PHENYLBUTAZONE - phenylbutazone injection Aspen Veterinary Resources, Ltd.

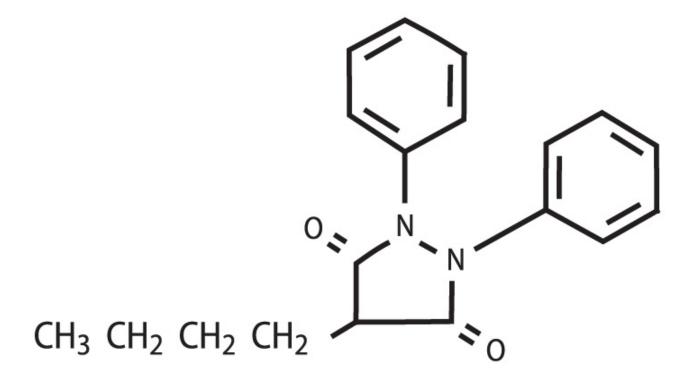
Phenylbutazone 20% Injection 200 mg/mL

KEEP OUT OF REACH OF CHILDREN

FOR HORSES ONLY

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

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 Denko⁶ 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 Yourish¹⁰ Lieberman¹¹ 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. Joshua¹² observed objective improvement without toxicity following long-term therapy of two aged arthritic dogs. Ogilvie and Sutter¹³ 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.

Camberos¹⁴ 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, achronic pain in the trapezius muscles, and generalized arthritis). Results were less favorable in cases of traumatism, muscle rupture, strains and inflammations of the third phalanx. Sutter¹⁵ 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 2°-8°C (36° - 46°F)

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 contians 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.

- 1. Kuzell, W.C., Schaffarzick, R.W., Naugler, W.G., and Mankle, E.A.: AMA Arch. Int. Med. 92:646, 1953.
- 2. Kuzell, W.C., Schaffarzick, R.W., Brown, B. and Mankle, E.A.: Jour. Amer. Med. Assoc. 149:729, 1952.
- 3. Kuzell, W.C., Schaffarzick, R.W., Calif. Med. 777:319, 1952.
- 4. Payne, R.W., Shetlar, M.R., Farr, C., Hellbaum, A.A., and Ishmael, W.K.T.: J.Lab. Clin. Med. 45:331, 1955.
- 5. Fleming, J. and @Will, G.: Ann Rheumat. Dis. 12:95, 1953.
- 6. Denko, C.W., and Rumi, D.: Amer. Practit. 6:1865, 1955.
- 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.
- 9 Wilhelmi, G., and Pulver, R.: Arzneimittel-Forsch. 5:221, 1955.
- 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.
- 12. Joshua, J.O.: Vet. Rec. 68:60 (Jan 21), 1956.
- 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 for 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.



... 200 ma Benzyl Alcohol Sodium hydroxide to adjust pH to 9.5 to 10.0 Water For Injection ..

Store in a refrigerator between 2°C - 8°C (36°F - 46°F),

TAKE TIME OBSERVE LABEL DIRECTIONS

LOT NO: EXP. DATE:



KEEP OUT OF REACH OF CHILDREN FOR HORSES ONLY

CAUTION: Federal law restricts this drug to use by or on the order of a licensed veterinarian. Approved by FDA under ANADA # 200-371

NET CONTENTS: 3.38 fl oz (100 mL)

INDICATIONS: For relief of inflammatory conditions associated with the musculoskeletal system in horses. Intravenous dosage (not for 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.

Manufactured for: Aspen Veterinary Resources*, Ltd. Liberty, MO 64068

Printed in U.S.A. Mfd. in U.S.A.



- REFERENCES:
 1 Kusel, W.C., Art-Monck, R.W., Naugler, W.G., and Meritle, E.A.:
 1 Kusel, W.C., Schaffrack, R.W., Brown, B. and Meritle, E.A. Jour.
 Amer. Med. Assoc. 149729, 1923.
 2 Kusel, W.C., Schaffrack, R.W., Calif Med. 77319, 1922.
 3 Kusel, W.C., Schaffrack, R.W., Calif Med. 77319, 1922.
 3 Kusel, W.C., Schaffrack, R.W., Calif Med. 77319, 1922.
 3 Kusel, W.C., Schaffrack, R.W., Calif Med. 77319, 1922.
 5 Flamming, J. and Will, G. Ann Rhaumat Chot. 1298; 1933.
 5 Flamming, J. and Will, G. Ann Rhaumat Chot. 1298; 1933.
 5 Flamming, J. and Will, G. Ann Rhaumat Chot. 1298; 1935.
 7 Fabric, J. and Burge, A. Semanne Hop, Gent 31:37, 1935.
 7 Fabric, J. and Rhum, D. Anno, Prost. 61:305.
 7 William H.G., and Pulme, R.-Arzmeinttell Forch, 3-388, 1935.
 9 William I.G., and Pulme, R.-Arzmeinttell Forch, 3-288, 1935.
 10 Novinity, N. Patrick, R. B. and Burns, J.J. AMA. Arch. Christopher, J. Patrick, R. B. and Burns, J.J. AMA. Arch. Christopher, M.C., Wer, Rec. dec. 3010, 21, 1958.
 13 Cophie, F.B. and Sustey, M.D. Vet Mied. 52:482–494, 1957.
 14 Commons, M.R. Rev. Med. Vet M. Blaeno, News, 3:83, 1956.
 15 Sustey, M.D. Vet Med. 3:283.1960, 1958.

INDICATIONS: For relief of inflammatory conditions associated with the musculoskeletal system in horses. Intravenous dosage (not for 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.

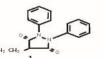
Manufactured for: Aspen Veterinary Resources*, Ltd. Liberty, MO 64068

Printed in U.S.A. Mfd. in U.S.A.

PHENYLBUTAZONE 20% INJECTION (PHENYLBUTAZONE)

For Horses Only

CAUTION: Federal law restricts this drug to use by or on the CAUTION Federal law restrict the drug to use by or our DESCRIPTION. Pearly buttone 200 linguish phanelbuttone) is a synthetic, non-horizontal arti-inflammatory, analyzed compound useful in the management of inflammatory compound useful in the management of inflammatory analyzed compound useful in the management of inflammatory incorporate and the compound a student flammatory properties. One micely phanelbuttone are described to the compound a student law section of the compound a student law section of the compound and the com



BACKGROUND PHARMACOLOGY: Kuzeli, 1.2.3 Payre, 4
Theming and Dentice demonstrated chinaci effectiveness of
various other meumatoid disorders in man. Artic-freements and
various other meumatoid disorders in man. Artic-freements and
various other meumatoid disorders in man. Artic-freements and
anti-inflammanoy activity has been well established by Fable;
Domen or, 5 Withinim, ⁹ and Yourich ¹⁰ Liberman ¹¹ reported
on the effective use of phyribydozone in the treatment of
pannts conditions of the impactional state in your man.
Pannts of the massacional state in your man of the pannts of the impact and joints. Joshua ¹² observed objective improvement
without tozony following long-freem therapy of two aged
arthritis dogs. Oglivis and State ¹⁸ reported rapid response to
including posterior pleasings observed weakens, atthritis,
rhaumassim, and other conditions associated with lamenass
and muscul dyselectal weakings.
Camberos ¹⁴ reported favorable results with pheryldutzoone

2

following intermittent treatment of Thoroughbred horses for arthrists and chronic serbicis (e.g., osecontimits of medial distal bones of the host, arthrists of stiffe and hijs, arthrists of the spine, chronic part in trapezus muscles, and generalized arthrists. Best trevel less fevorities in cases of traumation, muscle rigiditure, strains and inflammations of the source of the spine of the sp

REDUCE IN NOO Cases within one consistent was influenced used to support the property of the p

therapy is required.

Store in a refrigerator between 2°C-8°C (36°F-46°F).

HOISSS INTRAMENOUSLY: 1 to 2 g per 1,000 lbs of body weight (5 to 10 mG/1,000 lbs daly. Injection about be given slowly and with care. Limit intravenous administration to a maximum of 5 successive days, which may be followed by oral phery fluctazone

approach.

J. In animals, phenylbuszone is largely metabolized in 8 hours.
It is recommended that a third of the daily dose be administered at 6 hour intervals. Reduce dosage as symptoms ragress. In some cases, treatment may be given only when symptoms paper with no need for continuous medication.

PHENYLBUTAZONE

phenylbutazone injection

Product Information

Product Type PRESCRIPTION ANIMAL DRUG Item Code (Source) NDC:46066-282 **Route of Administration INTRAVENOUS**

Active Ingredient/Active Moiety

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

Packaging

Item Code Package Description Marketing Start Date Marketing End Date 1 NDC:46066-282-04 100 mL in 1 VIAL

Marketing Information

Marketing Application Number or Monograph Marketing Start **Marketing End**

Category	Citation	Date	Date
ANADA	ANADA200371	07/31/2007	

Labeler - Aspen Veterinary Resources, Ltd. (627265361)

Revised: 8/2023 Aspen Veterinary Resources, Ltd.