FLUNAZINE-S- flunixin meglumine injection, suspension
Bimeda, Inc.

Flunazine®-S

(flunixin meglumine injection)

50 mg/mL

For intramuscular use in swine.

Not for use in breeding swine.

CAUTION

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

DESCRIPTION

Each milliliter of Flunazine-S (flunixin meglumine injection) contains 50 mg flunixin (equivalent to 83 mg flunixin meglumine), 0.1 mg edetate disodium, 2.2 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.

CLINICAL PHARMACOLOGY

Flunixin meglumine is a potent non-narcotic, nonsteroidal, analgesic agent with anti-inflammatory and antipyretic activity. It is significantly more potent that 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 (β half-life) of flunixin after a single intramuscular injection of flunixin meglumine injection (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

Flunazine-S (flunixin meglumine injection) 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.

100 mL: Use within 28 days of first puncture and puncture a maximum of 19 times. If using a needle larger than 16 gauge, discard any remaining product in the vial immediately after use.

250 mL: Use within 28 days of first puncture and puncture a maximum of 30 times with a needle or 5 times with a dosage delivery device. If using a needle larger than 4 gauge, discard any remaining product in the vial immediately after use.

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 flunixin meglumine injection 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.

ADVERSE REACTIONS

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.

To report suspected adverse drug events, for technical assistance or to obtain a copy of the Safety Data Sheet (SDS), contact Bimeda, Inc. at 1-888-524-6332. For additional information about adverse drug experience reporting for animal drugs, contact FDA at 1-888-FDA-VETS or online at www.fda.gov/reportanimalae.

ANIMAL SAFETY

Minimal toxicity manifested itself as statistically significant increased spleen weight at elevated doses (5X or higher daily for 9 days) with no change in microscopic architecture.

HOW SUPPLIED

Flunazine-S (flunixin meglumine injection), 50 mg/mL, is available in 100 mL and 250 mL multi-dose vials.

STORE BETWEEN 2°C - 30°C (36°F - 86°F). Do not freeze.

Approved by FDA under ANADA # 200-489.

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

2. Odensvik K. Pharmacokinetics of flunixin and its effect on prostaglandin $F_{2\alpha}$ metabolite concentrations after oral and intravenous administration in heifers. *J Vet Pharmacol Ther*. 1995; 18:254-259.

Manufactured for:

Bimeda, Inc.

Le Seuer, MN 56058

www.bimeda.com

FLUNAZINE-S

flunixin meglumine injection, suspension

Product Information			
Product Type	PRESCRIPTION ANIMAL DRUG	**Item Code (Source)**	NDC:61133-6015
Route of Administration	INTRAMUSCULAR		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**

Flunixin Meglumine (UNII: 8Y3JK0JW3U) (Flunixin - UNII:356IB1O400)	Flunixin Meglumine	50 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
edetate disodium (UNII: 7FLD91C86K)	0.1 mg in 1 mL
sodium formaldehyde sulfoxylate (UNII: X4ZGP7K714)	2.2 mg in 1 mL
diethanolamine (UNII: AZE05TDV2V)	4.0 mg in 1 mL
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	207.2 mg in 1 mL
PHENOL (UNII: 339NCG44TV)	5.0 mg in 1 mL
water (UNII: 059QF0KO0R)	
HYDROCHLORIC ACID (UNII: QTT17582CB)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:61133-6015-2	100 mL in 1 VIAL, MULTI-DOSE		
2	NDC:61133-6015-3	250 mL in 1 VIAL, MULTI-DOSE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANADA	ANADA200489	03/01/2010	

Labeler - Bimeda, Inc. (060492923)

Registrant - Bimeda, Inc. (060492923)

Establishment

Name	Address	ID/FEI	Business Operations
Bimeda-MTC Animal Health		256232216	manufacture

Revised: 4/2024 Bimeda, Inc.