

**PHENYLBUTAZONE- phenylbutazone paste**  
**Covetrus North America**

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**Phenylbutazone**  
**Paste for horses**

NDC 11695-4858-1

ANADA 200-266, Approved by the FDA.

***For animal use only***

**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 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.

**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 the 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.

Manufactured by:  
Med-Pharmex, Inc.  
Pomona, CA 91767-1861

## **PRINCIPAL DISPLAY PANEL - 60 mL Syringe Label**

**Covetrus**

NDC #11695-4858-1

**Phenylbutazone  
Paste for horses**

**For animal use only**

**APPLE FLAVOR**

Each syringe contains 20 g phenylbutazone.

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

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

**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 the back of tongue by depressing plunger that has been previously set to deliver the correct dose.

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See package insert for additional information.

Store at 15°-30°C (59°-86°F).

ANADA #200-266, Approved by FDA

**Net Volume: 2.02 fl oz (60 mL)**

**Reorder #044015**

**Questions?**

(855) 724-3461

Distributed by:  
Covetrus North America  
Dublin, OH 43017

**covetrus.com**

AH-044015-L-01

REV:08/19

Lot #/Exp. Date:



NDC: 11695-4858-1

Reorder #044015

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Covetrus North America  
400 Metro Place North  
Dublin, OH 43017  
[covetrus.com](http://covetrus.com)

AH-044015-L-01  
REV: 0819

Lot # /  
Exp. Date:

**PHENYLBUTAZONE**

phenylbutazone paste

**Product Information**

<b>Product Type</b>	PREScription ANIMAL DRUG	<b>Item Code (Source)</b>	NDC:11695-4858
<b>Route of Administration</b>	ORAL		

**Active Ingredient/Active Moiety**

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
Phenylbutazone (UNII: GN5P7K3T8S) (Phenylbutazone - UNII:GN5P7K3T8S)	Phenylbutazone	35.1 g in 100 g

**Product Characteristics**

<b>Color</b>		<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	APPLE	<b>Imprint Code</b>	
<b>Contains</b>			

**Packaging**

#	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:11695-4858-1	60 g in 1 SYRINGE		

**Marketing Information**

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
ANADA	ANADA200266	10/24/2019	

**Labeler** - Covetrus North America (603750329)**Registrant** - Vetoquinol USA, Inc. (106824209)**Establishment**

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
Med-Pharmex, Inc.		025353699	MANUFACTURE

**Establishment**

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
SintenoVO SA DE CV		812039808	API MANUFACTURE