

PHENYLBUTE - phenylbutazone paste
Clipper Distributing Company LLC

Phenylbutazone Paste

DESCRIPTION: Phenylbutazone Paste is a synthetic, non-hormonal anti-inflammatory, antipyretic compound useful in the management of inflammatory conditions. The apparent analgesic effect is probably related mainly to the compound's anti-inflammatory properties.

Chemically, Phenylbutazone Paste is 4-butyl-1,2-diphenyl-3,5-pyrazolidinedione. It is a pyrazolone derivative, entirely unrelated to the steroid hormones.

INDICATIONS: For the relief of inflammatory conditions associated with the musculoskeletal system in horses.

CONTRAINDICATIONS: Use with caution in patients who have a history of drug allergy.

WARNING: Not for use in horses intended for food.

PRECAUTIONS: Stop medication at the first sign of gastrointestinal upset, jaundice or blood dyscrasia. Authenticated cases of agranulocytosis associated with the drug have occurred in man; fatal reactions, although rare, have been reported in dogs after long-term therapy. To guard against this possibility, conduct routine blood counts at weekly intervals during the early phase of therapy and at intervals of two weeks thereafter. Any significant fall in the total white blood cell count, relative decrease in granulocytes, or black or tarry stools should be regarded as a signal for immediate cessation of therapy and institution of appropriate counter-measures. In the treatment of inflammatory conditions associated with infections, specific anti-infective therapy is required.

CAUTION: Federal (U.S.A.) law restricts this drug to use by or on the order of a licensed veterinarian.

ADMINISTRATION AND DOSAGE: Orally - 1 to 2 g of phenylbutazone per 500 lb. of body weight daily. Do not exceed 4 g daily.

Guidelines to Successful Therapy: Use a relatively high dose for the first 48 hours, then reduce gradually to a maintenance dose. Maintain lowest dose capable of producing desired clinical response. Response to Phenylbutazone Paste therapy is prompt, usually occurring within 24 hours. If no significant clinical effect is evident after five days, re-evaluate diagnosis and therapeutic approach.

When administering Phenylbutazone Paste, the oral cavity should be empty. Deposit paste on back of tongue by depressing plunger that has been previously set to deliver the correct dose. Many chronic conditions will respond to Phenylbutazone Paste therapy, but discontinuance of treatment may result in recurrence of symptoms.

STORAGE: Store at 15°C - 30°C (59°-86°F)

KEEP OUT OF REACH OF CHILDREN

HOW SUPPLIED: Syringes containing 20 g of Phenylbutazone

Phenylbutazone Paste for Horses

NDC 57319-602-73

ANADA #200-266, Approved by FDA

Phenylbutate[®] Paste

Phenylbutazone Paste for Horses

FOR VETERINARY USE ONLY

Each syringe contains 20 g phenylbutazone.

Each 3 mL marking on the plunger contains: Phenylbutazone....1 g.

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See package insert for additional information.

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Net Volume: 60 mL

**PHOENIX**

Trademarks are property
of Clipper Distributing Company, LLC

Manufactured For:
Clipper Distributing Company LLC
St. Joseph, MO USA

Rev. 07/12

Lot No. / Exp. Date

ANADA 200-266, Approved by the FDA.

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for Horses

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Manufactured by:
Med-Pharmex, Inc.
Pomona, CA 91767-1861
rev 06/12

PHENYLBUTE

phenylbutazone paste

Product Information

Product Type	PRESCRIPTION ANIMAL DRUG	Item Code (Source)	NDC:57319-602
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
Phenylbutazone (UNII: GN5P7K3T8 S) (Phenylbutazone - UNII:GN5P7K3T8 S)	Phenylbutazone	35.1 g in 100 g

Product Characteristics

Color		Score	
Shape		Size	
Flavor	APPLE (Apple Flavor)	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:57319-602-73	60 g in 1 SYRINGE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANADA	ANADA200266	08/31/2012	

Labeler - Clipper Distributing Company LLC (150711039)**Registrant** - Med-Pharmex, Inc (025353699)**Establishment**

Name	Address	ID/FEI	Business Operations
Med-Pharmex, Inc		025353699	manufacture

Revised: 9/2012

Clipper Distributing Company LLC