BANAMINE- flunixin meglumine paste Merck Sharp & Dohme Corp.

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 antiinflammatory 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.

	BANAMINE					
Syringe Mark [*]	Horse Weight (lbs)	Paste Delivered (g)	Mg Flunixin Delivered			
0	_	_				
250	250	2.5	125			
500	500	5.0	250			
750	750	7.5	375			
1000	1000	10.0	500			

DOSAGE TABLE

* 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[®] (flunixin meglumine paste) Paste

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MERCK Animal Health



BANAMINE

flunixin meglumine paste					
Product Information					
Product T ype	PRESCRIPTION ANIMAL DRUG	Ite m	Code (Source)	NDC:0	061-0214
Route of Administration	ORAL				
Active Ingradient/Active Mai	. .				
Active Ingredient/Active Moie	ety				
Ingredient Name		Basis of Strength		ı 1	Strength
Flunixin Meglumine (UNII: 8 Y3JK0 JW	3U) (Flunixin - UNII:356IB1O400)		Flunixin	1500	0 mg in 1 g
Inactive Ingredients					
macuve mgreatents	The same diama and all successions			6.4	
	Ingredient Name			Stre	ength
Starch, Corn (UNII: O8232NY3SJ)					
Propylene Glycol (UNII: 6DC9Q167V3)				
Carboxymethylcellulose (UNII: 05JZI7	B19X)				
Water (UNII: 059QF0KO0R)					

Packaging									
#	Item Code	Package Description	Marketing Start Date		Mark	Marketing End Date			
1 NDC	2:0061-0214-02	30 g in 1 SYRINGE							
Marketing Information									
Mar	keting Inform	nation							
	0	nation Application Number or Monogra	aph Citation	Marketing Start	Date N	larketing End Date			
	eting Category		aph Citation	Marketing Start	Date M	larketing End Date			

Labeler - Merck Sharp & Dohme Corp. (001317601)

Revised: 9/2019

Merck Sharp & Dohme Corp.