

HFA 305

0319 '02 APR 12 A6:35

Date of Approval DEC 18 2001

FREEDOM OF INFORMATION SUMMARY

ANADA 200-293

Indication for use: It is used for the treatment of edema associated with cardiac insufficiency, acute noninflammatory tissue edema, physiological parturient edema of the mammary gland and associated structures.

Sponsored by:
Phoenix Scientific, Inc.
St. Joseph, MO 64503

FOIS-1

FREEDOM OF INFORMATION SUMMARY

1. GENERAL INFORMATION:

ANADA Number	200-293
	JINAD 10-179
Sponsor:	Phoenix Scientific, Inc. 3915 S. 48 th St. Terrace St. Joseph, MO 64503
	21 CFR 510.600: Labeler Code 059130
Established Name:	Furosemide Injection 5 %
Trade/Proprietary Name:	Furosemide Injection 5 %
Dosage Form:	Injectable
How Supplied:	50 & 100 mL multidose vials
How Dispensed:	Rx
Amount of Active Ingredients:	Each mL contains 50 mg of furosemide as diethanolamine
Route of Administration:	Intramuscularly or intravenously
Species:	Cattle, horses, dogs and cats
Labeled Dosage	Dog and cat-1/4 to 1/2 mL/10 lbs BID or SID Horse-5 to 10 mL BID or SID Cattle-5 mL BID or 10 mL SID
Indications for Use:	Diuretic-saluretic for prompt relief of edema
Pharmacological Category:	Diuretic-saluretic

Pioneer Product:

Lasix[®] 5% Injection manufactured by
Intervet, Inc. (NADA 034-478)

2. TARGET ANIMAL SAFETY and DRUG EFFECTIVENESS

Under the provisions of the Federal Food, Drug, and Cosmetic Act, as amended by the Generic Animal Drug and Patent Term Restoration Act, (53 FR 50460, December 15, 1988, First GADPTRA Policy Letter) an abbreviated new animal drug application (ANADA) may be submitted for a generic version of an approved new animal drug (pioneer product). New target animal safety data, drug effectiveness data, and human food safety data (other than tissue residue data) are not required for approval of an ANADA. An ANADA relies on the target animal safety, drug effectiveness, and human food safety data in the pioneer's new animal drug application. The ANADA sponsor is required to show that the generic product is bioequivalent to the pioneer. ANADA's for drug products for food-producing animals will generally be required to include bioequivalence and tissue residue studies. A tissue residue study will generally be required to accompany clinical end-point and pharmacologic end-point bioequivalence studies, and blood level bioequivalence studies that can not quantify the concentration of the drug in blood throughout the established withdrawal period. For certain dosage forms, the agency will grant a waiver from conducting an *in vivo* bioequivalence study (55 FR 24645, June 18, 1990; Fifth GADPTRA Policy Letter; Bioequivalence Guideline, October, 2000).

Based upon the formulation characteristics of the generic product, Phoenix Scientific, Inc. was granted a waiver on September 29, 1997, from conducting an *in vivo* bioequivalence study for Furosemide Injection 5 %. The generic and pioneer products contain the same active and inactive ingredients and are injectable solutions.

3. HUMAN FOOD SAFETY:

WITHDRAWAL TIME

When a waiver from the requirement of an *in vivo* bioequivalence study is granted, the withdrawal times are those previously assigned to the pioneer product. The withdrawal time for furosemide is established under 21 CFR 522.1010- 48 hours in cattle. Milk taken during treatment and for 48 hours (four milkings) after the last treatment must not be used for food.

Currently, there is no tolerance listed for the chemical component 'furosemide' in the Code of Federal Register(section 21 CFR 556).

HUMAN SAFETY RELATIVE TO POSSESSION, HANDLING, AND ADMINISTRATION:

Labeling contains adequate caution/warning statements.

4. AGENCY CONCLUSIONS:

This Abbreviated New Animal Drug Application (ANADA) filed under section 512(b) of the Federal, Food, Drug and Cosmetic (FFD&C) Act satisfies the requirements of section 512(n) of the Act and demonstrates that Furosemide Injection 5 % is safe and effective for its labeled indications, when used under its proposed conditions of use.

5. LABELING:

Attachments:

Pioneer Labeling:

Package Insert

50 mL vial

Generic Labeling:

Package Insert

50 mL & 100mL vials

Copies of applicable labels may be obtained by writing to the:

Food and Drug Administration
Freedom of Information Staff (HFI-35)
5600 Fishers Lane
Rockville, MD 20857

Or requests may be sent via fax to: (301) 443-1726. If there are problems sending a fax, call (301) 827-6567.

Pioneer Labeling

✓ ✓ ✓ ✓ ✓
DOGS, CATS, & HORSES: A diuretic-saluretic for parenteral use alone or in combination with Lasix® (furosemide) Tablets in the treatment of edema (pulmonary congestion, ascites) associated with cardiac insufficiency and acute non-inflammatory tissue edema.
CATTLE: A diuretic-saluretic indicated for the treatment of physiological parturient edema of the mammary gland and associated structures.
DIRECTIONS: Dog & Cat: Administer IV or IM 1/4 to 1/2 mL per 10 lb. body weight once or twice daily at 6- to 8-hour intervals. Horse: Administer IV or IM 5 to 10 mL once or twice daily at 6- to 8-hour intervals. Cattle: Administer IV or IM 10 mL once daily or 5 mL twice daily at 12-hour intervals. Do not treat for more than 48 hours postparturition.
WARNING: Cattle: Milk taken from animals during treatment and for 48 hours (four milkings) after the last treatment must not be used for food. Cattle must not be slaughtered for food within 48 hours following last treatment.
Horses: Do not use in horses intended for food.

NDC 12799-092-07
Lasix®
(furosemide)
Injection 5% 50 mL

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

DESCRIPTION: Each mL contains 50 mg furosemide as a diethanolamine salt preserved with chlorbutol 0.02%, EDTA sodium-gamma-picolinium 0.1% with sodium chloride 0.2% in water for injection, pH adjusted with sodium hydroxide. See insert for full prescribing information. Store between 59 and 86° F. Protect from freezing. Keep this and all medication out of the reach of children.
Lasix REG. TM HOECHST AG **Hoechst®**
Manufactured by:
Taylor Pharmaceuticals
Decatur, IL 62522
Distributed by:
Hoechst Roussel Vet
Wayne, NJ 07099

Lot:
Exp.:

692070-6/97

Exp:

Lot:

Lasix[®]
(furosemide)
Injection 5%



Lasix[®]
(furosemide)
Injection 5%

DOGS, CATS, & HORSES: A diuretic-saluretic for parenteral use alone or in combination with Lasix[®] (furosemide) tablets in the treatment of edema (pulmonary congestion, ascites) associated with cardiac insufficiency and acute non-inflammatory tissue edema.

CATTLE: A diuretic-saluretic indicated for the treatment of physiological parturient edema of the mammary gland and associated structures.

DESCRIPTION: Each mL contains 50 mg furosemide as a diethanolamine salt preserved and stabilized with myristyl-gamma-picolinium chloride 0.02%, EDTA sodium 0.1%, sodium sulfite 0.1% with sodium chloride 0.2% in water for injection, pH adjusted with sodium hydroxide.

Keep this and all medication out of the reach of children.

Store between 59° and 86° F.
Protect from freezing.

Hoechst[®]
Hoechst Roussel Vet
A member of the Hoechst Group

TOXICOLOGY

Acute Toxicity:

The following table illustrates low acute toxicity of Lasix® in three different species.

(Two values indicate two different studies.)

SPECIES	LD ₅₀ of Lasix®	
	ORAL	INTRAVENOUS
Mouse	1050-1500	308
Rat	2650-4600*	680
Dog	>1000 and >4640	>300 and >464

*NOTE: The lower value for the rat oral LD₅₀ was obtained in a group of fasted animals; the higher figure is from a study performed in fed rats.

Toxic doses lead to convulsions, ataxia, paralysis and collapse. Animals surviving toxic dosages may become dehydrated and depleted of electrolytes due to the massive diuresis and salturesis.

Chronic Toxicity:

Chronic toxicity studies with Lasix® 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, cats, horses, and cattle) of furosemide during the second trimester period did unexplained maternal deaths and abortions occur. The administration of Lasix® is not recommended during the second trimester of pregnancy.

REFERENCES

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Lasix® Injection 5%
Manufactured by:
Taylor Pharmaceuticals
Decatur, IL 62522

Lasix® Tablets 12.5 mg and 50 mg
Manufactured by:
Global Pharm Inc.
Don Mills, Ontario M3B 1Y6
Made in Canada

Distributed by:
Hoechst Roussel Vet
Warren, NJ 07059 USA

Hoechst
Hoechst Roussel Vet
A member of the Hoechst Group

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Revised 6/97

Front = OK

*copy of insert
in DER jacket
has both
front & back;
however copy
of label's show
only have
2 back
pages*

*ed by
carr
Phad*

uction of the edema, or maintained after
termining a carefully programmed dosage
edule to prevent recurrence of edema. For
-term treatment, the dose can generally be
ered after the edema has once been
uced. Re-examination and consultations
client will enhance the establishment of
a satisfactorily programmed dosage schedule.
ical examination and serum BUN, CO₂ and
ctrolyte determinations should be per-
red during the early period of therapy and
odically thereafter, especially in refractory
es. Abnormalities should be corrected or
rug temporarily withdrawn.

SAGE: ORAL

D AND CAT

half to one 50 mg scored tablet per 25
nds body weight.

12.5 mg tablet per 5 to 10 pounds body
ght.

minister once or twice daily, permitting a 6-
-hour interval between treatments. In
actory or severe edematous cases, the
age may be doubled or increased by incre-
ts of 1 mg per pound body weight as rec-
nded in preceding paragraphs, "Dosage
Administration".

ENTERAL:

D AND CAT

minister intramuscularly or intravenously 1/4
/2 mL per 10 pounds body weight.

minister once or twice daily, permitting a 6-
-hour interval between treatments. In
actory or severe edematous cases, the
age may be doubled or increased by incre-
ts of 1 mg per pound body weight as rec-
nded in preceding paragraphs, "Dosage
Administration".

SE

individual dose is 250 mg to 500 mg (5 to
nL) administered intramuscularly or intra-
usly once or twice daily at 6- to 8-hour
rvats until desired results are achieved.
veterinarian should evaluate the degree of
na present and adjust dosage schedule
rdingly. Do not use in horses intended
ood.

TLE

individual dose administered intramuscu-
or intravenously is 500 mg (10 mL) once
or 250 mg (5 mL) twice daily at 12-hour
vals. Treatment not to exceed 48 hours
parturition.

taken from animals during treatment
for 48 hours (four milkings) after the last
ment must not be used for food. Cattle
t not be slaughtered for food within 48
rs following last treatment.

V SUPPLIED

nteral: Lasix® (furosemide) Injection 5%
1 mL contains: 50 mg furosemide as a
anolanine salt preserved and stabilized
myristyl-gamma-picolinium chloride 0.02%,
A sodium 0.1%, sodium sulfite 0.1% with
um chloride 0.2% in distilled water, pH
sted with sodium hydroxide.
lable in 50 mL multidose vials.

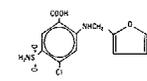
ets:

g (scored) tablets

1 tablet contains 50.0 milligrams of
emide: 4-chloro-N-furfuryl-5-sulfamoylan-
ilic acid.

mg tablets

1 tablet contains 12.5 milligrams of
emide: 4-chloro-N-furfuryl-5-sulfamoylan-
ilic acid.
able in bottles of 500 tablets.

<p>Following last treatment.</p> <p>HOW SUPPLIED</p> <p>Parenteral: Furosemide Injection 5% Each ml contains 50 mg furosemide as a diethanolamine salt preserved and stabilized with myristyl gamma-oxocinnamate chloride 0.2%, EDTA sodium 0.1%, sodium metabisulfite 0.1% with sodium chloride 0.2% in Water For Injection, USP, pH adjusted with sodium hydroxide.</p> <p>Available in 50 ml multidose vials for dogs, cats, horses and camels and 100 ml multidose vials for horses and cattle.</p> <p>TOXICOLOGY</p> <p>Acute Toxicity:</p> <p>The following table illustrates low acute toxicity of Furosemide Injection 5% in three different species.</p> <p>(Two values indicate two different studies.)</p>	<p>1050 of Furosemide Injection 5% in mg/kg body weight</p> <table border="1"> <thead> <tr> <th>SPECIES</th> <th>ORAL</th> <th>INTRAVENOUS</th> </tr> </thead> <tbody> <tr> <td>Mouse</td> <td>1050-1500</td> <td>300</td> </tr> <tr> <td>Rat</td> <td>2050-4500</td> <td>600</td> </tr> <tr> <td>Dog</td> <td>>1000 and >640</td> <td>>300 and >64</td> </tr> </tbody> </table> <p>*NOTE: The lower value for the oral LD50 was obtained in a group of fasted animals, the higher figure is from a study performed in fed rats.</p> <p>Toxic doses lead to convulsions, ataxia, paralysis and collapse. Animals surviving toxic dosages may become dehydrated and depleted of electrolytes due to the massive diuresis and salivary.</p> <p>Chronic Toxicity:</p> <p>Chronic toxicity studies with Furosemide Injection 5% were done in a one-year study in rats and dogs. In a one-year study</p>	SPECIES	ORAL	INTRAVENOUS	Mouse	1050-1500	300	Rat	2050-4500	600	Dog	>1000 and >640	>300 and >64	<p>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.</p> <p>Reproductive Studies:</p> <p>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, cats, horses, and cattle) of furosemide during the second trimester period did unexplained maternal deaths and abortions occur. The administration of Furosemide Injection 5% is not recommended during the second trimester of pregnancy.</p> <p>Safe between 15°C and 30°C (59°F-86°F).</p> <p>60059</p> <p>Rev. 01-00</p> <p>Manufactured by Phoena Scientific, Inc. St. Joseph, MO 64503</p>	<p>DESCRIPTION: Each ml contains 50 mg furosemide as a diethanolamine salt preserved and stabilized with myristyl gamma-oxocinnamate chloride 0.2%, EDTA sodium 0.1%, sodium metabisulfite 0.1% with sodium chloride 0.2% in Water For Injection, USP, pH adjusted with sodium hydroxide.</p> <p>WARNING: Cattle: Milk taken from animals during treatment and for 48 hours (four milkings) after the last treatment must not be used for food. Camels must not be slaughtered for food within 48 hours following last treatment. Horses: Do not use in horses intended for food.</p> <p>Store between 15°C and 30°C (59°F-86°F).</p> <p>60059</p> <p>Rev. 01-00</p> <p>Manufactured by Phoena Scientific, Inc. St. Joseph, MO 64503</p>	<p>ANADA 200-253, Approved by FDA</p> <p>FUROSEMIDE INJECTION 5%</p> <p>A diuretic, selected for prompt relief of edema.</p> <p>Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian.</p> <p>DESCRIPTION</p> <p>Furosemide Injection 5% is a chemically distinct diuretic and saluretic pharmacodynamically characterized by the following:</p> <p>1) A high degree of efficacy, low inherent toxicity and a high therapeutic index.</p> <p>2) A rapid onset of action and of comparatively short duration.</p> <p>3) A pharmacological action in the functional area of the</p>	<p>nephron, i.e., proximal and distal tubules and the ascending limb of the loop of Henle.</p> <p>4) A dose-response relationship and a ratio of minimum to maximum effective dose greater than tenfold.</p> <p>The intravenous route produces the most rapid diuretic response.</p> <p>The CAS Registry Number is 54-31-9.</p> <p>Furosemide Injection 5%, a diuretic, is an anthranic acid derivative with the following structural formula:</p> 	<p>Generic name: Furosemide (except in United Kingdom: furosemide); Chemical name: 4-chloro-N-(furfuryl)-5-sulfamoylfranzamide acid.</p> <p>ACTIONS</p> <p>The therapeutic efficacy of Furosemide Injection 5% is from the activity of the intact and unaltered molecule throughout the nephron, attributing 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 minimize the possibility of its accumulation in tissues and organs or crystalluria. Furosemide Injection 5% has no inhibitory effect on carbonic dehydratase or aldosterone activity in the distal tubule. The drug possesses diuretic activity either in presence of acidosis or alkalosis.</p>	<p>INDICATIONS</p> <p>Dogs, Cats & Horses:</p> <p>Furosemide Injection 5% 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 Injection 5% is indicated for the treatment of edema, (pulmonary congestion, ascites) associated with cardiac insufficiency and acute noninflammatory tissue edema.</p> <p>The combined use of heart stimulants, such as digitalis or its glycosides is indicated in cases of edema involving cardiac insufficiency.</p> <p>Cattle:</p> <p>Furosemide Injection 5% is indicated for the treatment of physiological parturient edema of the mammary gland and associated structures.</p>
SPECIES	ORAL	INTRAVENOUS																	
Mouse	1050-1500	300																	
Rat	2050-4500	600																	
Dog	>1000 and >640	>300 and >64																	

<p>CONTRAINDICATIONS-PRECAUTIONS</p> <p>Furosemide Injection 5% 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 patient's 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, deglut, gastro-intestinal disturbances and tachycardia. Special attention should be given to potassium levels. Furosemide Injection 5% may lower serum calcium levels and cause tetany in rare cases of animals having an existing hypocalcemic tendency.</p> <p>Although diabetes mellitus is a rarely reported disease in animals, acute or latent diabetes mellitus may on rare occasions be exacerbated by Furosemide Injection 5%. While it has not been reported in animals the use of high doses of salicylates, as in rheumatic diseases, in conjunction with</p>	<p>Furosemide Injection 5% may result in salicylate toxicity because of competition for renal excretion sites.</p> <p>Transient loss of auditory capacity has been experimentally produced in cats following intravenous injection of excessive doses of Furosemide Injection 5% at a very rapid rate.</p> <p>Electrolyte balance should be monitored prior to surgery in patients receiving Furosemide Injection 5%. Imbalances must be corrected by administration of suitable fluid therapy.</p> <p>Furosemide Injection 5% is contraindicated in anuria. Therapy should be discontinued in cases of progressive renal disease if increasing anorexia and oliguria occur during the treatment. Sudden alterations of fluid and electrolyte imbalance in an animal with uremia 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</p>	<p>with potassium-depleting steroids.</p> <p>WARNINGS</p> <p>Furosemide Injection 5% is a highly effective diuretic and if given in excessive amounts as with any diuretic may lead to excessive diuresis which 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.</p> <p>It is important to correct potassium deficiency with dietary supplementation. Caution should be exercised in prescribing enteric-coated potassium tablets.</p> <p>There have been several reports in human literature,</p>	<p>published and unpublished, concerning non-specific small-bowel lesions consisting of stenosis, with or without ulceration, associated with the administration of enteric-coated diuretics with potassium salts. These lesions may occur with enteric-coated potassium tablets alone or when they are used with nonenteric-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, caution potassium-containing formulations should be administered only when indicated and should be discontinued immediately if abdominal pain, distention, nausea, vomiting, or gastro-intestinal bleeding occurs.</p> <p>Human patients with known sulfonamide sensitivity may show allergic reactions to Furosemide Injection 5%; however, these reactions have not been reported in animals.</p>	<p>Sulfonamide diuretics have been reported to decrease animal responsiveness to prazosin amines and to enhance the effect of tubocurarine. Caution should be exercised in administering curare or its derivatives to patients undergoing therapy with Furosemide Injection 5% and it is advisable to discontinue Furosemide Injection 5% for one day prior to any elective surgery.</p> <p>WARNING</p> <p>CATTLE: Milk taken from animals during treatment and for 48 hours (four milkings) after the last treatment must not be used for food. Cattle must not be slaughtered for food within 48 hours following last treatment.</p> <p>HORSES: Do not use in horses intended for food.</p> <p>DOSAGE AND ADMINISTRATION</p> <p>The usual dosage of Furosemide Injection 5% is 1 to 2 mg/kg.</p>	<p>body weight (approximately 2.5 to 5 mg/kg). The lower dosage is suggested for cats. Administer once or twice daily at 6 to 8-hour intervals either intravenously or intramuscularly. A pruritic dermatitis usually resolves with the usual treatment. Diuresis may be initiated by the parenteral administration of Furosemide Injection 5%.</p> <p>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 per pound body weight. The established effective dose should be administered twice or twice daily. The daily schedule of administration can be timed to control the period of micururia for 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.</p> <p>Diuretic therapy should be discontinued after reduction of the</p>	<p>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 been reduced. Re-examination and consultation with client will enhance the establishment of a satisfactorily programmed dosage schedule. Clinical examination and serum BUN, ClO₂ 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.</p> <p>DOSAGE:</p> <p>DOGS & CATS</p> <p>Administer intramuscularly or intravenously 1/4 to 1/2 ml per 10 pounds body weight. Administer once or twice daily, providing a 6 to 8-hour interval between treatments. In refractory or severe edematous cases the dosage may be</p>	<p>doubled or increased by increments of 1 mg per pound body weight as recommended in preceding paragraphs. "Doseage and Administration".</p> <p>HORSE</p> <p>The individual dose is 250 to 500 mg (5 to 10 ml) administered intramuscularly or intravenously once or twice daily at 6- to 8-hour intervals until desired results are achieved. The veterinarian should evaluate the degree of edema present and adjust dosage schedule accordingly. Do not use in horses intended for food.</p> <p>CATTLE</p> <p>The individual dose administered intramuscularly or intravenously is 500 mg (10 ml) once daily or 250 mg (5 ml) twice daily at 12-hour intervals. Treatment not to exceed 48 hours postparturition.</p> <p>Milk taken from animals during treatment and for 48 hours (four milkings) after the last treatment must not be used for food. Cattle must not be slaughtered for food within 48 hours</p>
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DOGS, CATS & HORSES: A diuretic-saluretic for parenteral use alone or in combination with furosemide tablets in the treatment of edema (pulmonary congestion, ascites) associated with cardiac insufficiency and acute non-inflammatory tissue edema.

CATTLE: A diuretic-saluretic indicated for the treatment of physiological parturient edema of the mammary gland and associated structures.

See insert for full prescribing information.

DIRECTIONS: Dog & Cat: Administer IV or IM 1/4 to 1/2 mL per 10 lb. body weight once or twice daily at 6- to 8- hour intervals. Horses: Administer IV or IM 5 to 10 mL once or twice daily at 6- to 8- hour intervals. Cattle: Administer IV or IM 10 mL once daily or 5 mL twice daily at 12-hour intervals. Do not treat for more than 48 hours postparturition.

Lot No.
Exp. Date

NDC 59130-709-11

FUROSEMIDE INJECTION 5%

Diuretic-Saluretic

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

FOR ANIMAL USE ONLY

KEEP OUT OF REACH OF CHILDREN

ANADA 200-293, Approved by FDA

NET CONTENTS: 50 mL

AmTech
Group, Inc.

DESCRIPTION: Each mL contains 50 mg furosemide as a diethanolamine salt preserved and stabilized with myristyl-gamma-picolinium chloride 0.02%, EDTA sodium 0.1%, sodium metabisulfite 0.1%, with sodium chloride 0.2% in Water For Injection, USP, pH adjusted with sodium hydroxide.

WARNING: Cattle: Milk taken from animals during treatment and for 48 hours (four milkings) after the last treatment must not be used for food. Cattle must not be slaughtered for food within 48 hours following last treatment. Horses: Do not use in horses intended for food.

Store between 15°C and 30°C (59°-86°F).
600038

Rev. 01-00

Manufactured by
Phoenix Scientific, Inc.
St. Joseph, MO 64503

TAKE TIME



OBSERVE LABEL
DIRECTIONS

OPEN
HERE
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HORSES: A diuretic-saluretic for parenteral use alone or in combination with furosemide tablets in the treatment of edema (pulmonary congestion, ascites) associated with cardiac insufficiency and acute non-inflammatory tissue edema.

CATTLE: A diuretic-saluretic indicated for the treatment of physiological parturient edema of the mammary gland and associated structures. See insert for full prescribing information.

DIRECTIONS: **Horses:** Administer IV or IM 5 to 10 mL once or twice daily at 6- to 8-hour intervals. **Cattle:** Administer IV or IM 10 mL once daily or 5 mL twice daily at 12-hour intervals. Do not treat for more than 48 hours postparturition.

Lot No.

Exp. Date

NDC 59130-709-01

FUROSEMIDE INJECTION 5%

Diuretic-Saluretic

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

**FOR ANIMAL USE ONLY
KEEP OUT OF REACH OF CHILDREN**

ANADA 200-293, Approved by FDA

NET CONTENTS: 100 mL

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600098

Rev. 01-00

TAKE TIME



OBSERVE LABEL DIRECTIONS

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St. Joseph, MO 64503

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