

Date of Approval: DEC 18 2008

## FREEDOM OF INFORMATION SUMMARY

### SUPPLEMENTAL ABBREVIATED NEW ANIMAL DRUG APPLICATION

ANADA 200-387

FLUNAZINE  
(flunixin meglumine)  
Injectable Solution

Horses and Cattle

Effect of the Supplement: addition of a new indication for the control of pyrexia associated with acute bovine mastitis that is no longer protected by marketing exclusivity

Sponsored by:

Cross Vetpharm Group, Ltd.

2009-200-387  
FDA-2008-N-0039

FOIS

**FREEDOM OF INFORMATION SUMMARY*****I. GENERAL INFORMATION:***

- a. File Number: ANADA 200-387
- b. Sponsor: Cross Vetpharm Group Ltd.  
Broomhill Rd.  
Tallaght, Dublin 24, Ireland
- Drug Labeler Code: 061623
- U.S. Agent:  
Linda M. Duple  
Director,  
North American Regulatory Affairs  
Bimeda, Inc.  
2836 Dolliver Park Avenue  
Lehigh, IA 50557
- c. Established Name: Flunixin meglumine
- d. Proprietary Name: FLUNAZINE
- e. Dosage Form: Injectable solution
- f. How Supplied: 100 and 250 mL multiple dose vials
- g. How Dispensed: Rx
- h. Amount of Active Ingredient: Each mL contains flunixin meglumine equivalent to 50 mg of flunixin.
- i. Route of Administration: For intramuscular or intravenous use in horses and intravenous use in beef and dairy cattle
- j. Species/Class: Horses, not intended for human consumption; beef cattle; dairy cattle; calves, excluding veal calves. Not intended for use in dry dairy cows.
- k. Recommended Dosage: Horses:  
For musculoskeletal disorders is 0.5 mg/lb (1 mL/100 lbs) body weight once daily. Treatment may be given by intravenous or intramuscular injection and repeated for up to 5 days.  
For the alleviation of pain associated with equine colic is 0.5 mg per pound of body weight.

Intravenous administration is recommended for prompt relief.

Cattle:

For control of pyrexia associated with bovine respiratory disease and endotoxemia and control of inflammation in endotoxemia is 1.1 to 2.2 mg/kg (0.5 to 1 mg/lb; 1 to 2 mL per 100 lbs) body weight given by slow intravenous administration either once a day as a single dose or divided into two doses at 12-hour intervals for up to 3 days. The total daily dose should not exceed 2.2 mg/kg (1.0 mg/lb) of body weight. For acute bovine mastitis it is 2.2 mg/kg (1.0 mg/lb; 2 mL per 100 lbs) of body weight given once by intravenous administration.

l. Pharmacological Category:

Anti-inflammatory, anti-pyretic

m. Indications:

Horses: FLUNAZINE Injectable Solution is recommended for the alleviation of inflammation and pain associated with musculoskeletal disorders in the horse. It is also recommended for the alleviation of visceral pain associated with colic in the horse.

Cattle: FLUNAZINE Injectable Solution is indicated for the control of pyrexia associated with bovine respiratory disease, endotoxemia, and acute bovine mastitis. FLUNAZINE Injectable Solution is also indicated for control of inflammation in endotoxemia.

n. Pioneer Product:

BANAMINE Injectable Solution; flunixin meglumine; NADA 101-479; Schering-Plough Animal Health Corp.

o. Effect of Supplement:

The supplement requests the addition of a new indication, "for the control of pyrexia associated with acute bovine mastitis", that is no longer protected by marketing exclusivity.

## **2. TARGET ANIMAL SAFETY AND DRUG EFFECTIVENESS:**

Refer to the original Freedom of Information (FOI) Summary dated March 2, 2006 (A-200387-E-0003).

### 3. *HUMAN SAFETY:*

The following are assigned to this product for cattle:

- **Tolerances for Residues:**

The tolerances established for the pioneer product apply to the generic product. A tolerance of 125 parts per billion (ppb) is established for flunixin free acid residues (the marker residue) in the uncooked edible tissues of the liver (the target tissue), 25 ppb in the muscle, and 2 ppb in milk under 21 CFR 556.286.

- **Withdrawal Times:**

Under the CVM Bioequivalence Guidelines, when a generic product is granted a waiver of the *in vivo* bioequivalence testing, the withdrawal period established for the pioneer product is also assigned to the generic product.

For this reason, a withdrawal period of 4 days has been established for flunixin meglumine in cattle (21 CFR 522.970), and milk that has been taken during treatment and for 36 hours after the last treatment must not be used for food. A withdrawal period has not been established for this product in preruminating calves.

- **Regulatory Method for Residues:**

The analytical method for the determination of flunixin meglumine in bovine liver is a high performance liquid chromatography (HPLC) method. The validated methods are on file at the Center for Veterinary Medicine, 7500 Standish Place, Rockville, MD 20855.

### 4. *AGENCY CONCLUSIONS:*

This ANADA submitted under section 512(b)(2) of the Federal Food, Drug, and Cosmetic Act satisfies the requirements of section 512(n) of the act and demonstrates that FLUNAZINE Injectable Solution, when used under its proposed conditions of use, is safe and effective for its labeled indications.

### 5. *ATTACHMENTS:*

Facsimile generic labeling and currently approved pioneer labeling are attached as indicated below:

Generic Labeling for ANADA 200-124

FLUNAZINE Injectable Solution- 100 mL and 250 mL vial labels; and package outserts

Pioneer Labeling for NADA 101-479:

BANAMINE Injectable Solution- 100 mL and 250 mL vial labels, package insert, and 100 mL and 250 mL carton labels

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**Furozime**  
Furozime (furosemide) Injection Solution

For information on Furozime (furosemide) Injection Solution, please contact your pharmacist or call 1-800-368-3772. For more information on Furozime (furosemide) Injection Solution, please visit our website at [www.furozime.com](http://www.furozime.com).

Each box contains 10 vials of Furozime (furosemide) Injection Solution, 10 mg/mL, 10 mL. Each vial contains 100 mg of furosemide.

For information on Furozime (furosemide) Injection Solution, please contact your pharmacist or call 1-800-368-3772. For more information on Furozime (furosemide) Injection Solution, please visit our website at [www.furozime.com](http://www.furozime.com).

10 mg/mL (10 mg/10 mL)  
 20 mg/mL (20 mg/10 mL)  
 40 mg/mL (40 mg/10 mL)  
 80 mg/mL (80 mg/10 mL)  
 160 mg/mL (160 mg/10 mL)

**INDICATIONS:** Furozime is indicated for the treatment of hypertension and edema associated with congestive heart failure, pulmonary edema, and renal insufficiency. Furozime is also indicated for the treatment of hypertension in patients who are intolerant to thiazide diuretics.

**CONTRAINDICATIONS:** Furozime is contraindicated in patients with anuria, severe renal insufficiency, or severe electrolyte imbalance.

**Warnings:** Furozime may cause hypotension, especially in patients who are already receiving antihypertensive therapy. Patients should be monitored for signs and symptoms of hypotension, such as dizziness, lightheadedness, or fainting. If hypotension occurs, the patient should be placed in a supine position and the intravenous infusion should be discontinued until the patient's blood pressure returns to normal.

**Adverse Reactions:** The most common adverse reactions are hypotension, dizziness, and lightheadedness. Other adverse reactions include dehydration, electrolyte imbalance, and renal insufficiency.

**Drug Interactions:** Furozime may interact with other antihypertensive agents, such as beta-blockers and calcium channel blockers. It may also interact with digoxin, lithium, and other drugs that are excreted in the urine.

**Use in Specific Populations:** Furozime should be used with caution in patients with renal impairment, hepatic impairment, or a history of electrolyte imbalance.

**How Supplied:** Furozime is available in 10 mg/mL, 20 mg/mL, 40 mg/mL, 80 mg/mL, and 160 mg/mL injection solutions.

**How to Use:** Furozime should be administered intravenously over a 15-minute period. The dosage should be adjusted based on the patient's clinical response.

**Storage and Stability:** Furozime injection solutions should be stored at room temperature (20°C to 25°C) and should be protected from light.

**Bimeda**  
Manufactured by  
Bimeda Pharmaceuticals, Inc.  
10000 W. 10th Avenue  
Denver, CO 80202

10 mg/mL (10 mg/10 mL)  
 20 mg/mL (20 mg/10 mL)  
 40 mg/mL (40 mg/10 mL)  
 80 mg/mL (80 mg/10 mL)  
 160 mg/mL (160 mg/10 mL)

**Pharmacokinetics:** Furozime is rapidly absorbed after intravenous administration. The elimination half-life is approximately 1.5 hours. Furozime is primarily excreted in the urine as the active metabolite, furosemide.

**Pharmacodynamics:** Furozime is a loop diuretic that acts by inhibiting the Na<sup>+</sup>/K<sup>+</sup>/2Cl<sup>-</sup> cotransporter in the thick ascending loop of Henle, leading to increased excretion of sodium, potassium, and calcium.

**Pharmacokinetics in Specific Populations:** The pharmacokinetics of furozime are similar in patients with renal impairment and in the elderly.

**How to Use:** Furozime should be administered intravenously over a 15-minute period. The dosage should be adjusted based on the patient's clinical response.

**Storage and Stability:** Furozime injection solutions should be stored at room temperature (20°C to 25°C) and should be protected from light.

**Warnings:** Furozime may cause hypotension, especially in patients who are already receiving antihypertensive therapy. Patients should be monitored for signs and symptoms of hypotension, such as dizziness, lightheadedness, or fainting. If hypotension occurs, the patient should be placed in a supine position and the intravenous infusion should be discontinued until the patient's blood pressure returns to normal.

**Adverse Reactions:** The most common adverse reactions are hypotension, dizziness, and lightheadedness. Other adverse reactions include dehydration, electrolyte imbalance, and renal insufficiency.

**Drug Interactions:** Furozime may interact with other antihypertensive agents, such as beta-blockers and calcium channel blockers. It may also interact with digoxin, lithium, and other drugs that are excreted in the urine.

**Use in Specific Populations:** Furozime should be used with caution in patients with renal impairment, hepatic impairment, or a history of electrolyte imbalance.

**How Supplied:** Furozime is available in 10 mg/mL, 20 mg/mL, 40 mg/mL, 80 mg/mL, and 160 mg/mL injection solutions.

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Manufactured by  
Bimeda Pharmaceuticals, Inc.  
10000 W. 10th Avenue  
Denver, CO 80202

10 mg/mL (10 mg/10 mL)  
 20 mg/mL (20 mg/10 mL)  
 40 mg/mL (40 mg/10 mL)  
 80 mg/mL (80 mg/10 mL)  
 160 mg/mL (160 mg/10 mL)

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Veterinary  
Injectable Solution  
**Banamine®**  
(FLUNIXIN MEGLUMINE)

Each mL contains: flunixin meglumine equivalent to 50 mg flunixin, 0.1 mg edetate disodium, 2.5 mg sodium formaldehyde sulfoxylate, 4.0 mg diethanolamine, 207.2 mg propylene glycol, 5.0 mg phenol as preservative, hydrochloric acid, water for injection qs.

**RESIDUE WARNINGS:** Cattle must not be slaughtered for human consumption within 4 days of the last treatment. Milk that has been taken during treatment and for 36 hours after the last treatment must not be used for food. Not for use in dry dairy cows. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal. Not for use in horses intended for food.

Read accompanying directions carefully.  
Store between 2° and 30°C  
(36° and 86°F).

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Union, NJ 07083.

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Made in Germany.

03E-1044

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FS003

100 mL  
Multiple-Dose Vial  
50 mg/mL  
Sterile

NDC 0061-0851-03

**Banamine®**  
(FLUNIXIN MEGLUMINE)

Injectable Solution  
Veterinary

For intravenous or intramuscular use  
in horses, and for intravenous use in  
beef and dairy cattle.  
Not for use in dry dairy cows  
and veal calves.



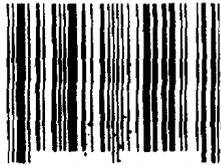
**Banamine®**  
(FLUNIXIN MEGLUMINE)

Injectable Solution  
Veterinary

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

NADA #101-479, Approved by FDA.

Schering-Plough  
Animal Health



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**Banamine®**  
(FLUNIXIN MEGLUMINE)

Injectable Solution  
Veterinary

For intravenous or intramuscular use  
in horses, and for intravenous use in  
beef and dairy cattle.  
Not for use in dry dairy cows  
and veal calves.

**RESIDUE WARNINGS:** Cattle must not be slaughtered for human consumption within 4 days of the last treatment. Milk that has been taken during treatment and for 36 hours after the last treatment must not be used for food. Not for use in dry dairy cows. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal. Not for use in horses intended for food.  
Store between 2° and 30°C  
(36° and 86°F).

100 mL  
Multiple-Dose Vial  
50 mg/mL  
Sterile

**Banamine®**  
(FLUNIXIN MEGLUMINE)  
Injectable Solution  
Veterinary

Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian.  
NADA #101-479, Approved by FDA.  
Schering-Plough Animal Health

For intravenous or intramuscular use in horses, and for intravenous use in beef and dairy cattle. Not for use in dry dairy cows and veal calves.  
Read accompanying directions carefully.  
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NO INSERT

**RESIDUE WARNINGS:** Cattle must not be slaughtered for human consumption within 4 days of the last treatment. Milk that has been taken during treatment and for 36 hours after the last treatment must not be used for food. Not for use in dry dairy cows. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal. Not for use in horses intended for food.

Store between 2° and 30°C  
(36° and 86°F).

NDC 0061-0851-04

250 mL  
Multiple-Dose Vial  
50 mg/mL

Sterile

**Banamine**<sup>®</sup>  
(FLUNIXIN MEGLUMINE)  
Injectable Solution  
Veterinary

Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian.  
NADA #101-479, Approved by FDA.



Schering-Plough Animal Health

For intravenous or intramuscular use in horses, and for intravenous use in beef and dairy cattle.

Not for use in dry dairy cows and veal calves.

Read accompanying directions carefully.

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LOT  
EXP

250 mL  
Multiple-Dose Vial  
50 mg/mL

Sterile

NDC 0061-0851-04

**Banamine**<sup>®</sup>

(FLUNIXIN MEGLUMINE)

Injectable Solution  
Veterinary

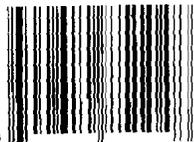
For intravenous or intramuscular use  
in horses, and for intravenous use in  
beef and dairy cattle.  
Not for use in dry dairy cows  
and veal calves.

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

NADA #101-479, Approved by FDA.



Schering-Plough  
Animal Health



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**Banamine**<sup>®</sup>

(FLUNIXIN MEGLUMINE)

Injectable Solution  
Veterinary

For intravenous or intramuscular use  
in horses, and for intravenous use in  
beef and dairy cattle.  
Not for use in dry dairy cows  
and veal calves.

Injectable Solution  
Veterinary  
**Banamine**<sup>®</sup>  
(FLUNIXIN MEGLUMINE)

Each mL contains: flunixin meglumine  
equivalent to 50 mg flunixin, 0.1 mg edetate  
disodium, 2.5 mg sodium formaldehyde  
sulfoxylate, 4.0 mg diethanolamine, 207.2 mg  
propylene glycol; 5.0 mg phenol as preservative,  
hydrochloric acid, water for injection qs.

**RESIDUE WARNINGS:** Cattle must not  
be slaughtered for human consumption  
within 4 days of the last treatment. Milk  
that has been taken during treatment  
and for 36 hours after the last treatment  
must not be used for food. Not for use in  
dry dairy cows. A withdrawal period has  
not been established for this product in  
preruminating calves. Do not use in  
calves to be processed for veal. Not for  
use in horses intended for food.

Read accompanying directions carefully.  
Store between 2° and 30°C  
(36° and 86°F).

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**Banamine**<sup>®</sup>

(FLUNIXIN MEGLUMINE)

Injectable Solution  
Veterinary

For intravenous or intramuscular use  
in horses, and for intravenous use in  
beef and dairy cattle.  
Not for use in dry dairy cows  
and veal calves.

USA0612004CA  
FS025

NADA #101-479, Approved by FDA.

**Banamine®**  
(FLUNIXIN MEGGLUMINE)**Injectable Solution**  
**50 mg/mL**  
**Veterinary****For Intravenous or Intramuscular  
Use in Horses, and for Intravenous  
Use in Beef and Dairy Cattle.  
Not for Use in Dry Dairy Cows  
and Veal Calves.****CAUTION** Federal law restricts this drug to use by or on the order of a licensed veterinarian.**DESCRIPTION** Each milliliter of BANAMINE Injectable Solution contains flunixin meglumine equivalent to 50 mg flunixin, 0.1 mg edetate disodium, 2.5 mg sodium formaldehyde sulfoxylate, 4.0 mg diethanolamine, 207.2 mg propylene glycol, 5.0 mg phenol as preservative, hydrochloric acid, water for injection qs.**PHARMACOLOGY** Flunixin meglumine is a potent, non-narcotic, nonsteroidal, analgesic agent with anti-inflammatory and antipyretic activity. It is significantly more potent than pentazocine, meperidine, and codeine as an analgesic in the rat yeast paw test.**Horse:** Flunixin is four times as potent on a mg-per-mg basis as phenylbutazone as measured by the reduction in lameness and swelling in the horse. Plasma half-life in horse serum is 1.8 hours following a single dose of 1.1 mg/kg. Measurable amounts are detectable in horse plasma at 8 hours postinjection.**Cattle:** Flunixin meglumine is a weak acid (pKa=5.82)<sup>1</sup> which exhibits a high degree of plasma protein binding (approximately 99%).<sup>2</sup> However, free (unbound) drug appears to readily partition into body tissues (V<sub>ss</sub> predictions range from 297 to 782 mL/kg.<sup>2a</sup> Total body water is approximately equal to 570 mL/kg.<sup>3</sup> in cattle, elimination occurs primarily through biliary excretion.<sup>7</sup> This may, at least in part, explain the presence of multiple peaks in the blood concentration/time profile following IV administration.<sup>2</sup>In healthy cattle, total body clearance has been reported to range from 90 to 151 mL/kg/hr.<sup>2a</sup> These studies also report a large discrepancy between the volume of distribution at steady state (V<sub>ss</sub>) and the volume of distribution associated with the terminal elimination phase (V<sub>t</sub>). This discrepancy appears to be attributable to extended drug elimination from a deep compartment.<sup>4</sup> The terminal half-life has been shown to vary from 3.14 to 8.12 hours.<sup>2a</sup>Flunixin persists in inflammatory tissues<sup>8</sup> and is associated with anti-inflammatory properties which extend well beyond the period associated with detectable plasma drug concentrations.<sup>4,1</sup> These observations account for the counterclockwise hysteresis associated with flunixin's pharmacokinetic/pharmacodynamic relationships.<sup>9</sup>

Therefore, prediction of drug concentrations based upon the estimated plasma terminal elimination half-life will likely underestimate both the duration of drug action and the concentration of drug remaining at the site of activity.

**INDICATIONS** **Horse:** BANAMINE Injectable Solution is recommended for the alleviation of inflammation and pain associated with musculoskeletal disorders in the horse. It is also recommended for the alleviation of visceral pain associated with colic in the horse.**Cattle:** BANAMINE Injectable Solution is indicated for the control of pyrexia associated with bovine respiratory disease, endotoxemia and acute bovine mastitis. BANAMINE Injectable Solution is also indicated for the control of inflammation in endotoxemia.**DOSE AND ADMINISTRATION** **Horse:** The recommended dose for musculoskeletal disorders is 0.5 mg per pound (1 mL/100 lbs) of body weight once daily. Treatment may be given by intravenous or intramuscular injection and repeated for up to 5 days. Studies show onset of activity is within 2 hours. Peak response occurs between 12 and 16 hours and duration of activity is 24-36 hours.

The recommended dose for the alleviation of pain associated with equine colic is 0.5 mg per pound of body weight. Intravenous administration is recommended for prompt relief. Clinical studies show pain is alleviated in less than 15 minutes in many cases. Treatment may be repeated when signs of colic recur. During clinical studies approximately 10% of the horses required one or two additional treatments. The cause of colic should be determined and treated with concomitant therapy.

**Cattle:** The recommended dose for control of pyrexia associated with bovine respiratory disease and endotoxemia and control of inflammation in endotoxemia, is 1.1 to 2.2 mg/kg (0.5 to 1 mg/lb; 1 to 2 mL per 100 lbs) of body weight given by slow intravenous administration either once a day as a single dose or divided into two doses administered at 12-hour intervals for up to 3 days. The total daily dose should not exceed 2.2 mg/kg (1.0 mg/lb) of body weight. Avoid rapid intravenous administration of the drug.

The recommended dose for acute bovine mastitis is 2.2 mg/kg (1 mg/lb; 2ml per 100lbs) of body weight given once by intravenous administration.

**CONTRAINDICATIONS** **Horse:** There are no known contraindications to this drug when used as directed. Intra-arterial injection should be avoided. Horses inadvertently injected intra-arterially can show adverse reactions. Signs can be ataxia, incoordination, hyperventilation, hysteria, and muscle weakness. Signs are transient and disappear without antidotal medication within a few minutes. Do not use in horses showing hypersensitivity to flunixin meglumine.**Cattle:** There are no known contraindications to this drug in cattle when used as directed. Do not use in animals showing hypersensitivity to flunixin meglumine. Use judiciously when renal impairment or gastric ulceration are suspected.**RESIDUE WARNINGS:** Cattle must not be slaughtered for human consumption within 4 days of the last treatment. Milk that has been taken during treatment and for 36 hours after the last treatment must not be used for food. Not for use in dry dairy cows. A withdrawal period has not been established for this product in peruminating calves. Do not use in calves to be processed for veal. Not for use in horses intended for food.**PRECAUTIONS** As a class, cyclo-oxygenase inhibitory NSAIDs may be associated with gastrointestinal and renal toxicity. Sensitivity to drug-associated adverse effects varies with the individual patient. Patients at greatest risk for renal toxicity are those that are dehydrated, on concomitant diuretic therapy, or those with renal, cardiovascular, and/or hepatic dysfunction.

Since many NSAIDs possess the potential to induce gastrointestinal ulceration, concomitant use of BANAMINE Injectable Solution with other anti-inflammatory drugs, such as other NSAIDs and corticosteroids, should be avoided or closely monitored.

**Horse:** The effect of BANAMINE Injectable Solution on pregnancy has not been determined. Studies to determine activity of BANAMINE Injectable Solution when administered concomitantly with other drugs have not been conducted. Drug compatibility should be monitored closely in patients requiring adjunctive therapy.**Cattle:** Do not use in bulls intended for breeding, as reproductive effects of BANAMINE Injectable Solution in these classes of cattle have not been investigated. NSAIDs are known to have potential effects on both parturition and the estrous cycle. There may be a delay in the onset of estrus if flunixin is administered during the prostaglandin phase of the estrous cycle. The effects of flunixin on imminent parturition have not been evaluated in a controlled study. NSAIDs are known to have the potential to delay parturition through a tocolytic effect. Do not exceed the recommended dose.**SAFETY** **Horse:** A 3-fold intramuscular dose of 1.5 mg/lb of body weight daily for 10 consecutive days was safe. No changes were observed in hematology, serum chemistry, or urinalysis values. Intravenous dosages of 0.5 mg/lb daily for 15 days; 1.5 mg/lb daily for 10 days; and 2.5 mg/lb daily for 5 days produced no changes in blood or urine parameters. No injection site irritation was observed following intramuscular injection of the 0.5 mg/lb recommended dose. Some irritation was observed following a 3-fold dose administered intramuscularly.**Cattle:** No flunixin-related changes (adverse reactions) were noted in cattle administered a 1X (2.2 mg/kg; 1.0 mg/lb) dose for 9 days (three times the maximum clinical duration). Minimal toxicity manifested itself at moderately elevated doses (3X and 5X) when flunixin was administered daily for 9 days, with occasional findings of blood in the feces and/or urine. Discontinue use if hematuria or fecal blood are observed.**ADVERSE REACTIONS** In horses, isolated reports of local reactions following intramuscular injection, particularly in the neck, have been received. These include localized swelling, sweating, induration, and stiffness. In rare instances in horses, fatal or nonfatal clostridial infections or other infections have

been reported in association with intramuscular use of BANAMINE Injectable Solution. In horses and cattle, rare instances of anaphylactic-like reactions, some of which have been fatal, have been reported, primarily following intravenous use.

**HOW SUPPLIED** BANAMINE Injectable Solution, 50 mg/mL, is available in 50-mL (NDC 0061-0851-02), 100-mL (NDC 0061-0851-03), and 250-mL (NDC 0061-0851-04) multi-dose vials.

Store between 2° and 30°C (36° and 86°F).

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March 2003

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