

FLUNIXIN-S- flunixin meglumine injection, solution
Norbrook Laboratories Limited

Flunixin Injection -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 Flunixin Injection -S (flunixin meglumine injection) contains 50 mg flunixin (equivalent to 83 mg flunixin meglumine), 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.

CLINICAL 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. Flunixin is known to persist in inflammatory tissues¹ and is associated with anti-inflammatory properties which extend well beyond the period associated with detectable plasma drug concentrations². 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 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-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

Flunixin Injection -S (flunixin meglumine injection) is indicated for the control of pyrexia associated with swine respiratory disease.

DOSE 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 flunixin meglumine injection have not been investigated in this class of swine.

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ADVERSE REACTIONS

Flunixin was mildly irritating at the injection sites. No other flunixin-related changes (adverse reactions) were noted in swine administered a 1 x (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 Norbrook at 1-866-591-5777. 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 normal microscopic architecture.

HOW SUPPLIED

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

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

REFERENCES

1. Lees P, Higgins AJ. Flunixin inhibits prostaglandin E₂ production in equine inflammation. *Res Vet Sci.* 1984; 37:347-349.
2. Odensvik K. Pharmacokinetics of flunixin and its effect on prostaglandin F_{2α} metabolite concentrations after oral and intravenous administration in heifers. *J Vet Pharmacol Ther.* 1995; 18:254-259.

Restricted Drug - California. Use Only as Directed.

Approved by FDA under ANADA # 200-476

Made in the UK.

Manufactured by:

Norbrook Laboratories Limited
Newry, Co. Down, BT35 6PU
Northern Ireland.

Dec 2019

010670I02

Norbrook®

Principal Display Panel - 250 mL Carton Label

NDC 55529-030-04

Sterile

Multiple-Dose Vial

50 mg/mL

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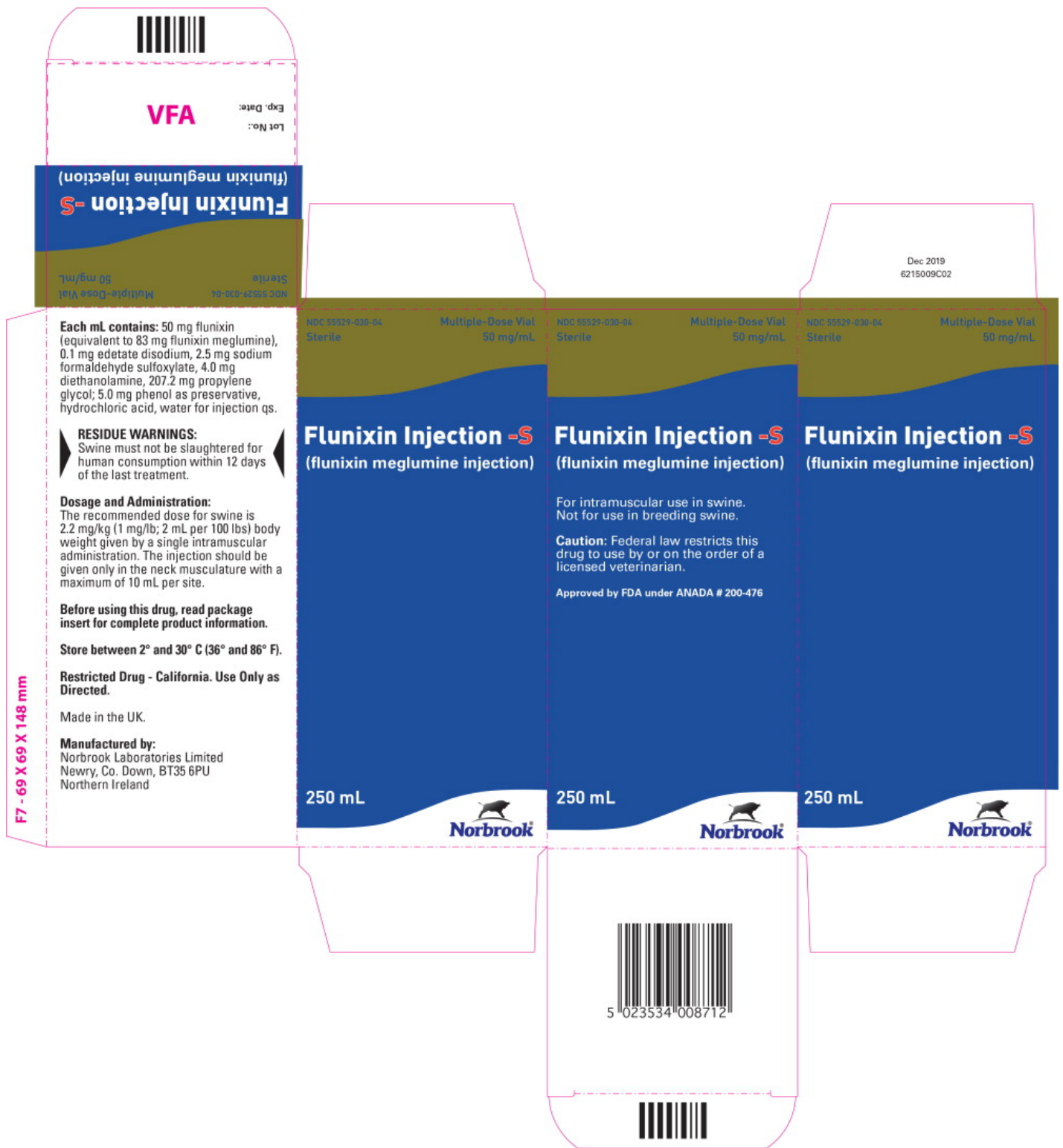
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Before using this drug, read package insert for complete product information.

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Lot No.:
Exp. Date:
Dec 2019
009670L02



FLUNIXIN-S

flunixin meglumine injection, solution

Product Information

Product Type	PRESCRIPTION ANIMAL DRUG	Item Code (Source)	NDC:55529-030
Route of Administration	INTRAMUSCULAR		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
flunixin meglumine (UNII: 8Y3JK0JWB3U) (flunixin - UNII:3561B1O400)	flunixin	50 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
sodium formaldehyde sulfoxylate (UNII: X4ZGP7K714)	2.5 mg in 1 mL
edetate disodium (UNII: 7FLD91C86K)	0.1 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
hydrochloric acid (UNII: QTT17582CB)	
water (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55529-030-02	1 in 1 CARTON		
1		100 mL in 1 VIAL, GLASS		
2	NDC:55529-030-04	1 in 1 CARTON		
2		250 mL in 1 VIAL, GLASS		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANADA	ANADA200476	10/05/2009	

Labeler - Norbrook Laboratories Limited (214580029)

Establishment

Name	Address	ID/FEI	Business Operations
Norbrook Laboratories Limited		211218325	ANALYSIS, LABEL, MANUFACTURE, PACK

Establishment

Name	Address	ID/FEI	Business Operations
ISP Chemicals LLC		078413681	API MANUFACTURE

Revised: 3/2022

Norbrook Laboratories Limited