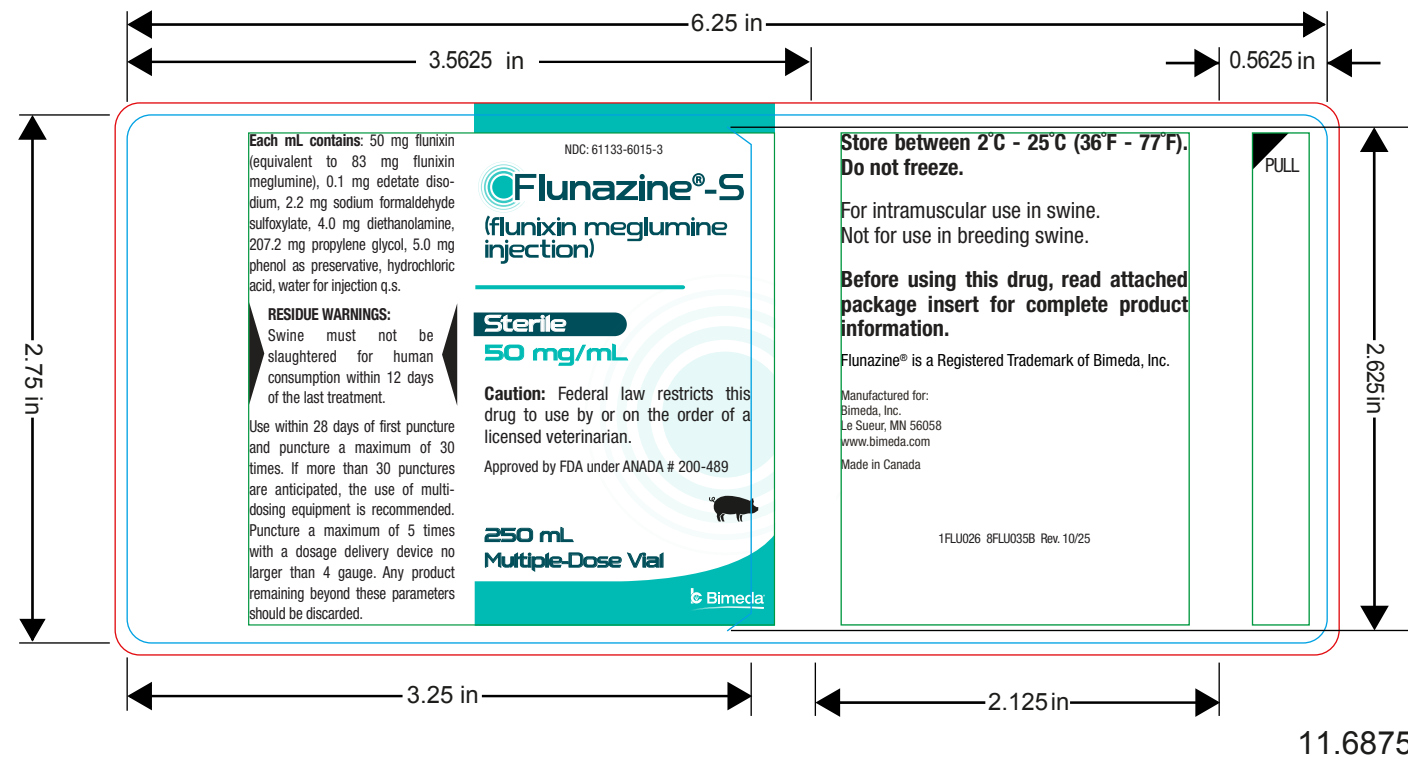


ARTWORK/PACKAGING/PRODUCTION	
File Name:	8FLU035A_FlunazineS_250mL.ai
Artwork Date:	September 30, 2025 (Version) v.1 (REV) 10/25
Item Size:	2.75" (h) x 6.25" (w)
Dieline:	Lofton - 250 mL 6 panel
CMYK	Scale: 100%
CMYK + SPOT	Label (✓) Carton () Insert ()
SPOT COLORS (Pantone)	Content Smallest Font: 7 pt
PMS (Black 100%)	Registration Smallest Font: 5 pt
PMS 3165 c	Verified Dieline (Y) (N)
PMS 3262 c	Verified Batch Area (Y) (N)
PMS	Mock-Up Approved (Y) (N)
ONSET	Unwind # (1) (2) (3) (4)
BLEED LIMIT	
ONSET PLACEMENT TOLERANCE	
NO VARNISH	



- = ONSET
- = BLEED LIMIT
- = DIELINE
- = COPY LIMIT
- = ONSET PLACEMENT TOLERANCE

2.75" x 2.125" Onset Area
 1.8125" x 2.5625" Onset Copy Area
 2.75" x 2.375" Onset Placement Tolerance

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. CONTACT INFORMATION 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 http://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 Flunazine-S (flunixin meglumine injection), 50 mg/mL, is available in 100 mL and 250 mL multi-dose vials.	Store between 2°C - 25°C (36°F - 77°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. <i>Res Vet Sci.</i> 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. <i>J Vet Pharmacol Ther.</i> 1995; 18:254-259. 	Store between 2°C - 25°C (36°F - 77°F). Do not freeze. For intramuscular use in swine. Not for use in breeding swine. Before using this drug, read attached package insert for complete product information. Flunazine® is a Registered Trademark of Bimeda, Inc. Manufactured for: Bimeda, Inc. Le Sueur, MN 56058 www.bimeda.com Made in Canada
1.9375"	1.9375"	1.875"	1.875"	1.9375"	2.125"

2.75"

 (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 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 (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 ₍₀₋₁₀₀₎ 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.	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. Use within 28 days of first puncture and puncture a maximum of 30 times. If more than 30 punctures are anticipated, the use of multi-dosing equipment is recommended. Puncture a maximum of 5 times with a dosage delivery device no larger than 4 gauge. Any product remaining beyond these parameters should be discarded.	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.
2.125"	1.9375"	1.875"	1.875"	1.9375"	1.9375"

2.75"