

ETODOLAC Veterinary—Systemic[†]

A commonly used *brand name* for a veterinary-labeled product is *Etogesic*.

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

[†]Not commercially available in Canada.

Category: Anti-inflammatory (nonsteroidal); analgesic; antipyretic.

Indications

Accepted

Inflammation, musculoskeletal (treatment)¹; or
Pain, musculoskeletal (treatment)¹—*Dogs*: Etodolac tablets are indicated in the management of inflammation and pain associated with osteoarthritis.^{R-1}

¹Not included in Canadian product labeling or product not commercially available in Canada.

Regulatory Considerations

U.S.—

Etodolac is labeled for use only by or on the order of a licensed veterinarian.^{R-1}

Chemistry

Chemical group: Pyranocarboxylic acid.^{R-1}

Chemical name: Pyrano[3,4-*b*]indole-1-acetic acid, 1,8-diethyl-1,3,4,9-tetrahydro-(±).^{R-2}

Molecular formula: C₁₇H₂₁NO₃.^{R-1; 2}

Molecular weight: 287.37.^{R-17}

Other characteristics: N-octanol:water partition coefficient of 11.4 at pH 7.4.^{R-1}

Description: White crystalline solid.^{R-1; 17}

pKa: 4.65.^{R-1}

Solubility: Insoluble in water; soluble in alcohols, in chloroform, in dimethyl sulfoxide, and in aqueous polyethylene glycol.^{R-1}

Pharmacology/Pharmacokinetics

Mechanism of action/Effect: Anti-inflammatory—

Inhibition of cyclooxygenase (COX) occurs with etodolac administration.^{R-1} COX-1, present in most cells and tissues, is believed to produce cytoprotective prostaglandins active in maintaining normal gastrointestinal and renal function in mammals while COX-2 produces prostaglandins involved in inflammation.^{R-1} Although *in vitro* studies of human enzymes show etodolac selectively inhibiting COX-2 over COX-1, one *in vitro* experiment using canine cells demonstrated a fairly equal inhibition of COX-1 and COX-2.^{R-5} Another study reported a 7-fold selectivity of etodolac for COX-2 over COX-1 using a canine whole blood assay.^{R-18}

The roles of COX-1 and COX-2 in normal physiological function and in production of inflammation are not yet completely defined. Based on early evidence that their effects may overlap, some authors have stated that, at certain dosages, a finely balanced partial inhibition of both COX-1 and COX-2 may be preferred to maximize the inhibition of inflammation and protection of gastrointestinal mucosa; more research is necessary.^{R-19} It may be that COX inhibition by etodolac is not the predominant mechanism in its production of anti-inflammatory effects.^{R-12} Etodolac also inhibits macrophage chemotaxis *in vivo* and *in vitro*.^{R-1}

Chirality: Etodolac exists in two enantiomeric forms.^{R-9} Differences in

pharmacokinetics and pharmacodynamics between the two enantiomers have not been defined in animals.

Absorption:

Dogs—Oral administration: Rapidly and nearly completely absorbed.^{R-1; 8} Administration with food does not affect bioavailability but does lower and delay the peak serum concentration.^{R-10}

Horses—Bioavailability (oral dose of 20 mg/kg): 77% (range, 43 to 100%).^{R-16}

Rats—Oral administration: Nearly completely absorbed.^{R-8}

Distribution: Volume of distribution (steady state)—*Horses*: 0.29 ± 0.09 Liter per kg.^{R-16}

Protein binding: *Dogs, human beings, and rats*—Highly protein-bound (>95%).^{R-8}

Half-life: Elimination—

Dogs:

Adult—Intravenous administration: 9.7 ± 0.97 hours.^{R-8}

5 months of age (beagles)—Oral dose of 12 to 17 mg/kg:

Terminal half-life—

Fasted: 7.66 ± 2.05 hours.^{R-1}

Fed: 11.98 ± 5.52 hours.^{R-1}

Horses:

Intravenous administration—2.85 hours (harmonic mean).^{R-16}

Oral dose of 20 mg/kg—2.72 hours (harmonic mean).^{R-16}

Human beings: 7 hours.^{R-8}

Rats: 16.6 ± 1.0 hours.^{R-8}

Peak concentration:

Dogs, 5 months of age (beagles)—Oral dose of 12 to 17 mg/kg:

Fasted—Peak plasma concentration of 22.0 ± 6.42 microgram per mL (mcg/mL) at 1.69 ± 0.69 hours after administration.^{R-1}

Fed—Peak plasma concentration of 16.9 ± 8.84 mcg/mL at 1.08 ± 0.46 hours after administration.^{R-1}

Horses—Oral dose of 20 mg/kg: 32.6 ± 11.0 mcg/mL at 1.03 ± 0.27 hours.^{R-16}

Elimination:

Dogs—Primarily eliminated by hepatic metabolism and excretion into the feces (91%).^{R-8} Etodolac is thought to undergo extensive enterohepatic metabolism.^{R-1; 8} Only about 6 to 10% of the dose is excreted into the urine;^{R-1; 7; 8} one-third as free etodolac, one-third as a glucuronide metabolite, and the remainder as polar metabolites.^{R-8}

Rats—Primarily eliminated by hepatic metabolism and excretion into the feces (81%).^{R-8} Etodolac is thought to undergo extensive enterohepatic metabolism.^{R-8} Only about 11 to 15% of the dose is excreted into the urine, primarily as free etodolac with some polar metabolites present.^{R-1; 7; 8}

Horses—Three hydroxylated metabolites of etodolac have been identified in the urine of horses after oral administration.^{R-6} Systemic clearance: 4.14 ± 0.88 mL/min/kg.^{R-16}

Human beings and mice—About 65 and 53% of the dose is excreted into the urine in human beings and mice, respectively.^{R-7}

Precautions to Consider

Cross-sensitivity

Animals sensitive to one of the nonsteroidal anti-inflammatory drugs (NSAIDs) may be sensitive to any of the other NSAIDs also.

Pregnancy/Reproduction

The safety of etodolac in breeding, pregnant or lactating dogs has not been studied.^{R-1}

Fertility—A reduction in the number of fertilized eggs implanted was demonstrated in reproduction studies in rats receiving 8 mg/kg a day,

but no impairment of fertility was demonstrated in male or female rats receiving up to 16 mg/kg a day.^{R-13}

Pregnancy—Isolated alterations of limb development, including polydactyly, oligodactyly, syndactyly, and unossified phalanges, occurred in offspring of rats receiving 2 to 14 mg/kg a day. Also, oligodactyly and synostosis of metatarsals occurred in offspring of rabbits receiving 2 to 14 mg/kg a day. However, the frequency and dosage group distribution in initial and repeated studies did not establish a clear drug- or dose-response relationship.^{R-13}

NSAID administration during late pregnancy can cause prolonged gestation and dystocia. Delayed and prolonged parturition was associated with decreased rat pup survival in studies with etodolac.^{R-13}

Lactation

It is not known whether etodolac is distributed into milk.

Pediatrics

The safety of etodolac in dogs less than 1 year of age has not been studied.^{R-1}

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.

Angiotensin converting enzyme inhibitors (ACE inhibitors) or Furosemide

(because ACE inhibitors and furosemide act through the effects of vasodilatory prostaglandins on renal function, NSAIDs may decrease their effectiveness; there is not yet any evidence that this is clinically significant, but monitoring is recommended)

Anti-inflammatory medications,^{R-1} such as

Aspirin

Corticosteroids

Other nonsteroidal anti-inflammatory drugs

(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) (concurrent administration of two or more NSAIDs may alter the pharmacokinetic profile of at least one of the medications, which may alter the therapeutic effect and/or increase the risk of adverse effects; specifically, in human beings, aspirin decreases protein binding of ketoprofen and etodolac [but does not alter etodolac clearance])

Medications that are moderately to highly protein bound, other^{R-1}

(the potential exists for concurrent administration of significantly protein-bound medications with etodolac to cause displacement of one or the other drug from protein binding, causing higher or lower than predicted free-drug concentrations for each; it is recommended that the medications be monitored; specifically, aspirin and phenylbutazone decrease protein binding of etodolac in *in vitro* and human studies)

Human drug interactions:^{R-13}

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 1*; these drug interactions are intended for informational purposes only and may or may not be applicable to the use of etodolac in the treatment of animals:

Note: All of the following interactions have not been documented with every NSAID. However, they have been reported with several and should be considered potential precautions to the use of any NSAID, especially with chronic administration.

Anticoagulants, coumarin- or indandione-derivative or

Heparin or
Thrombolytic agents
(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)

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 and possibly because of displacement of the oral antidiabetics from serum proteins; dosage adjustments of the antidiabetic agent may be necessary)

Diuretics
(NSAIDs may decrease the diuretic, natriuretic, and antihypertensive effects of diuretics, probably by inhibiting renal prostaglandin synthesis)
(concurrent use of an NSAID and a diuretic may increase the risk of renal failure secondary to a decrease in renal blood flow caused by inhibition of renal prostaglandin synthesis)

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; dosage adjustment of the bone marrow depressant; if necessary, should be based on blood counts)

Cyclosporine or
Nephrotoxic medications, other
(inhibition of renal prostaglandin activity by NSAIDs may increase the plasma concentration of cyclosporine and/or the risk of cyclosporine-induced nephrotoxicity; patients should be carefully monitored during concurrent use)
(the risk of adverse renal effects may also be increased when an NSAID is used concurrently with other nephrotoxic medications)

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; the possibility should be considered that some of the other NSAIDs also may increase digoxin concentrations, leading to an increased risk of digitalis toxicity; increased monitoring and dosage adjustments of the digitalis glycoside may be necessary during and following concurrent NSAID therapy; however, studies have failed to show that flurbiprofen, ketoprofen, piroxicam, or tenoxicam increase digoxin concentrations, and phenylbutazone may decrease digitalis concentrations)

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 when NSAIDs were used concurrently with low to moderate doses of methotrexate, and especially with high-dose methotrexate infusion therapy; caution in concurrent use and adjustment of dosing is recommended)

Platelet aggregation inhibitors, other
(concurrent use of a platelet aggregation inhibitor with a NSAID may increase the risk of bleeding because of additive interferences with platelet function and/or the potential occurrence of NSAID-induced gastrointestinal ulceration or hemorrhage)

Probenecid
(probenecid may decrease excretion and increase serum concentrations of NSAIDs, possibly enhancing effectiveness and/or increasing the potential for toxicity; a decrease in

dosage of the NSAID may be necessary if adverse effects occur)

Laboratory value alterations

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

Note: No laboratory value alterations have been reported with short-term administration of etodolac to dogs at recommended dosages. Human laboratory value alterations have been reported and are included under *Human laboratory value alterations* below.

Human laboratory value alterations^[R-13]

The following laboratory value alterations have been reported in humans, and are included in the human monograph *Anti-inflammatory Drugs, Nonsteroidal (Systemic)* in the *USP DI Volume 1*; these laboratory value alterations are intended for informational purposes only and may or may not be applicable to the use of etodolac in the treatment of animals:

With diagnostic test results

Bilirubin, urine, determinations

(phenolic metabolites of etodolac may cause false-positive test results)

Ketones, urine, determinations

(false-positive test results may occur with dipstick method of determination)

With physiology/laboratory test values

Bleeding time

(may be prolonged by most NSAIDs because of suppressed platelet aggregation)

Hematocrit or

Hemoglobin

(values may be decreased, possibly because of gastrointestinal bleeding or microbleeding and/or hemodilution caused by fluid retention)

Leukocyte count or

Platelet count

(may be decreased)

Liver function tests, including:

Alkaline phosphatase, serum

Lactate dehydrogenase (LDH), serum

Transaminases, serum

(values may be increased; liver function test abnormalities may return to normal despite continued use; however, if significant abnormalities occur, clinical signs and symptoms consistent with liver disease develop, or systemic manifestations such as eosinophilia or rash occur, the medication should be discontinued)

Potassium, serum, concentrations

(may be increased)

Renal function tests, including:

Blood urea nitrogen (BUN)

Creatinine, serum

Electrolyte, blood and urine, concentrations

Urine volume

(NSAIDs may decrease renal function, resulting in increased BUN, serum creatinine, and serum electrolyte concentrations and in decreased urine volume and urine electrolyte concentrations; however, in some cases, water retention may exceed that of sodium, resulting in dilutional hyponatremia)

Uric acid concentrations

(serum uric acid concentrations may be decreased and urine concentrations increased by etodolac; in clinical trials with etodolac, the serum concentration was usually decreased by 1 to 2 mg per 100 mL [59 to 118 micromoles/L] after 4 weeks of therapy with 600 to 1000 mg per day and the reduction was maintained during the study period)

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 (» = major clinical significance).

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

- » Hypersensitivity to etodolac^(R-1)
(animals previously found to be hypersensitive should not receive etodolac)

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

- Bleeding disorders or
- Blood dyscrasias or
- Gastrointestinal disease
(may be exacerbated)^(R-1)
- 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 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 etodolac administration as well as regular follow-up blood chemistry testing should be considered)

Side/Adverse Effects

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

Those indicating need for medical attention

Incidence unknown

Dogs (categories listed in decreasing order of frequency)

Gastrointestinal effects (vomiting, diarrhea, inappetence, gastroenteritis, gastrointestinal bleeding, melena, gastrointestinal ulceration, hypoproteinemia, elevated pancreatic enzymes); **hepatic effects** (abnormal liver function tests, elevated hepatic enzymes, icterus, acute hepatitis); **hematologic effects** (anemia, hemolytic anemia, thrombocytopenia, prolonged bleeding time); **neurologic/behavioral/special sense effects** (ataxia, paresis, aggression, sedation, hyperactivity, disorientation, hyperesthesia, seizures, vestibular signs, keratoconjunctivitis sicca); **renal effects** (polydipsia, polyuria, urinary incontinence, azotemia, acute renal failure, proteinuria, hematuria); **dermatologic/immunologic** (pruritis, dermatitis, edema, alopecia, urticaria); **cardiovascular/respiratory** (tachycardia, dyspnea)

Note: The above were drawn from post-approval adverse drug experience reporting.^(R-1)

The primary adverse effect appears to be *gastrointestinal toxicity*.^(R-4) In a preapproval, placebo-controlled clinical field trial using the labeled dose for 8 days in 116 dogs, *vomiting* was the most common adverse effect, seen in 4.3% of dogs compared to 1.7% in placebo-treated dogs.^(R-1) However, as with other nonsteroidal anti-inflammatory drugs (NSAIDs), varying adverse effects may occur in individual animals with

administration of etodolac.

In the same preapproval clinical field trial, three dogs treated with etodolac developed *hypoproteinemia*; for two of them, an underlying cause could not be found and blood protein returned to normal when etodolac treatment ended.^{R-4}

Postapproval cases of *keratoconjunctivitis sicca* (KCS) in association with etodolac administration have been reported.^{R-14} The frequency of these reports between 1998 and 2002, based on tablets sold, was estimated by the manufacturer to be approximately 1 in 3000 dogs treated.^{R-15} However, the relationship between etodolac administration and the development of KCS has not been defined.

Note: Long-term administration—Dogs administered 10 mg/kg a day for twelve months or 15 mg/kg a day for 6 months, developed mild weight loss; loose, mucoid, mucosanguineous feces or diarrhea; and hypoproteinemia in some dogs.^{R-1} Erosions were found in the small intestine of the dogs treated with 15 mg/kg a day for 6 months.^{R-1} However, when etodolac was administered for only 9.5 weeks at the labeled dose, there was no increase reported in the incidence of fecal abnormalities.^{R-1}

Human side/adverse effects^{R-13}

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 1*; these side/adverse effects are intended for informational purposes only and may or may not be applicable to the use of etodolac in the treatment of animals:

Incidence more frequent

Abdominal cramps, pain, or discomfort, mild to moderate; bleeding from rectum; bloated feeling or gas; constipation; diarrhea; fluid retention and edema; headache, mild to moderate; indigestion; nausea; nervousness or irritability

Incidence less frequent

Blurred or double vision or any change in vision; cystitis; decreased appetite or loss of appetite; dizziness; drowsiness; general feeling of discomfort or illness; increased sweating; mental depression; ringing or buzzing in ears; skin rash; stomatitis, aphthous; trouble in sleeping; vomiting

Incidence rare

Agranulocytosis [granulocytopenia]; anaphylaxis or anaphylactoid reactions; anemia, hemolytic; bitter taste or other taste change; bleeding from vagina; blood in urine; bronchospastic allergic reactions; bulbous eruptions/blisters; cardiac arrhythmias; confusion; congestive heart failure or exacerbation of; conjunctivitis; decreased hearing or any change in hearing; dermatitis, allergic; dermatitis, exfoliative; dry, irritated, or swollen eyes; erythema or other skin discoloration; eye pain; fast heartbeat; forgetfulness; gastritis; gastrointestinal bleeding, gastrointestinal perforation and/or ulceration; hallucinations; hemoptysis; hepatitis or jaundice, toxic; hives; hypocoagulability; increased blood pressure; interstitial nephritis; irritation, dryness, or soreness of mouth; itching; laryngeal edema, lightheadedness/vertigo; loosening or splitting of fingernails or other nail disorders; migraine; muscle cramps; nephrotic syndrome; neuropathy, peripheral; nosebleeds, unexplained; pancreatitis; photoallergic or photosensitive dermatologic reaction; pounding heartbeat; renal impairment or failure; rhinitis, allergic; shortness of breath or troubled breathing; syncope; thirst, continuing; thrombocytopenia with or without purpura, trembling or twitching; weight loss, unexplained

Incidence unknown

Abdominal distention; amblyopia, toxic; angioedema; angitis; anxiety; aplastic anemia [pancytopenia]; bladder pain; bone marrow depression; chestpain; cholestatic hepatitis or jaundice; colitis or exacerbation of; convulsions; corneal deposits or opacity; crystalluria, renal calculi, or ureteral obstruction;

desquamation; disorientation; disseminated intravascular coagulation; dysarthria (trouble in speaking); dysphagia; dysuria; ecchymosis/bruising; eczema; edema, pulmonary; eosinophilia; epigastric pain; enteritis, regional or exacerbation of; enterocolitis; erythema multiforme; erythema nodosum; esophagitis; feeling of depersonalization or muzziness; fever; flushing or hotflashes; frequent urge to urinate; gastroenteritis; gingival ulceration; glomerulitis or glomerulonephritis; glossitis; headache, severe, especially in the morning; heartburn; hyperkalemia; incontinence; leukopenia [neutropenia]; Loeffler syndrome [eosinophilic pneumonitis]; lymphadenopathy; meningitis, aseptic; muscle weakness; nephrosis; oliguria/anuria; palpebral edema; pericarditis; petechia; photophobia; photosensitivity reactions; polyuria; proteinuria; psychotic reaction; renal papillary or tubular nephrosis; retinal or macular disturbances; scotomata; serum sickness-like reaction; Stevens-Johnson syndrome (bleeding or crusting sores on lips; chest pain; fever with or without chills; muscle cramps or pain; retinal hemorrhage; skin rash; sores, ulcers, or white spots in mouth; sore throat); strong-smelling urine; swelling of lips and tongue, syncope; systemic lupus erythematosus [SLE]-like syndrome; toxic epidermal necrolysis; trembling or twitching; unusual weakness with no other signs or symptoms; urethritis or urinary tract infection; vasculitis

Overdose

For 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.**

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:

Dogs

With a dose of 40 mg/kg a day for 52 weeks:^(R-1; 4)

Decreased erythroid parameters, including red blood cell count, hematocrit, and hemoglobin; decreased total serum protein and individual serum albumin and globulin concentrations; fecal occult blood; gastrointestinal erosion or ulceration; increased fibrinogen concentration; increased leukocyte counts; vomiting; weight loss

With a dose of 80 mg/kg a day for 52 weeks:^(R-1; 4)

Gastrointestinal ulceration (weight loss, frequent abnormal stools or vomiting, decreased food intake, pale mucous membranes, and profound changes in hematological and serum biochemical parameters, including decreased erythrocyte counts, increased leukocyte and platelet counts and hypoproteinemia, death); *renal tubular necrosis*—noted in one dog that died

Note: Six out of eight dogs in this study *died* from *gastrointestinal ulceration*; one within 3 weeks and the others after 3 to 9 months of treatment.^(R-1; 4)

Client Consultation

A client information sheet developed specifically for dog owners administering etodolac to their pet is provided by the United States manufacturer.

In providing consultation, consider emphasizing the following selected information:

Returning patients for periodic rechecks while they are on medication

Keeping water readily available during the treatment period to avoid dehydration

Counseling clients to contact their veterinarian and discontinue medication if any of the following are observed: decreased appetite, vomiting, diarrhea, dark or tarry stools, increased water consumption, increased urination, pale gums due to anemia, yellowing of gums, skin or whites of the eyes due to jaundice,

lethargy, incoordination, seizure, or behavioral changes^(R-1)
Keeping tablets out of the reach of children^(R-1)

Veterinary Dosing Information

For treatment of adverse effects

Recommended treatment consists of the following:

For *anaphylaxis*

- Parenteral epinephrine.^(R-6)
- Oxygen administration and respiratory support.

Oral Dosage Forms

ETODOLAC TABLETS USP

Usual dose:

Inflammation, musculoskeletal¹; or
Pain, musculoskeletal¹—*Dogs*: Oral, 10 to 15 mg per kg of body weight a day.^(R-1) The dose is adjusted, based on clinical response and tolerance;^(R-1) if longer-term administration is necessary, the minimum effective dose is the goal.

Size(s) usually available:

U.S.—^(R-1)

Veterinary-labeled product(s):
150 mg (Rx) [*Etogesic* (scored)].
300 mg (Rx) [*Etogesic* (scored)].
500 mg (Rx) [*Etogesic* (scored)].

Canada—

Veterinary-labeled product(s):
Not commercially available.

Packaging and storage: Store between 15 and 30 °C (59 and 86 °F),^(R-1) unless otherwise specified by the manufacturer.

USP requirements: Preserve in tight containers. Contain the labeled amount, within ± 10%. Meet the requirements for Identification, Uniformity of dosage units, and Dissolution (80% in 30 minutes in phosphate buffer [pH 6.8] in Apparatus 1 at 100 rpm).^(R-3)

¹Not included in Canadian product labeling or product not commercially available in Canada.

Developed: 2/6/04

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