VETRIBUTE - phenylbutazone paste MWI

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 he compound's anti-inflammatory properties.

Chemically, Phenylbtazone 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 13985-544-01

✓verone® VetriBute™

Paste

Phenylbutazone Paste for Horses

For veterinary use only. Keep out of reach of children.

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

ANADA 200-266, Approved by FDA

Each syringe contains 20 g phenylbutazone. Each 3 mL marking on the plunger contains Phenylbutazone: 1 g.

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DOSAGE: 1 to 2 g of phenylbutazone per 500 lb body weight, but not to exceed 4 g daily. Oral cavity should be empty. Deposit paste on back of tongue by depressing plunger that has been previously set to deliver the correct dose.

WARNING: Not for use in horses intended for food.

See package insert for additional information. Store at 15°-30°C (59°-86°F).

Distributed by: MWI Boise, ID 83705 (888) 694-8381 www.vetone.net





60 mL



Net Contents: 60 mL .

PHENYLBUTAZONE PASTE

for Horses

For Veterinary Use Only

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INDICATIONS: For the relief of inflammatory conditions associated with the musculoskeletal systems 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.

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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°-30°C (59°-86°F).

HOW SUPPLIED: Syringes containing 20 g of Phenylbutazone.

KEEP OUT OF REACH OF CHILDREN

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

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

VETRIBUTE							
phenylbutazone paste							
Product Information							
Product T ype	PRESCRIPTION ANIMAL DRUG	Item Code (Source)	NDC:13985-544				
Route of Administration	ORAL						

Active Ingredient/Active Moiety							
Ingredient Name			Basis o	f Strength	Streng	th	
Phenylbutazone (UNII: GN5P7K3T8S) (Phenylbutazone - UNII:GN5P7K3T8S)			Phenylbut	Phenylbutazone 35.		0 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		e	
1 NDC:13985-544-01	60 g in 1 SYRINGE						
Marketing Information							
Marketing Category	Application Number or Monograph Citation M		Marketing Start Date M		keting End I	Date	
ANADA	NADA200266 08		08/31/2012				

Labeler - MWI (019926120)

Registrant - Med-Pharmex, Inc (025353699)

Establishment

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

Revised: 9/2012

MWI