PHENYLBUTAZONE- phenylbutazone injection
MWI/VetOne

PHENYLBUTAZONE 20% INJECTION 200 mg/mL

For Horses Only

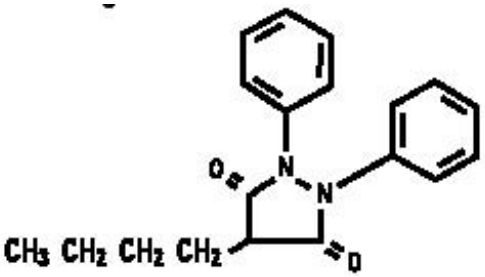
Not For Use in Humans

Keep Out of Reach of Children

CAUTION: Federal law restricts this drug to use by or on the order of a licensed veterinarian.

Approved by FDA under ANADA # 200-371

DESCRIPTION: Phenylbutazone 20% Injection (phenylbutazone) is a synthetic, nonhormonal 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 pyrazolon derivative entirely unrelated to the steroid hormones, and has the following structural formula:



BACKGROUND PHARMACOLOGY

Kuzell, [1, 2, 3] Payne,[4] Fleming,[5] and Denko[6] demonstrated clinical effectiveness of phenylbutazone in acute rheumatism, gout, gouty arthritis and various other rheumatoid disorders in man. Anti-rheumatic and anti-inflammatory activity has been well established by Fabre,[7] Domenjoz,[8] Wilhelmi,[9] and Yourish.[10] Lieberman [11] reported on the effective use of phenylbutazone in the treatment of painful conditions of the musculoskeletal system in dogs; including posterior paralysis associated with intervertebral disc syndrome, painful fractures, arthritis, and painful injuries to the limbs and joints. Joshua[12] observed objective improvement without toxicity following long-term therapy of two aged arthritic dogs. Ogilvie and Sutter[13] reported rapid response to phenylbutazone therapy in a review of 19 clinical cases including posterior paralysis, posterior weakness, arthritis, rheumatism, and other conditions associated with lameness and musculoskeletal weakness.

Camberos[14] reported favorable results with phenylbutazone following intermittent treatment of Thoroughbred horses for arthritis and chronic arthrosis (e.g., osteoarthritis of medial and distal bones of the hock, arthritis of stifle and hip, arthrosis of the spine, chronic hip pains, chronic pain in the trapezius muscles, and generalized arthritis). Results were less favorable in cases of traumatism, muscle rupture, strains

arthritis). Results were less favorable in cases of traumatism, muscle rupture, strains and inflammations of the third phalanx. Sutter[15] reported favorable response in chronic equine arthritis, fair results in a severely bruised mare, and poor results in two cases where the condition was limited to the third phalanx

INDICATIONS

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

CONTRAINDICATIONS

Treated animals should not be slaughtered for food purposes. Parenteral injections should be made intravenously only; do not inject subcutaneously or intramuscularly. Use with caution in patients who have a history of drug allergy.

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. To guard against this possibility, conduct routine blood counts at weekly intervals of two weeks thereafter. Any significant fall in th total white 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.

Store in refrigerator between 2º - 8ºC (36º - 46ºF)

DOSAGE AND ADMINISTRATION

HORSES

INTRAVENOUSLY: 1 to 2 g per 1,000 lbs of body weight (5 to 10 mL/1,000 lbs) daily. Injection should be given slowly and with care. Limit intravenous administration to a maximum of 5 successive days, which may be followed by oral phenylbutazone dosage forms.

GUIDELINES TO SUCCESSFUL THERAPY

1. 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.
2. Response to phenylbutazone therapy is prompt, usually occurring within 24 hours. If no significant clinical response is evident after 5 days, reevaluate diagnosis and therapeutic approach.
3. In animals, phenylbutazone is largely metabolized in 8 hours. It is recommended that a third of the daily dose be administered at 8 hour intervals. Reduce dosage as symptoms regress. In some cases, treatment may be given only when symptoms appear with no need for continuous medication. If long-term therapy is planned, oral administration is suggested.
4. Many chronic conditions will respond to phenylbutazone therapy, but discontinuance of treatment may result in recurrence of symptoms.

HOW SUPPLIED

INJECTABLE: **For Horses only: 100 mL vials, 200 mg/mL (1 g/5 mL)** Each mL contains 200 mg of phenylbutazone, 10.45 mg of benzyl alcohol as preservative, sodium hydroxide to adjust pH to 9.5 to 10.0, and water for injection, Q.S.

CONTACT INFORMATION

CONTACT INFORMATION: To report suspected adverse events, for technical assistance or to obtain a copy of the Safety Data sheet (SDS), contact Sparhawk Laboratories Inc at 1-800-255-6388 or 1-913-888-7500. For additional information about adverse drug experience reporting for animal drugs, contact FDA at 1-888-FDA-VETS or http://www.fda.gov/reportanimalae

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5. Fleming, J. and @Will, G.: Ann Rheumat. Dis. 12:95, 1953.
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7. Fabre, J. and Berger, A.: Semaine Hop. (Paris) 31:87, 1955.
8. Domenjoz, R., Theobald, W. and Morsdorf, K., Arzneimittel-Forsch. 5:488, 1955.
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10. Yoursh, N., Paton, B., Brodie, B.B and Burns, J.J.: AMA Arch. Ophth. 53:264, 1955.
11. Lieberman, L.L.: Jour. Amer. Vet. Med. Assoc. 125:128, 1954.
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13. Ogilvie, F.B. and Sutter, M.D.: Vet. Med 52:492-494, 1957.
14. Camberos, H.R.: Rev. Med. Vet. (Buenos Aires); 38:9, 1956.
15. Sutter, M.F.: Vet Med. 53:83 (Feb.), 1958.

INDICATIONS

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

Intravenous dosage (not subcutaneous or intramuscular use):

Horses: 1 to 2 g per 1,000 lb body weight (5 to 10 mL/1,000 lb) daily.

Not for use in Horses intended for food.

See package outsert for additional information.

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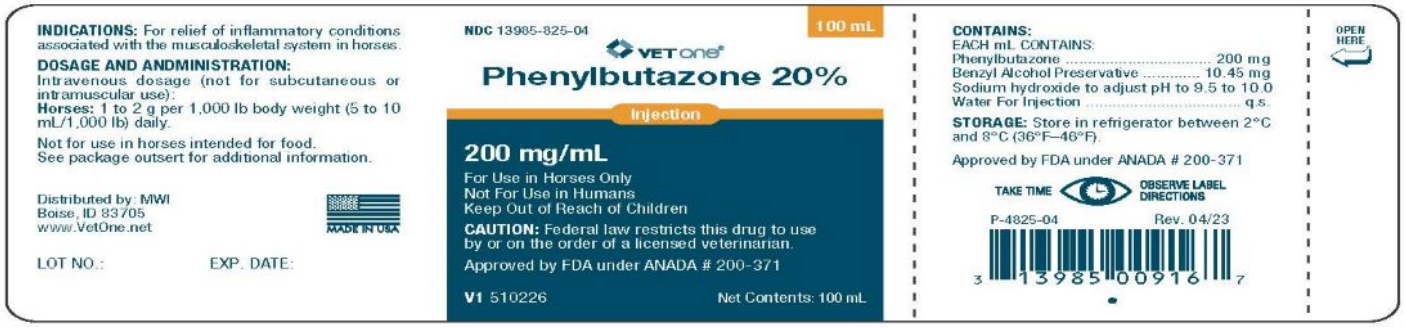
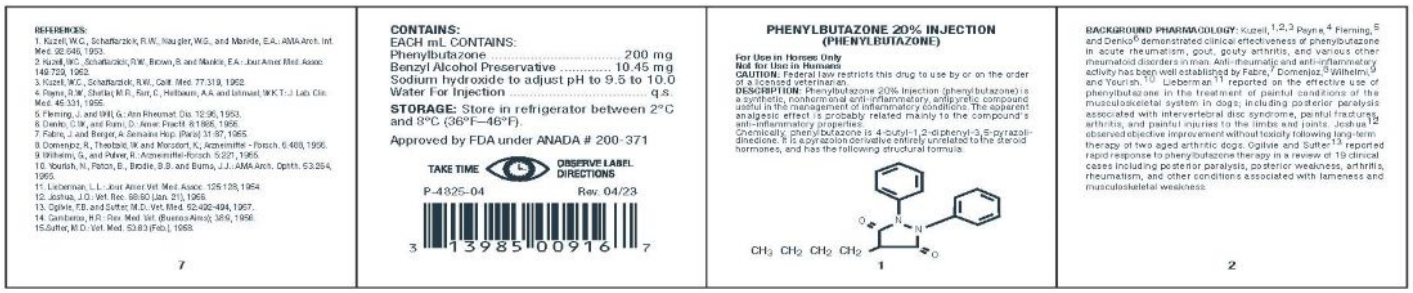
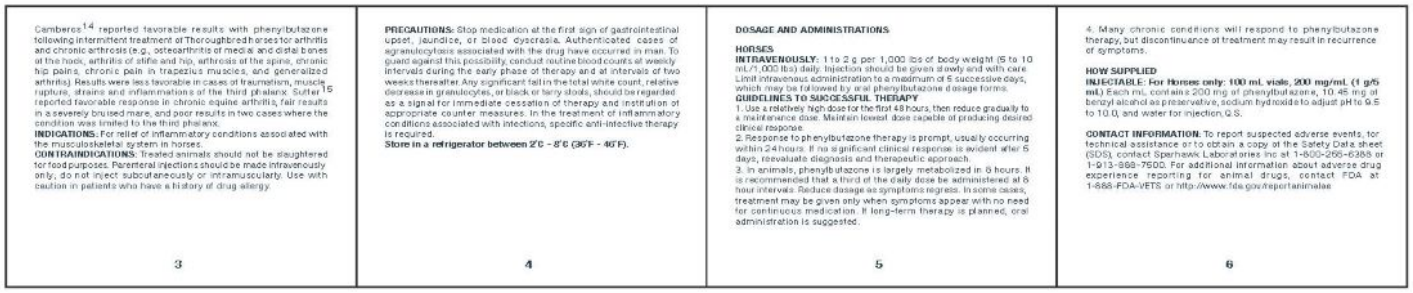
Each mL contains: Phenylbutazone ..... 200 mg
Benzyl Alcohol Preservative .....10.45 mg
Sodium hydroxide to adjust pH to 9.5 to 10.0
Water For Injection .....q.s.







PHENYLBUTAZONE

phenylbutazone injection

Product Information

Product Type	PRESCRIPTION ANIMAL DRUG	**Item Code (Source)**	NDC:13985-825
Route of Administration	INTRAVENOUS		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PHENYLBUTAZONE (UNII: GN5P7K3T8S) (PHENYLBUTAZONE - UNII:GN5P7K3T8S)	PHENYLBUTAZONE	200 mg in 1 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:13985-825-04	100 mL in 1 VIAL		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANADA	ANADA200371	11/16/2011	

Labeler - MWI/VetOne (019926120)

Revised: 7/2023 MWI/VetOne