PRODUCT BULLETIN

Banamine®-S

FLUNIXIN MEGLUMINE

Injectable Solution Veterinary

Indicated for the control of pyrexia associated with swine respiratory disease.

Advantages

Reduces fever in pigs. The sooner they feel better, the sooner they will be up, active, and eating.

- Quickly absorbed for rapid fever reduction
- The original FDA-approved flunixin meglumine anti-inflammatory approved for reducing fevers associated with swine respiratory disease.
- A potent non-steroidal anti-inflammatory drug (NSAID), having both analgesic and anti-fever properties

Important Safety Information: Swine must not be slaughtered for human consumption within 12 days of last treatment. Do not use in animals showing hypersensitivity to flunixin meglumine. Use judiciously, then renal impairment or gastric ulceration is expected. Not for use in breeding swine.

For complete information on Banamine®-S Injectable Solution use, contraindications, and warnings, see accompanying product package insert.

Code: 065477

Available as:
100 mL
Multiple-Dose Vial
50 mg/mL

MERCK
Animal Health

Banamine®-S

FLUNIXIN MEGLUMINE

Injectable Solution Veterinary

DESCRIPTION:

Each milliliter of BANAMINE-S 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 q.s.

PHARMACOLOGY:

Flunixin meglumine is a potent, non-narcotic, non-steroidal, 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.

Flunixin is known to persist in inflammatory tissues[1] and is associated with anti-inflammatory properties which extend well beyond the period associated with detectable plasma drug concentrations[2]. Therefore, prediction of drug concentrations based upon 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.

The pharmacokinetic profiles were found to follow a 2-compartmental model, although a deep (third) compartment was observed in some animals. The mean terminal elimination half-life (ß half-life) of flunixin after a single intramuscular injection of Banamine (2.2 mg/kg) to pigs was between 3 and 4 hours. The mean observed maximum plasma concentration was 2944 ng/mL, achieved at a mean time of approximately 0.4 hours. The mean $AUC^{(0\text{-}LOQ)}$ was 6431 ng*hr/mL. Following IM administration of flunixin, quantifiable drug concentration could be measured up to 18 hours post dose. The mean volume of distribution was 2003 mL/kg and the mean total clearance was 390 mL/hr/kg. The mean absolute bioavailability of flunixin following an intramuscular injection in the neck was 87%.

INDICATION:

BANAMINE-S Injectable Solution is indicated for the control of pyrexia associated with swine respiratory disease.

DOSAGE AND ADMINISTRATION:

The recommended dose for swine is 2.2 mg/kg (1 mg/lb.; 2 mL per 100 lbs.) body weight given by a single intramuscular administration. The injection should be given only in the neck musculature with a maximum of 10 mL per site. Note: Intramuscular injection may cause local tissue irritation and damage. In an injection-site irritation study, the tissue damage did not resolve in all animals by Day 28 post-injection. This may result in trim loss of edible tissue at slaughter.

CONTRAINDICATIONS:

There are no known contraindications to this drug in swine when used as directed. Do not use in animals showing hypersensitivity to flunixin meglumine. Use judiciously when renal impairment or gastric ulceration is suspected.

RESIDUE WARNINGS:

Swine must not be slaughtered for human consumption within 12 days of the last treatment.

PRECAUTIONS:

As a class, cyclo-oxygenase inhibitory NSAIDs may be associated with gastrointestinal, renal and hepatic toxicity. Sensitivity to drug-associated adverse events varies with the individual patient. Patients at greatest risk for adverse events are those that are dehydrated, on concomitant diuretic therapy, or those with existing renal, cardiovascular, and/or hepatic dysfunction. Concurrent administration of potentially nephrotoxic drugs should be carefully approached. NSAIDs may inhibit the prostaglandins that maintain normal homeostatic function. Such prostaglandin effects may result in clinically significant disease in patients with underlying or pre-existing disease that has not been previously diagnosed.

Since many NSAIDs possess the potential to produce gastrointestinal ulceration, concomitant use of flunixin meglumine with other anti-inflammatory drugs, such as other NSAIDs and corticosteroids, should be avoided.

Not for use in breeding swine. The reproductive effects of BANAMINE-S Injectable Solution have not been investigated in this class of swine.

Intramuscular injection may cause local tissue irritation and damage. In an injection site irritation study, the tissue damage did not resolve in all animals by Day 28 post-injection. This may result in trim loss of edible tissue at slaughter.

SAFETY:

Flunixin was mildly irritating at the injection sites. No other flunixin-related changes (adverse reactions) were noted in swine administered a 1X (2.2 mg/kg; 1.0 mg/lb) dose for 9 days. Minimal toxicity manifested itself as statistically significant increased spleen weight at elevated doses (5X or higher daily for 9 days) with no change in normal microscopic architecture.

CAUTIONS:

Federal law restricts this drug to use by or on the order of a licensed veterinarian. **Store at 2°C–30°C (35°F–86°F).**

REFERENCES:

1. Lees P, Higgins AJ. Flunixin inhibits prostaglandin E_2 production in equine inflammation. *Res Vet Sci.* 1984; 37:347-349.

2. Oldensvik K. Pharmacokinetics of flunixin and its effect on prostaglandin F_2 metabolite concentrations after oral and intravenous administration in heifers. *J Vet Pharmacol Ther.* 1995; 18:254-259.

READ AND FOLLOW LABEL DIRECTIONS
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