

PHENYLBUTAZONE- phenylbutazone powder
MWI/VetOne

VETONE Phenylbutazone Powder

For Oral Use In Horses Only

NON-STEROIDAL ANTI-INFLAMMATORY DRUG (NSAID)

CAUTION: Federal law restricts this drug to use by or on the order of a licensed veterinarian. Federal law prohibits the extralabel use of this product in female dairy cattle 20 months of age or older.

DESCRIPTION

Phenylbutazone chemically is 4-butyl-1,2-diphenyl-3,5-pyrazolidinedione.

$C_{19}H_{20}N_2O_2$

Mol. Wt. 308.38

Each 10 grams of powder contains 1 gram phenylbutazone

INDICATIONS

Phenylbutazone is for the relief of inflammatory conditions associated with the musculoskeletal system in horses. In the treatment of inflammatory conditions associated with infections, specific anti-infective therapy should be used concurrently.

DOSAGE AND ADMINISTRATION

For Horses Only: Administer orally (using the 0.6 ounce (18 mL) scoop provided) on a small amount of palatable feed and mix well. Give 1 to 2 level scoops per 500 pounds of body weight, but do not exceed 4 scoops per animal daily. Use the high dose for the first 48 hours, then gradually reduce to a maintenance dose.

CONTRAINDICATIONS

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

WARNING

Do not use in horses intended for human consumption.

HUMAN WARNING

Keep this and all medications out of the reach of children. Dispense in tight, child resistant containers.

PRECAUTION

Concomitant use with other anti-inflammatory drugs, such as NSAIDs or corticosteroids, should be avoided or closely monitored.

CLINICAL PHARMACOLOGY

Phenylbutazone was first synthesized in 1948 and introduced into human medicine in 1949. Kuzell (1), (2), (3), Payne (4), Fleming (5) and Denko (6) demonstrated the clinical effectiveness of phenylbutazone in gout, gouty arthritis, acute arthritis, acute rheumatism and various other rheumatoid disorders in humans. Fabre (7), Domenjoz (8), Wilhelmi (9) and Yourish (10) 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 mice (11) and dogs (12). Phenylbutazone has been used by Camberos (13) 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 period treatment of osteoarthritis of the stifle and hip, arthrosis of the trapezious muscles and general arthritis. Sutter (14) reported a favorable response in chronic equine arthritis of long duration, fair results in severely bruised mare and poor results in two cases where the condition was limited to the third phalanx.

HOW SUPPLIED

Phenylbutazone Powder is supplied in 1.1 lb (0.5 kg) jars and 2.2 lb (1 kg) jars each containing a dispensing scoop. One level scoop delivers 10 grams of powder containing 1 gram of phenylbutazone.

References

1. Kuzell, WC, Schaffarzick, RW, Naugler, WE, Gandia, C, and Mankle, EA: A.M.A. Arch. Inst. Med., 92:646 (1953).
2. Kuzell, WC, Schaffarzick, RW, Brown, B, and Mankle, EA: J.A.M.A., 149:729 (1952).
3. Kuzell, WC, and Schaffarzick, RW: Calif. Med., 77:319 (1952).
4. Payne, RW, Shelter, MR, Farr, CH, Hellbaum, AA, and Ishmall, WK: J. Lab. Clin. Med., 45:331 (1955).
5. Fleming, J, and Will, G: Ann. Rheumat., Dis., 12:95 (1953).
6. Denko, CW, and Rumi, D: American Pract., 6:1865 (1955).
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, and Burns, J: A.M.A. Arch. Ophth., 53:264 (1955).
11. Hazelton, LW, Tusing, TW, and Hollana, EG: J. Pharmacol. Exper. Ther., 109:387 (1953).
12. Ogilvie, FB, and Sutter, MD: Vet. Med. 52:492 (1957).
13. Camberos, HR: Rev. Med. Vet. (Buenos Aries), 38:9 (1956).
14. Sutter, MD: Vet. Med., 53:83 (1958).

Approved by FDA under ANADA # 200-334

Principal Display Panel - Phenylbutazone Powder (1.1 lb jar)

NDC 13985-991-11

VETONE

Phenylbutazone

Powder

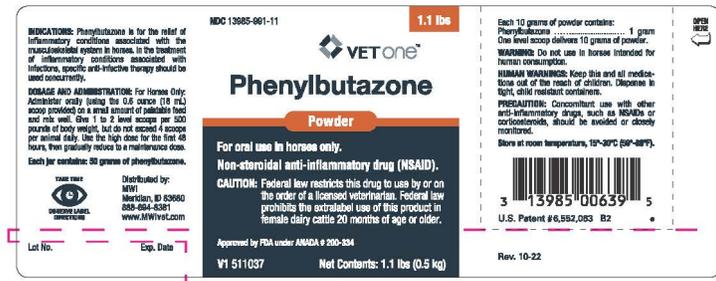
For Oral Use In Horses Only

NON-STEROIDAL ANTI-INFLAMMATORY DRUG (NSAID)

CAUTION: Federal law restricts this drug to use by or on the order of a licensed veterinarian. Federal law prohibits the extralabel use of this product in female dairy cattle 20 months of age or older.

Approved by FDA under ANADA # 200-334

Net Contents: 1.1 lb (0.5 kg)



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Est. 1987
TABCO INC.
www.tabcoinc.com
ph (913) 287-3333 • fax (913) 287-3338

Customer: A & G Pharmaceutical

CS Representative: Melanie Lincoln - milncoln@tabcoinc.com

P.O.#: Tabco Part #: 41963 (In)

Date: 9/26/22 11/08/22

Description: VetOne Phenylbutazone Powder jar 1.1 lb

Varnish: Pattern Flood Lamination: Size: 2.125 "x 5.50 " Unwind #: 4

Colors: Black PMS 159 PMS 303
 U.V. Varnish

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Approved by: _____ Date: _____

chronic equine arthritis of long duration, fair results in severely bruised mare and poor results in two cases where the condition was limited to the third phalanx.

HOW SUPPLIED: Phenylbutazone is supplied in 1.1 lb (0.5 kg) jars each containing a dispensing scoop. One level scoop delivers 10 grams of powder containing 1 gram of phenylbutazone.

Store at room temperature, 15°-30°C (59°-86°F).

References:

1. Kuzell, WC, Schaffarzik, RW, Naugle, WE, Gendis, C, and Mankin, EC: A.M.A. Arch. Int. Med., 82:68 (1952).
2. Kuzell, WC, Schaffarzik, RW, Brown, B, and Mankin, EC: J.A.M.A., 148:729 (1952).
3. Kuzell, WC, and Schaffarzik, RW: Calif. Med., 77:219 (1952).
4. Payne, RW, Shaber, MR, Ferr, CH, Holloman, AJ, and Ishimi, WC: J. Lab. Clin. Med., 46:331 (1956).
5. Fleming, J, and Will, G: Ann. Rheumat. Dis., 12:85 (1953).
6. Danko, CN, and Rumi, D: American Pract., 8:186 (1958).
7. Fabre, J, et al: Semain. Hop. (Paris), 31:87 (1956).
8. Domenjoz, R, et al: Arzneimittel-Forsch., 5:468 (1955).
9. Wilhelm, G, and Pulver, R: Arzneimittel-Forsch., 5:221 (1955).
10. Yourish, W, Paton, B, Brodie, B, and Burns, J: A.M.A. Arch. Ophth., 63:284 (1955).
11. Hazleton, LW, Tueling, TW, and Hollenz, EG: J. Pharmacol. Exper. Ther., 108:367 (1953).
12. Ogilvie, FB, and Sutter, MD: Vet. Med. 62:482 (1967).
13. Camberos, JR: Rev. Med. Vet. (Buenos Aires), 28:9 (1958).
14. Sutter, MD: Vet. Med., 63:83 (1968).

Approved by FDA under ANADA # 200-334
Rev. 10-22

Each 10 gram of powder contains:
Phenylbutazone 1 gram
One level scoop delivers 10 grams of powder.

WARNING: Do not use in horses intended for human consumption.

HUMAN WARNINGS: Keep this and all medications out of the reach of children. Dispense in tight, child resistant containers.

PRECAUTION: Concomitant use with other anti-inflammatory drugs, such as NSAIDs or corticosteroids, should be avoided or closely monitored.

Store at room temperature, 15°-30°C (59°-86°F).



U.S. Patent #6,552,063 B2

Phenylbutazone Powder

For Oral Use in Horses Only

NON-STEROIDAL ANTI-INFLAMMATORY DRUG (NSAID)

CAUTION: Federal law restricts this drug to use by or on the order of a licensed veterinarian. Federal law prohibits the extralabel use of this product in female dairy cattle 20 months of age or older.

DESCRIPTION: Phenylbutazone chemically is 4-butyl-1,2-diphenyl-3-pyrazolidinedione.
C18H24N2O2
Mol. Wt. 306.38

Each 10 grams of powder contains 1 gram phenylbutazone

INDICATIONS: Phenylbutazone is for the relief of inflammatory conditions associated with the musculoskeletal system in horses. In the treatment of inflammatory conditions associated with infections, specific anti-infective therapy should be used concurrently.

DOSEAGE AND ADMINISTRATION: For Horses Only: Administer orally (using the 0.8 ounce (18 mL) scoop provided) on a small amount of palatable feed and mix well. Give 1 to 2 level scoops per 500 pounds of body weight, but do not exceed 4 scoops per animal daily. Use the high dose for the first 48 hours, then gradually reduce to a maintenance dose.

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

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CLINICAL PHARMACOLOGY: Phenylbutazone was first synthesized in 1948 and introduced into human medicine in 1949. Kuzell (1), (2), (3), Payne (4), Fleming (5) and Danko (6) demonstrated the clinical effectiveness of phenylbutazone in goat, pony arthritis, acute arthritis, acute rheumatism and various other rheumatoid disorders in humans. Fabre (7), Domenjoz (8), Wilhelm (9) and Yourish (10) 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 mice (11) and dogs (12).

Phenylbutazone has been used by Camberos (13) in thoroughbred horses. Favorable results were reported in cases of inflammation, muscle rupture, strains and inflammations of the third phalanx. Results were not as favorable in the period treatment of osteoarthritis of the stifle and hip, arthritis of the trapezius muscles and general arthritis. Sutter (14) reported a favorable response in

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TABCO INC.
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ph (913) 287-3333 • fax (913) 287-3338

Customer: A & G Pharmaceuticals

CS Representative: Melanie Lincoln - mlincoln@tabcoinc.com

P.O.#: ---- Tabco Part #: 41963.1 (ln)

Date: 11/08/22

Description: Phenylbutazone Powder

Varnish: Pattern Flood

Lamination: Size: 1.75 " x 4.50 " Unwind #: _____

Colors: black PMS 303

SHEETS

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Principal Display Panel - Phenylbutazone Powder (2.2 lb jar)

NDC 13985-991-22

VETONE™

Phenylbutazone

Powder

For Oral Use In Horses Only

NON-STEROIDAL ANTI-INFLAMMATORY DRUG (NSAID).

CAUTION: Federal law restricts this drug to use by or on the order of a licensed veterinarian. Federal law prohibits the extralabel use of this product in female dairy cattle 20 months of age or older.

Approved by FDA under ANADA # 200-334

Net Contents: 2.2 lb (1 kg)

| | | | | | |
|--|--|--|--|--|--|
| INDICATIONS: Phenylbutazone is for the relief of inflammatory conditions associated with the musculoskeletal system in horses. In the treatment of inflammatory conditions associated with infections, specific anti-infective therapy should be used concurrently. | | NDC 13985-991-22 | | 2.2 lbs | |
| DOSAGE AND ADMINISTRATION: For Horses Only: Administer orally (using the 0.6 ounce (18 mL) scoop provided) on a small amount of palatable feed and mix well. Give 1 to 2 level scoops per 500 pounds of body weight, but do not exceed 4 scoops per animal daily. Use the high dose for the first 48 hours, then gradually reduce to a maintenance dose. Each jar contains: 100 grams of phenylbutazone. | |  Phenylbutazone | | Each 10 grams of powder contains: Phenylbutazone 1 gram One level scoop delivers 10 grams of powder. | |
|  | | Powder | | WARNING: Do not use in horses intended for human consumption. | |
| Distributed by: MWI Meridian, ID 83680 (888) 684-8381 | | For oral use in horses only. Non-steroidal anti-inflammatory drug (NSAID). | | HUMAN WARNINGS: Keep this and all medications out of the reach of children. Dispense in light, child resistant containers. | |
| CAUTION: Federal law restricts this drug to use by or on the order of a licensed veterinarian. Federal law prohibits the extralabel use of this product in female dairy cattle 20 months of age or older. | | Approved by FDA under ANADA # 200-334 | | PRECAUTION: Concomitant use with other anti-inflammatory drugs, such as NSAIDs or corticosteroids, should be avoided or closely monitored. | |
| Lot No. _____ Exp. Date _____ | | V1 510037 Net Contents: 2.2 lbs (1 kg) | | Store at room temperature, 15°-30°C (59°-86°F). | |
| | | | | U.S. Patent #6,552,063 B2 | |
| | | | | Rev. 10-22 | |

| | |
|--|--|
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| Customer: <u>A & G Pharmaceutical</u> | |
| CS Representative: <u>Melanie Lincoln • mlincoln@tabcoinc.com</u> | |
| P.O.#: _____ Tabco Part #: <u>41634 (In)</u> | |
| Date: <u>9/26/22</u> <u>11/08/22</u> | |
| Description: <u>VetOne Phenylbutazone Powder Jar 2.2 lb</u> | |
| Varnish: <input checked="" type="checkbox"/> Pattern <input type="checkbox"/> Flood Lamination: <input checked="" type="checkbox"/> Size: <u>3.00</u> " x <u>7.75</u> " Unwind #: <u>4</u> | |
| Colors: <input checked="" type="checkbox"/> Black <input type="checkbox"/> PMS 159 <input type="checkbox"/> PMS 303 | |
| <input type="checkbox"/> U.V. Varnish <input type="checkbox"/> | |
| <input type="checkbox"/> | |
| <input type="checkbox"/> | |
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| Approved by: _____ Date: _____ | |

phenylbutazone powder

Product Information

| | | | |
|--------------------------------|--------------------------|---------------------------|---------------|
| Product Type | PRESCRIPTION ANIMAL DRUG | Item Code (Source) | NDC:13985-991 |
| Route of Administration | ORAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|--------------------------|-----------------|
| PHENYLBUTAZONE (UNII: GN5P7K3T8S) (PHENYLBUTAZONE - UNII:GN5P7K3T8S) | PHENYLBUTAZONE | 1 g in 10 g |

Product Characteristics

| | | | |
|-----------------|------------------------------|---------------------|--|
| Color | orange (Light orange powder) | Score | |
| Shape | | Size | |
| Flavor | ORANGE (ORANGE FLAVOR) | Imprint Code | |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---------------------|----------------------|--------------------|
| 1 | NDC:13985-991-11 | 500 g in 1 JAR | | |
| 2 | NDC:13985-991-22 | 1000 g in 1 JAR | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| ANADA | ANADA200334 | 05/01/2009 | 01/10/2025 |

Labeler - MWI/VetOne (019926120)

Revised: 1/2025

MWI/VetOne