#### BANAMINE- flunixin meglumine paste Merck Sharp & Dohme Corp.

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Banamine® (flunixin meglumine paste)

Paste -1500 mg flunixin/syringe Veterinary

For Oral Use in Horses Only

### PRODUCT INFORMATION

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

**DESCRIPTION** Each 30-g syringe of BANAMINE Paste contains flunixin meglumine equivalent to 1500 mg flunixin.

**INDICATIONS BANAMINE** Paste is recommended for the alleviation of inflammation and pain associated with musculoskeletal disorders in the horse.

**ACTIVITY** Flunixin meglumine is a potent, nonnarcotic, 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. Oral studies in the horse show onset of flunixin activity occurs within 2 hours of administration. Peak response occurs between 12 and 16 hours and duration of activity is 24 to 36 hours.

**CONTRAINDICATIONS** There are no known contraindications to this drug when used as directed.

**WARNING** Do not use in horses intended for human consumption.

**PRECAUTIONS** The effect of BANAMINE Paste on pregnancy has not been determined. Studies to date show there is no detrimental effect on stallion spermatogenesis with or following the recommended dose of BANAMINE Paste.

**SIDE EFFECTS** During field studies with BANAMINE Paste, no significant side effects were reported.

**DOSAGE AND ADMINISTRATION** The recommended dose of flunixin is 0.5 mg per lb of body weight once daily. The BANAMINE Paste syringe, calibrated in twelve 250-lb weight increments, delivers 125 mg of flunixin for each 250 lbs (see dosage table). One syringe will treat a 1000-lb horse once daily for 3 days, or three 1000-lb horses one time.

# DOSAGE TABLE

	BANAMINE			
	Horse Weight	Paste	Mg Flunixin	
Syringe Mark <sup>*</sup>	(lbs)	Delivered (g)	Delivered	

0	—	—	—
250	250	2.5	125
500	500	5.0	250
750	750	7.5	375
1000	1000	10.0	500
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\* Use dial edge nearest syringe barrel to mark dose.

The paste is orally administered by inserting the nozzle of the syringe through the interdental space, and depositing the required amount of paste on the back of the tongue by depressing the plunger.

Treatment may be given initially by intravenous or intramuscular injection of BANAMINE Solution, followed by BANAMINE Granules or BANAMINE Paste on Days 2 to 5. BANAMINE treatment should not exceed 5 consecutive days.

**TOXICITY** No toxic effects were observed in rats given oral flunixin 2 mg/kg per day for 42 days. Higher doses produced ulceration of the gastrointestinal tract. The emetic dose in dogs is between 150 and 250 mg/kg. Flunixin was well tolerated in monkeys dosed daily with 4 mg/kg for 56 days. No adverse effects occurred in horses dosed orally with 1.0 or 1.5 mg/lb for fifteen consecutive days.

**HOW SUPPLIED** BANAMINE Paste, 1500 mg is available in a single 30-g syringe.

## Store below 25°C (77°F). Do not Freeze.

For patent information: <u>http://www.merck.com/product/patent/home.html</u>

## PRINCIPAL DISPLAY PANEL - 1500 mg Syringe Label

Syringe contains flunixin meglumine equivalent to

1500 mg

FLUNIXIN Net Wt 30 g

NDC 0061-0214-02

Banamine<sup>®</sup> (flunixin meglumine paste) Paste

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MERCK Animal Health



BANAMINE								
flunixin meglumine pa	aste							
Product Informat	tion							
Product Type		PRESCRIPTION ANIMA	L DRUG	ltem	Code (So	urce)	NDC:0061	-0214
Route of Administra	tion	ORAL						
A	/ <b>A</b> - <b>L</b>	<b>N 4</b> - <b>1</b> - <b>1</b>						
Active Ingredient/Active Moiety								
	Ingred	ient Name			Basis of S	Strength	Strer	ngth
FLUNIXIN MEGLUMINE	(UNII: 8Y3)	KOJW3U) (FLUNIXIN - U	NII:356IB1040	00)	FLUNIXIN		1500 mg	in 30 g
Packaging								
# Item Code	Packa	ge Description	Marketin	g Sta	art Date	Market	ing End	Date
<b>1</b> NDC:0061-0214-02	30 g in 1 s	SYRINGE						

Marketing Information					
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date		
NADA	NADA137409	11/11/2011			

Labeler - Merck Sharp & Dohme Corp. (001317601)

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Merck Sharp & Dohme Corp.