

**PHENYLBUTE- phenylbutazone powder**  
**Clipper Distributing Company LLC**

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**PHENYLBUTE (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).

# Principal Display Panel - Phenylbute Powder (1.1 lb jar)

NDC 57319-509-62

## Phenylbute® Powder

(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.

**Net Contents: 1.1 lb (0.5 kg)**

Approved by FDA under ANADA # 200-334

<p><b>INDICATIONS:</b> 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.</p> <p><b>DOSAGE AND ADMINISTRATION:</b> 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.</p> <p><b>Each jar contains: 50 grams of phenylbutazone.</b></p> <p>TAXI TIME  OBSERVE LABEL DIRECTIONS</p> <p>Trademarks are property of Clipper Distributing Company, LLC.</p>	<p>NDC 57319-509-62</p> <h1>Phenylbute® Powder</h1> <p>(Phenylbutazone Powder)</p> <p><b>For Oral Use In Horses Only</b> NON-STEROIDAL ANTI-INFLAMMATORY DRUG (NSAID)</p> <p><b>CAUTION:</b> 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.</p> <p><b>Net Contents: 1.1 lb (0.5 kg)</b> Approved by FDA under ANADA # 200-334</p> <p><b>PHOENIX™</b> Manufactured for: Clipper Distributing Company, LLC, St. Joseph, MO 64507</p>	<p>Each 10 grams of powder contains: Phenylbutazone ..... 1 gram One level scoop delivers 10 grams of powder.</p> <p><b>WARNING:</b> Do not use in horses intended for human consumption.</p> <p><b>HUMAN WARNINGS:</b> Keep this and all medications out of the reach of children. Dispense in tight, child resistant containers.</p> <p><b>PRECAUTION:</b> Concomitant use with other anti-inflammatory drugs, such as NSAIDs or corticosteroids, should be avoided or closely monitored.</p> <p><b>Store at room temperature, 15°-30°C (59°-86°F).</b></p> <p> 3 57319 50962 6</p>	<p>OPEN HERE </p>
<p>Lot No. _____ Exp. Date _____</p>		<p>U.S. Patent #6,552,063 B2 Rev. 10-22</p>	

<p>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.</p> <p><b>HOW SUPPLIED:</b> Phenylbute 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.</p> <p><b>Store at room temperature, 15°-30°C (59°-86°F).</b></p> <p><b>References:</b></p> <ol style="list-style-type: none"> <li>1. Kuze, WC, Schaffarzik, RW, Naugler, WE, Gandia, C, and Mankle, EA: A.M.A. Arch. Inst. Med., 92:846 (1953).</li> <li>2. Kuze, WC, Schaffarzik, RW, Brown, B, and Manide, EA: J.A.M.A., 149:729 (1952).</li> <li>3. Kuze, WC, and Schaffarzik, RW: Calif. Med., 77:319 (1952).</li> <li>4. Payne, RW, Shelter, MR, Farr, CH, Hebbelbaum, AA, and Ishmael, WK: J. Lab. Clin. Med., 45:331 (1955).</li> <li>5. Fleming, J, and Will, G: Ann. Rheumat. Dis., 12:95 (1953).</li> </ol> <p style="text-align: center;">4</p>	<ol style="list-style-type: none"> <li>6. Denko, CW, and Rumi, D: American Pract., 6:1865 (1955).</li> <li>7. Fabre, J, et al: Semain. Hop. (Paris), 31:87 (1955).</li> <li>8. Domenjoz, R, et al: Arzneimittel-Forsch., 5:488 (1955).</li> <li>9. Wilhelmi G, and Pulver, R: Arzneimittel-Forsch., 5:221 (1955).</li> <li>10. Yourish, W, Paton, B, Brodie, B, and Burns, J: A.M.A. Arch. Ophth., 53:264 (1955).</li> <li>11. Hazelton, LW, Tusing, TW, and Hollana, EG: J. Pharmacol. Exper. Ther., 109:387 (1953).</li> <li>12. Ogilvie, FB, and Sutter, MD: Vet. Med., 52:492 (1957).</li> <li>13. Camberos, HR: Rev. Med. Vet. (Buenos Aires), 38:9 (1956).</li> <li>14. Sutter, MD: Vet. Med., 53:83 (1958).</li> </ol> <p>Approved by FDA under ANADA # 200-334</p> <p>Rev. 10-22</p> <p style="text-align: center;">5</p>	<p>Each 10 grams of powder contains: Phenylbutazone ..... 1 gram One level scoop delivers 10 grams of powder.</p> <p><b>WARNING:</b> Do not use in horses intended for human consumption.</p> <p><b>HUMAN WARNINGS:</b> Keep this and all medications out of the reach of children. Dispense in tight, child resistant containers.</p> <p><b>PRECAUTION:</b> Concomitant use with other anti-inflammatory drugs, such as NSAIDs or corticosteroids, should be avoided or closely monitored.</p> <p><b>Store at room temperature, 15°-30°C (59°-86°F).</b></p> <div style="text-align: center;">  <p>3 57319 50962 6</p> </div>
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<p style="text-align: center;"><b>PHENYLBUTE</b> (phenylbutazone)</p> <p style="text-align: center;"><b>Powder</b> <b>For Oral Use In Horses Only</b></p> <p style="text-align: center;"><b>NON-STEROIDAL ANTHINFLAMMATORY DRUG (NSAID)</b></p> <p><b>CAUTION:</b> 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.</p> <p><b>DESCRIPTION:</b> Phenylbutazone chemically is 4-butyl-1,2-diphenyl-3,5-pyrazolidinedione.</p> <p><math>C_{19}H_{23}N_2O_2</math> Mol. Wt. 308.38</p> <p>Each 10 grams of powder contains 1 gram phenylbutazone</p> <p style="text-align: center;">1</p>	<p><b>INDICATIONS:</b> 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.</p> <p><b>DOSAGE AND ADMINISTRATION:</b> 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.</p> <p><b>CONTRAINDICATIONS:</b> Use with caution in patients who have history of drug allergy.</p> <p><b>WARNING:</b> Do not use in horses intended for human consumption.</p> <p><b>HUMAN WARNINGS:</b> Keep this and all medications out of the reach of children. Dispense in tight, child resistant containers.</p> <p><b>PRECAUTION:</b> Concomitant use with other anti-inflammatory drugs, such as NSAIDs or corticosteroids, should be avoided or closely monitored.</p> <p style="text-align: center;">2</p>	<p><b>CLINICAL PHARMACOLOGY:</b></p> <p>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.</p> <p>Toxicity of phenylbutazone has been investigated in rats and mice (11) and dogs (12).</p> <p>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 trapezius muscles and general arthritis. Sutter (14) reported a favorable response in</p> <p style="text-align: center;">3</p>
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**Principal Display Panel - Phenylbute Powder (2.2 lb jar)**

NDC 57319-509-61

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(Phenylbutazone Powder)

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Approved by FDA under ANADA # 200-334

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Each jar contains: 100 grams of phenylbutazone.



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NDC 57319-509-61

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**PHOENIX™**

Manufactured for:  
Clipper Distributing Company, LLC.  
St. Joseph, MO 64507

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



Lot No. Exp. Date

Rev. 10-22

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6. Denko, CW, and Rumi, D: American Pract., 6:1865 (1955).
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Rev. 10-22

5

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

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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 trapezius muscles and general arthritis. Sutter (14) reported a favorable response in

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# PHENYLBUTE

phenylbutazone powder

## Product Information

<b>Product Type</b>	PRESCRIPTION ANIMAL DRUG	<b>Item Code (Source)</b>	NDC:57319-509
<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	1 g in 10 g

## Product Characteristics

<b>Color</b>	orange (Light orange powder)	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>	ORANGE (ORANGE FLAVOR)	<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:57319-509-62	500 g in 1 JAR		
2	NDC:57319-509-61	1000 g in 1 JAR		

## Marketing Information

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
ANADA	ANADA200334	03/15/2012	

**Labeler** - Clipper Distributing Company LLC (150711039)

Revised: 10/2023

Clipper Distributing Company LLC