethal dose

LD_{50}: Oral—*Rat:* >2000 mg per kg of body weight (mg/kg).[R-3]

Clinical effects of overdose

The following effects have been selected on the basis of their potential clinical significance (possible signs in parentheses where appropriate)—not necessarily inclusive:

Puppies, 10 to 13 weeks of age

With a dose of 5 mg/kg a day for six months:[R-1; 2]

Periportal hepatic fatty change, subclinical—reported in 3 of 6 puppies at this dose

With a dose of 15 to 25 mg/kg a day for six months:[R-1; 2]

Death or severe adverse reactions requiring euthanasia (moribund condition; associated signs included anorexia, depression, and/or vomiting); ***decreased rate of growth in weight; hepatic enzyme elevation; hepatic fatty change; serum albumin, decreased; thalamic vacuolization; ulceration, duodenal***

Note: The five puppies that *died* or were *euthanized* during this safety study of 18 dogs all had moderate to severe periportal hepatic fatty change, two had duodenal ulceration, and two had pancreatic edema. One puppy had renal casts and one had renal hyaline droplets but no lesions were seen on histopathology.

Thalamic vacuolization was reported on brain histopathology for about one-half of the puppies at this dosage range, but the clinical significance is unknown.

Dogs, 7 to 11 months of age

With a dose of 15 to 25 mg/kg a day for six months:[R-1; 2]

Diarrhea and/or vomiting; focal inflammation in the pylorus or small intestine; hypoalbuminemia, transient; leukocytosis, transient; serum alanine aminotransferase (ALT [SGPT]) elevation to high normal range; ulcer, ileal

With a dose of ≥50 mg/kg a day for 22 days:[R-1; 2]

Anorexia or decreased food consumption; diarrhea and vomiting, sporatic; erosion or ulceration, intestinal—in 3 of 4 dogs treated; ***hepatic fatty change; low serum albumin or hypoalbuminemia***—in all dogs treated; ***weight loss, mild***

Horses

With a dose of 0.3 to 0.5 mg/kg a day for 30 days:[R-5; 11]

Ulcers, oral, increased incidence of

With a dose of 0.1 to 0.5 mg/kg a day for 42 days:[R-5; 11]

Blood urea nitrogen (BUN) and/or creatinine, mildly elevated—with 0.5 mg/kg; ***buccal mucosal bleeding time (BMBT), prolonged***—with 0.5 mg/kg; ***papillary necrosis and/or tubulointerstitial nephropathy***—with 0.3 to 0.5 mg/kg; ***ulcers, oral, delayed healing of or increased incidence of***

Note: One horse with an *elevated BUN and/or creatinine* and *prolonged BMBT* had a dilated pelvis of the right kidney, one had bilateral *tubulointerstitial nephropathy* and bilateral *papillary necrosis,* and a third had no gross changes seen at necropsy.

With a dose of 0.25 to 1.25 mg/kg a day for 92 days:[R-5; 11]

Erosions of the skin of the mandible and head—with 0.25 to 1.25 mg/kg; ***hepatic enzymes, elevated, including alanine aminotransferase (ALT), aspartate aminotransferase (AST), gamma-glutamyltransferase (GGT), and sorbital dehydrogenase (SDH)***—with 1.25 mg/kg; ***papillary necrosis and/or tubulointerstitial nephropathy; renal hemorrhage and nephropathy*** (urine GGT and protein levels increased)—with 0.25 mg/kg; ***ulcers, gastric, increased incidence of***—with 0.25 to 0.75

mg/kg; ***ulcers of the lips, gingiva, and tongue*—**with 0.25 to 1.25 mg/kg

Note: Six horses administered 1.25 mg/kg a day in the safety study summarized above were monitored for about 56 days after treatment. Partial to full resolution of oral and skin ulcers occurred, but no recovery from tubulointerstitial nephropathy was seen.

Treatment of overdose

There is no specific antidote for firocoxib overdose. In the event of toxicity, treatment that may be helpful includes:

- Early gastric lavage to prevent absorption of any remaining drug
- Supportive treatment may include administration of intraveneous fluids and gastric protectants. Blood values, such as complete blood count and chemistry, may be monitored.

Client Consultation

In providing consultation, consider emphasizing the following selected information:

Providing the manufacturer-generated *Client Information Sheet* for either oral paste or tablets{R-1; 11}

Counseling clients to discontinue treatment and contact the veterinarian if specific side/adverse effects are seen

For dogs, owners should report changes in behavior, such as aggression, incoordination, an increase or decrease in activity, or seizure; changes in bowel movements; changes in drinking habits; changes in skin; changes in urination habits; increase or decrease in appetite; unexpected weight loss; vomiting; or yellowing of mucous membranes, skin, or whites of eyes.{R-6}

For horses, owners should report sores or ulcers on the tongue and inside the mouth; sores, scabs, redness, or rubbing of the facial skin, especially around the mouth; changes in eating or drinking habits; changes in behavior, such as an increase or decrease in activity; changes in urination habits; unexpected weight loss; or yellowing of gums, skin, or whites of eyes.{R-12}

Keeping water readily available to animals receiving firocoxib to avoid dehydration

Keeping medications out of the reach of children and animals

General Dosing Information

Consider washout times if it becomes necessary to switch from one nonsteroidal anti-inflammatory drug to another.{R-1}

Oral Dosage Forms

Note: The text between [EL]US and [EL] describes uses not included in U.S. product labeling. Text between [EL]CAN and [EL] describes uses that are not included in Canadian product labeling.

The [EL]US or [EL]CAN designation can signify a lack of product availability in the country indicated. See also the *Strength(s) usually available* section for each dosage form.

FIROCOXIB ORAL PASTE

Usual dose:

[EL]US,CAN Inflammation, musculoskeletal[EL]; or

[EL]US,CAN Pain, musculoskeletal[EL]—*Horses:* Oral, 0.1 mg per kg of body weight every twenty-four hours for up to fourteen days.{R-11}

Withdrawal times—This product is not labeled for use in horses intended for human consumption.{R-11} Global Food Animal Residue Avoidance Databank programs (gFARAD) do not have the data required to make a withdrawal recommendation.{R-10}

Note: During animal safety studies performed for product approval, toxicity occurred with the recommended dose if administration continued for more than thirty days.{R-5}

Strength(s) usually available:

U.S.—{R-11}

Veterinary-labeled product(s):

8.2 mg per gram of paste (0.82% w/w) (Rx) [*Equioxx*].

Canada—

Veterinary-labeled product(s):

Not commercially available.

Packaging and storage: Store below 30 °C (86 °F), preferably between 15 and 30 °C (59 and 86 °F), with only brief excursions up to 40 °C (104 °F), unless otherwise specified by the manufacturer.{R-11}

Caution: Consult a physician if accidental ingestion by human beings occurs.{R-1} Keep out of the reach of children and animals.{R-11}

USP requirements: Not in USP.{R-7}

FIROCOXIB TABLETS

Usual dose:

[EL]CAN Inflammation, musculoskeletal[EL]; or

[EL]CAN Pain, musculoskeletal[EL]—*Dogs:* Oral, 5 mg per kg of body weight every twenty-four hours.{R-1}

Note: Administration of dosages higher than 5 mg per kg of body weight a day to puppies less than seven months of age has been fatal.{R-1}

Product labeling does not recommend use in dogs weighing less than seven pounds because accurate dosing cannot be done.{R-1}

Strength(s) usually available:

U.S.—{R-1}

Veterinary-labeled product(s):

57 mg (Rx) [*Previcox* (chewable; half-scored)].

227 mg (Rx) [*Previcox* (chewable; half-scored)].

Canada—

Veterinary-labeled product(s):

Not commercially available.

Packaging and storage: Store between 15 and 30 °C (59 and 86 °F), with only brief excursions up to 40 °C (104 °F), unless otherwise specified by the manufacturer.{R-1}

Caution: Consult a physician if accidental ingestion by human beings occurs.{R-1} Keep out of the reach of children and animals.{R-5}

USP requirements: Not in USP.{R-7}

Developed: 11/06/06

Revised: 08/08/07

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