EQUI-BUTE - phenylbutazone paste Aspen Veterinary Resources Ltd

Phenylbutazone Paste

Description

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

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

Contraindications

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

Warning

WARNING: Not for use in horses intended for food.

Precautions

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

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

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

KEEP OUT OF REACH OF CHILDREN

How Supplied

HOW SUPPLIED: Syringes containing 20 g of Phenylbutazone

Phenylbutazone Paste for Horses

NDC 46066-089-60 ANADA 200-266 Approved by FDA

Equi-bute Paste

Phenylbutazone Paste for Horses

FOR VETERINARY USE ONLY



NET CONTENTS: 60 mL

For Animal Use Only Keep Out of Reach of Children

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INGREDIENTS:

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

KEEP OUT OF REACH OF CHILDREN.

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

Manufactured for: A156MP Rev. 6-12 Aspen Veterinary Resources,® Ltd. Liberty, MO 64068





Exp. Date

of No

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for Horses

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

EQUI-BUTE

phenylbutazone paste

Product Information			
Product Type	PRESCRIPTION ANIMAL DRUG	Item Code (Source)	NDC:46066-089
Route of Administration	ORAL		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
Phenylbutazone (UNII: GN5P7K3T8S) (Phenylbutazone - UNII:GN5P7K3T8S)	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
NDC:46066-089-60	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 - Aspen Veterinary Resources Ltd (627265361)

Registrant - Med-Pharmex, Inc (025353699)

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

Revised: 10/2012 Aspen Veterinary Resources Ltd