

PREVAIL- flunixin meglumine paste MWI

Prevail® (flunixin meglumine paste) Equine Paste

Apple Flavored

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

DESCRIPTION: Each 30-g syringe of Flunazine Equine Paste contains flunixin meglumine equivalent to 1500 mg flunixin.

INDICATIONS: Prevail Equine 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 1 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.

For oral use in horses only

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 flunixin meglumine 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 flunixin meglumine.

SIDE EFFECTS: During field studies with flunixin meglumine, no significant side effects were reported.

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-VET or online at www.fda.gov/reportanimaladuration of activity is 24 to 36 hours.

DOSAGE AND ADMINISTRATION: The recommended dose of flunixin is 0.5 mg per lb of body weight once daily. The Prevail Equine 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

Syringe Mark*	Horse Weight (lbs)	Prevail™ Equine Paste Delevered (g)	mg flunixin Delivered
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250	250	2.5	125
500	500	5.0	250
750	750	7.5	375
1000	1000	10.0	500

* 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 of Prevail™ Injectable Solution, followed by Prevail™ Equine Paste on Days 2 to 5. Flunixin meglumine treatment should not exceed 5 consecutive days.

TOXICITY: No toxic effects were observed in rats given oral flunixin meglumine 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 5 consecutive days.

Store at 20°C - 25°C (68°F - 77°F); excursions permitted between 15°C - 30°C (between 59°F - 86°F)

See product information sheet for additional information.

Approved by FDA under ANADA # 200-581



PREVAIL

flunixin meglumine paste

Product Information

Product Type	PRESCRIPTION ANIMAL DRUG	Item Code (Source)	NDC:13985-707
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
FLUNIXIN MEGLUMINE (UNII: 8Y3JK0JW3U) (FLUNIXIN - UNII:356IB1O400)	FLUNIXIN MEGLUMINE	1500 mg in 30 g

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13985-707-15	30 g in 1 SYRINGE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANADA	ANADA200581	02/26/2015	

Labeler - MWI (019926120)

Registrant - Bimeda Inc. (060492923)

Establishment

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

Revised: 4/2024

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