

BUTEQUINE- phenylbutazone paste
Vetoquinol USA, Inc.

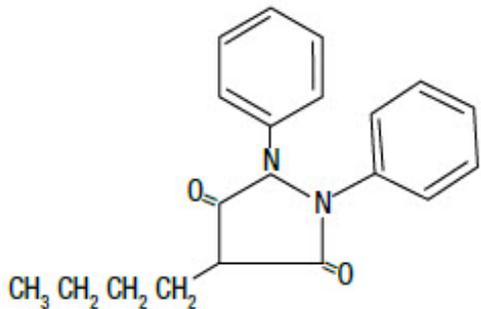
BUTEQUINE™ (phenylbutazone)
Paste for Horses

NDC 17030 100 60

Approved by FDA under ANADA # 200-266

For Veterinary Use Only

DESCRIPTION: Butequine™ 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 is 4-butyl-1, 2-diphenyl-3, 5-pyrazolidinedione. It is a pyrazalone derivative, entirely unrelated to the steroid hormones, and has the following structural formula:



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: Do not use in horses intended for human consumption.

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 the 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.

ADMINISTRATION AND DOSAGE: Orally - 1 to 2 g of phenylbutazone per 500 lb. (227 kg) of body weight daily. Do not exceed 4 g daily. 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.

Guidelines to Successful Therapy:

1. **Important - To avoid overdosing and to ensure the correct first dose, move ring on plunger to the appropriate dosage position before administration (see Figure 1). The edge of the ring closest to the syringe barrel should be aligned to the gram/dosage mark on the plunger.**
2. When administering Butequine™ paste the oral cavity should be empty. Set ring on plunger to deliver the appropriate dosage based on weight (see Figure 1). Deposit paste on the back of tongue by depressing plunger.



3. Use a relatively high dose for the first 48 hours (not to exceed 4 g daily), then reduce gradually to a maintenance dose. Maintain lowest dose capable of producing desired clinical response.
4. Response to Butequine™ paste therapy is prompt, usually occurring within 24 hours. If no significant clinical response is evident after 5 days, reevaluate diagnosis and therapeutic approach.
5. Many chronic conditions will respond to Butequine™ paste therapy, but discontinuance of treatment may result in recurrence of symptoms.

STORAGE: Store at 15°-25°C (59°-77°F).

HOW SUPPLIED: Syringes containing 20 g phenylbutazone.

KEEP OUT OF REACH OF CHILDREN

Keep Butequine™ in a secure location out of reach of dogs, cats, and other animals to prevent accidental ingestion or overdose.

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

CONTACT INFORMATION:

To report suspected adverse events, contact Vetoquinol USA, Inc. at 1-800-835-9496. For technical assistance or to obtain a copy of the Safety Data Sheet (SDS), contact Vetoquinol USA, Inc. at 1-800-267-5707. For additional information about adverse drug experience reporting for animal drugs, contact FDA at 1-888-FDAVETS or online at www.fda.gov/reportanimalae

Manufactured for:
Vetoquinol USA, Inc.
Ft. Worth, TX (USA) 76137
www.vetoquinolusa.com

439185
Rev 01/2023
Hold for Canada
Reference #####

PRINCIPAL DISPLAY PANEL - 60 mL Syringe Carton

FOR VETERINARY USE ONLY

Butequine™
(phenylbutazone)
Paste for Horses

NDC 17030 100 60

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vetoquinol

Each syringe contains 20 g phenylbutazone

Each 3 mL marking on the plunger contains: phenylbutazone: 1 g

Net Volume: 60 mL

<p>INDICATIONS: For the relief of inflammatory conditions associated with the musculoskeletal system in horses.</p> <p>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.</p> <p>WARNING: Do not use in horses intended for human consumption.</p>	<p>CAUTIONS: Federal (U.S.A.) law restricts this drug to use by or on the order of a licensed veterinarian. KEEP OUT OF REACH OF CHILDREN. Keep Butequine™ in a secure location out of reach of dogs, cats, and other animals to prevent accidental ingestion or overdose. See package insert for additional information. To report suspected adverse events, contact Vetoquinol USA, Inc. at 1-800-835-9496. For technical assistance or to obtain a copy of the Safety Data Sheet (SDS), contact Vetoquinol USA, Inc. at 1-800-267-5707. For additional information about adverse drug experience reporting for animal drugs, contact FDA at 1-888-FDAVETS or online at www.fda.gov/reportanimalae. Store at 15° – 25°C (59° – 77°F).</p>	<p> Manufactured for: Vetoquinol USA, Inc. Ft. Worth, TX (USA) 76137 1 (800) 267-5707 www.vetoquinolusa.com</p>	
<p>FOR VETERINARY USE ONLY</p>  <p>Butequine™ (phenylbutazone) Paste for Horses</p> <p>NDC 17030 100 60 Approved by FDA under ANADA # 200-266</p> <p></p> <p>Each syringe contains 20 g phenylbutazone Each 3 mL marking on the plunger contains: phenylbutazone: 1g Net Volume: 60 mL</p>	<p>INDICATIONS: For the relief of inflammatory conditions associated with the musculoskeletal system in horses.</p> <p>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.</p> <p>WARNING: Do not use in horses intended for human consumption.</p>	<p>CAUTIONS: Federal (U.S.A.) law restricts this drug to use by or on the order of a licensed veterinarian. KEEP OUT OF REACH OF CHILDREN. Keep Butequine™ in a secure location out of reach of dogs, cats, and other animals to prevent accidental ingestion or overdose. See package insert for additional information. To report suspected adverse events, contact Vetoquinol USA, Inc. at 1-800-835-9496. For technical assistance or to obtain a copy of the Safety Data Sheet (SDS), contact Vetoquinol USA, Inc. at 1-800-267-5707. For additional information about adverse drug experience reporting for animal drugs, contact FDA at 1-888-FDAVETS or online at www.fda.gov/reportanimalae. Store at 15° – 25°C (59° – 77°F).</p>	<p> Manufactured for: Vetoquinol USA, Inc. Ft. Worth, TX (USA) 76137 1 (800) 267-5707 www.vetoquinolusa.com</p>
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NO VARNISH

BUTEQUINE

phenylbutazone paste

Product Information

Product Type	PRESCRIPTION ANIMAL DRUG	Item Code (Source)	NDC:17030-100
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PHENYLBUTAZONE (UNII: GN5P7K3T8S) (PHENYLBUTAZONE - UNII:GN5P7K3T8S)	PHENYLBUTAZONE	1 g in 3 mL

Product Characteristics

Color		Score	
Shape		Size	
Flavor	APPLE	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:17030-100-60	1 in 1 CARTON		
1		60 mL in 1 SYRINGE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANADA	ANADA200266	01/15/2020	

Labeler - Vetoquinol USA, Inc. (106824209)

Establishment

Name	Address	ID/FEI	Business Operations
Nantong Jinghua Pharmaceutical Co., Ltd		421303119	API MANUFACTURE

Establishment

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

Establishment

Name	Address	ID/FEI	Business Operations
Vetoquinol N.-A. INC		202919940	ANALYSIS, API MANUFACTURE, LABEL, MANUFACTURE, PACK

