

PRIBUTAZONE - phenylbutazone tablet **FIRST PRIORITY INCORPORATED**

Pributazone® (phenylbutazone boluses)

For Oral Use in Horses Only.

Non-steroidal anti-inflammatory drug (NSAID)

CAUTION:

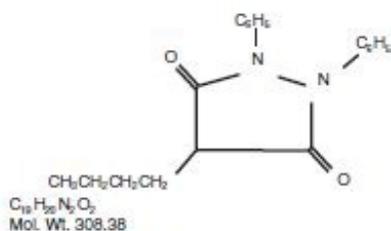
Federal law restricts this drug to use by closed when not in use. or on the order of a licensed veterinarian. Federal law prohibits the extra-label use of this product in female dairy cattle 20 months of age or older.

Not for Use in Humans • Keep Out of Reach of Children

Approved by FDA under ANADA # 200-433

DESCRIPTION & PHARMACOLOGY:

Phenylbutazone chemically is 4-butyl-1, 2- diphenyl-3, 5-pyrazolidinedione. It has the following structural formula:



Phenylbutazone was first synthesized in 1948 and introduced into human medicine in 1949, Kuzell^{1,2,3}, Payne⁴, Fleming⁵, and Denko⁶, demonstrated the clinical effectiveness of phenylbutazone in gout, gouty arthritis, acute arthritis, acute rheumatism and various other rheumatoid disorders in humans. Fabre⁷, Domenjoz⁸, Wilhelmi⁹, and Yourish¹⁰, have established the anti-rheumatic and anti-inflammatory activity of phenylbutazone. It is entirely unrelated to the steroid hormones.

Toxicity of phenylbutazone has been investigated in rats and mice¹¹, Ogilvie and Sutter¹², have also made a study on the chronic toxicity of phenylbutazone in dogs. They have shown that dogs receiving 10 mg. and 100 mg. per Kg. body weight, per day for 90 days, maintain good appetites, excrete normal feces, gain weight and maintain a normal blood picture. They also report no abnormal macroscopic or microscopic changes in sacrificed animals which could have been attributed to the drug.

Phenylbutazone has been used by Camberos¹³ in thoroughbred horses. Favorable results were reported in cases of traumatism, muscle rupture, strains and inflammations of the third phalanx. Results were not as favorable in the periodic treatment of osteoarthritis of medial and distal bones of the hock, arthritis of the stifle and hip, arthrosis of the trapezious muscles, and generalized arthritis. Sutter¹⁴ reported a favorable response in chronic equine arthritis of long duration, fair results in a severely bruised mare, and poor results in two cases where the condition was limited to the third

phalanx.

INDICATIONS:

Phenylbutazone is for the relief of inflammatory conditions associated with the musculoskeletal system in horses.

DOSAGE & ADMINISTRATION:

For horses only.

HORSES: Orally - 1 to 2 boluses per 500 lb. body weight. Do not exceed 4 grams daily. Reduce dosage as symptoms regress. Intermittent treatment given only when symptoms appear may be indicated.



INGREDIENTS:

Each bolus contains:

Phenylbutazone, U.S.P. 1 gram

Plus excipients.

CONTRAINDICATIONS:

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

PRECAUTION:

Concomitant use with other antiinflammatory drugs, such as NSAIDS or corticosteroids, should be avoided or closely monitored. In the treatment of inflammatory conditions associated with infections, specific anti-infective therapy should be used concurrently.

WARNING:

Not for use in humans. Keep out of reach of children.

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

Do not use in horses intended for human consumption.

CONTACT INFORMATION:

To report suspected adverse events, for technical assistance or to obtain a copy of the Safety Data Sheet (SDS), contact First Priority, Inc. at (800) 650-4899 or

www.prioritycare.com. 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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AVAILABILITY:

Available in 1 gm. boluses - 100 boluses per bottle.

Reorder No. OM036PC

STORAGE:

Store at controlled room temperature between 15°-30°C (59°-86°F). Keep container tightly closed when not in use.

Lot No. Exp. Date

REFERENCES

1. Kuzell, W.C., Schafferzick, R.W., Naugler, W.E., Gandia, G. and Mankle, E.A.: A.M.A. Arch. Inst. Med., 92; 646 (1953).
2. Kuzell, W.C., Schafferzick, R.W., Brown, B. and Mankle, E.A.: J.A.M.A. 149; 729 (1952).
3. Kuzell, W.C., and Schafferzick, R.W.: Calif. Med. 77; 319 (1952).
4. Payne, R.W., Shelter, M.R., Farr, C.H., Hellbaum, A.A. and Ishmall, W.K.: J. Lab. Clin. Med., 45; 331 (1955).
5. Fleming, J., and Will, G.: Ann. Rheumat. Dist., 12; 95 (1953).
6. Denko, C.W., and Rumi, D.: American Pract. 6; 1865 (1956).
7. Fabre, J., et al: Semain. Hop. (Paris) 31; 87 (1955).
8. Domenjoz, R., et al: Arzneimittel-Forsch, 5; 488 (1955).
9. Wilhelmi, G. and Pulver, R.: Arzneimittel- Forsch, 5; 221 (1955).
10. Yourish, W., Paton, B., Brodie, B., Burns, J.: A.M.A. Arch. Ophth., 53; 264 (1955).
11. Hazelton, L.W., Tusing, T.W. and Hollana, E.G.: J. Pharmacol. Exper. Ther., 109; 387 (1953).
12. Ogilvie, F.B. and Sutter, M.D.: Vet. Med. 52; 492-4 (1957).
13. Camberos, H.R.: Rev. Med. Vet. (Buenos Aires) 38; 9 (1956).
14. Sutter, M.D.: Vet. Med., 53; 83 (Feb. 1958).

Priority Care and Pributazone are registered trademarks of First Priority, Inc.

Rev. 10-22

Made in U.S.A.

Manufactured By: FIRST PRIORITY, INC., Elgin, IL 60123

NOT RETURNABLE IF OUTDATED

Net Contents: 100 Boluses

NDC# 58829-334-10

INDICATIONS: Phenylbutazone is for relief of inflammatory conditions associated with the musculoskeletal system in horses.

PRECAUTION: Concomitant use with other anti-inflammatory drugs, such as NSAIDs or corticosteroids, should be avoided or closely monitored. In the treatment of inflammatory conditions associated with infections, specific anti-infective therapy should be used concurrently.

DOSAGE AND ADMINISTRATION: Orally - 1 to 2 boluses per 500 lb. of body weight, but not to exceed 4 grams daily. Reduce dosage as symptoms regress.

See package insert for complete instructions.

TAKE TIME DESIGN LABEL DIRECTOR

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Lot No. _____ Exp. Date _____

NO VARNISH

Reorder No. 0M038PC

NOT RETURNABLE IF OUTDATED

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Manufactured By:
FIRST PRIORITY, INC., Elgin, IL 60123

www.prioritycare.com

PRIBUTAZONE

phenylbutazone tablet

Product Information

Product Type	PRESCRIPTION ANIMAL DRUG	Item Code (Source)	NDC:58829-334
Route of Administration	ORAL		

Active Ingredient/Active Moiety

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

Product Characteristics

Color	white (WHITE)	Score	2 pieces
Shape	ROUND (ROUND)	Size	18mm
Flavor		Imprint Code	BUTE;1GM
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58829-334-10	12 in 1 CASE		
1		100 in 1 BOTTLE, PLASTIC		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANADA	ANADA200433	09/21/2023	

Labeler - FIRST PRIORITY INCORPORATED (179925722)

Establishment

Name	Address	ID/FEI	Business Operations
FIRST PRIORITY INCORPORATED		179925722	manufacture

Revised: 11/2023

FIRST PRIORITY INCORPORATED