Furosemide Syrup 1%

(10 mg/mL)

Rx

- **Approved by FDA under ANADA # 200-373**
- **Furosemide Syrup 1% is approved by the FDA as equivalent to the pioneer product Lasix® Syrup 1%.[1]**
- **Furosemide Syrup 1% is supplied in 60 mL (2 fl oz) amber glass bottles with a calibrated safety dropper included.**
- **10 mg/mL: 1 to 2 mL (10-20 mg) for each 10 lb body weight.**
- **See insert for full prescribing information (see back page).**

A diuretic liquid for use in dogs. Active in the proximal and distal tubules and also the ascending limb of the loop of Henle.

Size	Reorder No.	Lbs/Case	Case Pack
2 fl oz (60 mL)	OM070	5 lbs.	12 x 1

INDICATIONS: A diuretic-saluretic for oral use alone or in combination with furosemide injection in the treatment of edema (pulmonary congestion, ascites) associated with cardiac insufficiency and acute noninflammatory tissue edema.

DIRECTIONS: DOG: 1 to 2 mL (10-20 mg) Furosemide Syrup 1% for each 10 lb body weight. Administer once or twice daily at 6- to 8-hour intervals. Dispense in this container with calibrated safety dropper. Use dropper to measure and administer Furosemide Syrup 1%.

See insert for full prescribing information.

TAKE TIME OBSERVE LABEL DIRECTIONS

Priority Care® is a registered trademark of First Priority, Inc.

Rev. 09-22

NDC# 58829-303-60

Priority Care®

Furosemide Syrup 1% (10 mg/mL)

With Calibrated Safety Dropper

FOR USE IN DOGS ONLY

CAUTION: Federal law restricts this drug to use by or on the order of a licensed veterinarian.

Not for Use in Humans • Keep Out of Reach of Children

Net Contents: 2 fl oz (60 mL)

Approved by FDA under ANADA # 200-373

INGREDIENTS: Alcohol 11.5% USP as a preservative, and FD&C Yellow #6 and D&C Yellow #10 as color additives.

CAUTIONS: Keep container tightly closed. Discard opened bottle after 60 days. Protect from light.

STORAGE: Store at controlled room temperature (59°-86°F).

DO NOT USE AFTER

DATE:_____

Lot No. Exp. Date

NOT RETURNABLE IF OUTDATED

3 62308 30360 4

Reorder No. OM070PC

Made in U.S.A.

Manufactured By:
FIRST PRIORITY, INC., Elgin, IL 60123

www.prioritycare.com

[1] Lasix® is a registered trademark of Validus Pharmaceuticals LLC, Parsippany, NJ

For a complete list of Priority Care distributors, please call our Customer Service Department at: 1-800-650-4899, or visit our Website: www.prioritycare.com

Revised: 05/03/24

Furosemide Syrup 1% (10 mg/mL)

FOR USE IN DOGS ONLY

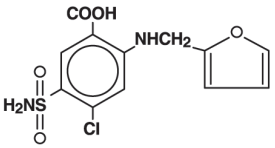
A diuretic-saluretic for prompt relief of edema.

Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian.

DESCRIPTION: Furosemide Syrup 1% is a chemically distinct diuretic and saluretic pharmacodynamically characterized by the following:

1) A high degree of efficacy, low-inherent toxicity and a high therapeutic index.
2) A rapid onset of action of comparatively short duration. [1,2]
3) A pharmacologic action in the functional area of the nephron, i.e., proximal and distal tubules and the ascending limb of the loop Henle. [2,4]
4) A dose-response relationship and a ratio of minimum to maximum effective dose range greater than ten fold. [1,2]
5) It is administered orally. It is readily absorbed from the intestinal tract and well tolerated.

The CAS Registry Number is: 54-31-9.
This product contains alcohol 11.5% USP as a preservative, and FD&C Yellow #6 and D&C Yellow #10 as color additives.
Furosemide Syrup 1%, a diuretic, is an anthranilic acid derivative with the following structural formula:



Generic name: Furosemide (except in United Kingdom-frusemide). Chemical name: 4-chloro-N-furfuryl-5-sulfamoylanthranilic acid.

ACTIONS
The therapeutic efficacy of Furosemide Syrup 1% is from the activity of the intact and unaltered molecule throughout the nephron, inhibiting the reabsorption of sodium not only in the proximal and distal tubule, but also in the ascending limb of the loop of Henle. The prompt onset of action is a result of the drug's rapid absorption and a poor lipid solubility. The low lipid solubility and a rapid renal excretion minimizes the possibility of lipid accumulation in tissues and organs or of crystalluria. Furosemide Syrup 1% has no inhibitory effect on carbonic anhydrase or aldosterone activity in the distal tubule.The drug possesses diuretic activity in the presence of either acidosis or alkalosis. [1-7]

INDICATIONS
DOG
Furosemide Syrup 1% is an effective diuretic possessing a wide therapeutic range. Pharmacologically it promotes the rapid removal of abnormally retained extracellular fluids. The rationale for the efficacious use of diuretic therapy is determined by the clinical pathology producing the edema.
Furosemide Syrup 1% is indicated for the treatment of edema (pulmonary congestion, ascites) associated with cardiac insufficiency and acute noninflammatory tissue edema. The continued use of heart stimulants, such as digitalis or its glycosides, is indicated in cases of edema involving cardiac insufficiency.

CONTRAINDICATIONS-PRECAUTIONS
Furosemide Syrup 1% is a highly effective diuretic-saluretic which if given in excessive amounts may result in dehydration and electrolyte imbalance. Therefore, the dosage and schedule may have to be adjusted to the patients' needs. The animal should be observed for early signs of electrolyte imbalance, and corrective measures administered. Early signs of electrolyte imbalance are: Increased thirst, lethargy, drowsiness or restlessness, fatigue, oliguria, gastrointestinal disturbances and tachycardia. Special attention should be given to potassium levels.

Furosemide may lower serum calcium levels and cause tetany in rare cases of animals having an existing hypocalcemic tendency. [10-14]
Although diabetes mellitus is a rarely reported disease in animals, active or latent diabetes mellitus may on rare occasions be exacerbated by Furosemide Syrup 1%. While it has not been reported in animals, the use of high doses of salicylates, as in rheumatic diseases, in conjunction with Furosemide Syrup 1% may result in salicylate toxicity because of competition for renal excretory sites. Electrolyte balance should be monitored prior to surgery in patients receiving Furosemide Syrup 1%. Imbalances must be corrected by administration of suitable fluid therapy.

Furosemide Syrup 1% is contraindicated in anuria. Therapy should be discontinued in cases of progressive renal disease if increasing azotemia and oliguria occur during the treatment. Sudden alterations of fluid and electrolyte imbalance in an animal with cirrhosis may precipitate hepatic coma; therefore, observation during period of therapy is necessary. In hepatic coma and in states of electrolyte depletion, therapy should not be instituted until the basic condition is improved or corrected. Potassium supplementation may be necessary in cases routinely treated with potassium depleting steroids.

WARNINGS
Furosemide Syrup 1% is a highly effective diuretic and, as with any diuretic, if given in excessive amounts may lead to excessive diuresis that could result in electrolyte imbalance, dehydration and reduction of plasma volume, enhancing the risk of circulatory collapse, thrombosis, and embolism. Therefore, the animal should be observed for early signs of fluid depletion with electrolyte imbalance, and corrective measures administered. Excessive loss of potassium in patients receiving digitalis or its glycosides may precipitate digitalis toxicity. Caution should be exercised in animals administered potassium-depleting steroids.

It is important to correct potassium deficiency with dietary supplementation. Caution should be exercised in prescribing enteric-coated potassium tablets.

There have been several reports in human literature, published and unpublished, concerning nonspecific small-bowel lesions consisting of stenosis, with or without ulceration, associated with the administration of enteric-coated thiazides with potassium salts. These lesions may occur with enteric-coated potassium tablets alone or when they are used with non-enteric-coated thiazides, or certain other oral diuretics. These small-bowel lesions may have caused obstruction, hemorrhage, and perforation. Surgery was frequently required, and deaths have occurred. Available information tends to implicate enteric-coated potassium salts, although lesions of this type also occur spontaneously. Therefore, coated potassium-containing formulations should be administered only when indicated, and should be discontinued immediately if abdominal pain, distension, nausea, vomiting, or gastrointestinal bleeding occurs. Human patients with known sulfonamide sensitivity may show allergic reactions to Furosemide Syrup 1%; however, these reactions have not been reported in animals.

Sulfonamide diuretics have been reported to decrease arterial responsiveness to pressor amines and to enhance the effect of tubocurarine. Caution should be exercised in administering curare or its derivatives to patients undergoing therapy with Furosemide Syrup 1% and it is advisable to discontinue Furosemide Syrup 1% for one day prior to any elective surgery.
Keep Furosemide Syrup 1% in a secure location out of the reach of dogs, cats, and other animals to prevent accidental ingestion or overdose.

CONTACT INFORMATION:
To report suspected adverse events, for technical assistance or to obtain a copy of the Safety Data Sheet (SDS), contact First Priority, Inc. at (800) 650-4899 or www.priority-care.com. For additional information about adverse drug experience reporting for animal drugs, contact FDA at 1-888-FDA-VETS or http://www.fda.gov/reportanimalae

DOSAGE AND ADMINISTRATION
The usual dose of Furosemide Syrup 1% is 1 to 2 mg/lb body weight (approximately 2.5 to 5 mg/kg). Administer once or twice daily at 6- to 8-hour intervals orally. A prompt diuresis usually ensues from the initial treatment. Diuresis may be initiated by the parenteral administration of furosemide injection and then maintained by oral administration.
The dosage should be adjusted to the individual's response. In severe edematous or refractory cases, the dose may be doubled or increased by increments of 1 mg/lb body weight. The established effective dose should be administered once or twice daily. The daily schedule of administration can be timed to control the period of micturition of the convenience of the client or veterinarian. Mobilization of the edema may be most efficiently and safely accomplished by utilizing an intermittent daily dosage schedule, i.e., every other day or 2 to 4 consecutive days weekly.
Diuretic therapy should be discontinued after reduction of the edema, or maintained after determining a carefully programmed dosage schedule to prevent recurrence of edema. For long-term treatment, the dose can generally be lowered after the edema has once been reduced. Re-examination and consultations with client will enhance the establishment of a satisfactorily programmed dosage schedule. Clinical examination and serum BUN, CO^2 and electrolyte determinations should be performed during the early period of therapy and periodically thereafter, especially in refractory cases. Abnormalities should be corrected or the drug temporarily withdrawn.

DOSAGE
ORAL:
DOG-Syrup 1%
One (1) to two (2) mL (10 to 20 mg furosemide) per 10 lb body weight (approximately 2.5 to 5 mg/kg).
Administered once or twice daily, permitting a 6- to 8-hour interval between treatments. In refractory or severe edematous cases, the dosage may be doubled or increased by increments of 1 mg/lb body weight as recommended in preceding paragraphs, "DOSAGE AND ADMINISTRATION."

HOW SUPPLIED
Oral:
Furosemide Syrup 1% (10 mg/mL), available in 60 mL bottles with calibrated safety dropper.

TOXICOLOGY
Acute Toxicity:
The following table illustrates low acute toxicity of Furosemide in three different species. (Two values indicated two different studies).

LD_{50} of Furosemide in mg/kg body weight

SPECIES	ORAL	INTRAVENOUS
Mouse	1050-1500	308
Rat	2650-4600*	680
Dog	>1000 and >4640	>300 and >464

*NOTE: The lower oral LD_{50} value for the rat was obtained in a group of fasted animals; the higher figure is from a study performed on fed rats.
Toxic doses lead to convulsions, ataxia, paralysis and collapse. Animals surviving toxic doses may become dehydrated and depleted of electrolytes due to the massive diuresis and saluresis.

Chronic Toxicity:
Chronic toxicity studies with furosemide were done in a one-year study in rats and dogs. In a one-year study in rats, renal tubular degeneration occurred with all doses higher than 50 mg/kg. A six-month study in dogs revealed calcification and scarring of the renal parenchyma at all doses above 10 mg/kg.

Reproductive Studies:
Reproductive studies were conducted in mice, rats and rabbits. Only in rabbits administered high doses (equivalent to 10 to 25 times the recommended average dose of 2 mg/kg for dogs, horses and cattle) of furosemide during the second trimester did unexplained maternal deaths and abortions occur. Furosemide Syrup 1% should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. The effects of alcohol administered to pregnant Beagles at 3 and at 3.6 gms/kg/day throughout gestation suggests that alcohol may reduce the number of offspring per litter, the birth weight per pup and increase the incidence of stillbirths. There have been no studies conducted in pregnant dogs administered alcohol at levels found in Furosemide Syrup 1%.

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Rev. 09-22

TAKE TIME OBSERVE LABEL DIRECTIONS

Manufactured by:
First Priority, Inc.
Elgin, IL 60123

Approved by FDA under
ANADA # 200-373

Revised: 05/03/24