

**PHENYLBUTAZONE - phenylbutazone injection**  
**Aspen Veterinary Resources, Ltd.**

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**Phenylbutazone 20% Injection 200 mg/mL**

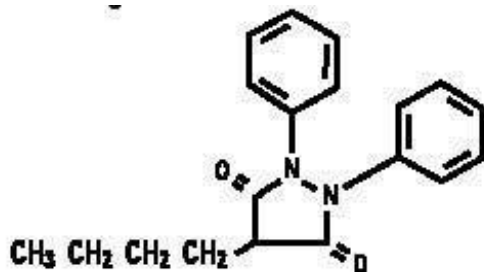
**NOT FOR USE IN HUMANS**

**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,<sup>1, 2, 3</sup> Payne,<sup>4</sup> Fleming,<sup>5</sup> and Denko<sup>6</sup> 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,<sup>7</sup> Domenjoz,<sup>8</sup> Wilhelmi,<sup>9</sup> and Yourish<sup>10</sup> Lieberman<sup>11</sup> 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<sup>12</sup> observed objective improvement without toxicity following long-term therapy of two aged arthritic dogs. Ogilvie and Sutter<sup>13</sup> 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<sup>14</sup> 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. Sutter<sup>15</sup> 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 the 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.

## **CONTACT INFORMATION:**

To report suspected adverse events for technical assistance or to obtain a copy of the Safety Data Sheet, 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>

## **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.

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 insert for additional information.



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



LOT NO.: EXP. DATE:

NDC #46066-282-04



**PHENYL BUTAZONE  
20% INJECTION**

**200 mg / mL**

**NOT FOR USE IN HUMANS  
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)**

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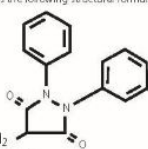
See package insert for additional information.

Manufactured for:  
 Aspen Veterinary Resources®, Ltd.  
 Liberty, MO 64068  
 www.aspenveterinaryresources.com

A155S  
 P-4825-04  
 Rev. 10-23

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



<p><b>REFERENCES:</b></p> <ol style="list-style-type: none"> <li>Kuzel, W.C., Schaffarid, R.W., Naugler, W.G., and Manlike, E.A.: <i>AMA Arch. Int. Med.</i> 92:646, 1953.</li> <li>Kuzel, W.C., Schaffarid, R.W., Brown, B. and Manlike, E.A.: <i>Jour. Amer. Med. Assoc.</i> 149:729, 1952.</li> <li>Kuzel, W.C., Schaffarid, R.W., Calif. <i>Med.</i> 77:319, 1952.</li> <li>Payne, R.W., Shetter, M.R., Farr, C., Hellbaum, A.A. and Ishmael, W.K.T.: <i>Lab. Clin. Med.</i> 4:5331, 1955.</li> <li>Fleming, J. and Will, G.: <i>Ann Rheumat. Dis.</i> 12:95, 1953.</li> <li>Denko, C.W., and Ruml, D.: <i>Amer. Pract.</i> 61:865, 1955.</li> <li>Fabre, J. and Berges, A.: <i>Semaine-Hosp (Paris)</i> 31:87, 1955.</li> <li>Domenjoz, B., Theobald, W. and Morsdorf, K.: <i>Arzneimittel - Forsch.</i> 5:488, 1955.</li> <li>Wilhelm, G. and Pulver, R.: <i>Arzneimittel-Forsch.</i> 5:221, 1955.</li> <li>Youtish, N., Paton, B., Brodie, B.B. and Burns, J.J.: <i>AMA Arch. Ophth.</i> 53:264, 1955.</li> <li>Lieberman, L.L.: <i>Jour. Amer. Vet. Med. Assoc.</i> 125:128, 1954.</li> <li>Joshua, J.D.: <i>Vet. Rec.</i> 68:60 (Jan. 21), 1956.</li> <li>Ogilvie, F.B. and Suter, M.D.: <i>Vet. Med.</i> 52:492-494, 1957.</li> <li>Camberos, H.R.: <i>Rev. Med. Vet. (Buenos Aires)</i> 38:9, 1956.</li> <li>Sutter, M.D.: <i>Vet. Med.</i> 53:83 (Feb.), 1958.</li> </ol> <p style="text-align: center;"><b>7</b></p>	<p><b>INDICATIONS:</b> For relief of inflammatory conditions associated with the musculoskeletal system in horses.</p> <p><b>Intravenous dosage (not for subcutaneous or intramuscular use):</b></p> <p><b>Horses:</b> 1 to 2 g per 1,000 lb body weight (5 to 10 mL/1,000 lb) daily.</p> <p>Not for use in Horses intended for food.</p> <p>See package insert for additional information.</p> <p>Manufactured for:        Aspen Veterinary Resources®, Ltd.        Liberty, MO 64068        www.aspenveterinaryresources.com</p> <p>A155S        P-4825-04        Rev. 10-23</p> <p style="text-align: right;">Printed in U.S.A. Mfd. in U.S.A.</p>	<p><b>PHENYL BUTAZONE 20% INJECTION (PHENYL BUTAZONE)</b></p> <p><b>NOT FOR USE IN HUMANS KEEP OUT OF REACH OF CHILDREN FOR HORSES ONLY</b></p> <p><b>CAUTION:</b> Federal law restricts this drug to use by or on the order of a licensed veterinarian.</p> <p><b>DESCRIPTION:</b> 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:</p> <div style="text-align: center;">  <p><b>1</b></p> </div>	<p><b>BACKGROUND PHARMACOLOGY:</b> Kuzel,<sup>1,2,3</sup> Payne,<sup>4</sup> Fleming,<sup>5</sup> and Denko<sup>6</sup> 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,<sup>7</sup> Domenjoz,<sup>8</sup> Wilhelm,<sup>9</sup> and Youtish.<sup>10</sup> Lieberman<sup>11</sup> reported on the effective use of phenylbutazone in the treatment of painful conditions of the musculoskeletal system in dogs; including posttoral paralysis associated with intervertebral disc syndrome, painful fractures, arthritis, and painful injuries to the limbs and joints. Joshua<sup>12</sup> observed objective improvement without toxicity following long-term therapy of two aged arthritic dogs. Ogilvie and Sutter<sup>13</sup> 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<sup>14</sup> reported favorable results with phenylbutazone.</p> <p style="text-align: center;"><b>2</b></p>
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<p>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 pain, chronic pain in trapezius muscles, and generalized arthritis). Results were less favorable in cases of traumatism, muscle rupture, strains and inflammations of the third phalanx. Sutter<sup>15</sup> 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.</p> <p><b>INDICATIONS:</b> For relief of inflammatory conditions associated with the musculoskeletal system in horses.</p> <p><b>CONTRAINDICATIONS:</b> 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.</p> <p style="text-align: center;"><b>3</b></p>	<p><b>PRECAUTIONS:</b> 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 during the early phase of therapy and at intervals of two weeks thereafter. Any significant fall in the 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.</p> <p><b>Store in a refrigerator between 2°C - 8°C (36°F - 46°F).</b></p> <p style="text-align: center;"><b>4</b></p>	<p><b>DOSAGE AND ADMINISTRATIONS</b></p> <p><b>HORSES</b></p> <p><b>INTRAVENOUSLY:</b> 1 to 2 g per 1,000 lbs of body weight (5 to 10 mL/1,000 lb) 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.</p> <p><b>GUIDELINES TO SUCCESSFUL THERAPY</b></p> <ol style="list-style-type: none"> <li>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.</li> <li>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.</li> <li>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.</li> </ol> <p style="text-align: center;"><b>5</b></p>	<p>If long-term therapy is planned, oral administration is suggested.</p> <p>4. Many chronic conditions will respond to phenylbutazone therapy, but discontinuance of treatment may result in recurrence of symptoms.</p> <p><b>CONTACT INFORMATION:</b> To report suspected adverse events for technical assistance or to obtain a copy of the Safety Data Sheet, 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 <a href="http://www.fda.gov/reportanimalae">http://www.fda.gov/reportanimalae</a></p> <p><b>HOW SUPPLIED</b></p> <p><b>INJECTABLE:</b> 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.</p> <p style="text-align: center;"><b>6</b></p>
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**PHENYL BUTAZONE**

phenylbutazone injection

<b>Product Information</b>			
<b>Product Type</b>	PRESCRIPTION ANIMAL DRUG	<b>Item Code (Source)</b>	NDC:46066-282
<b>Route of Administration</b>	INTRAVENOUS		

<b>Active Ingredient/Active Moiety</b>		
<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>PHENYL BUTAZONE (UNII: GN5P7K3T8S) (PHENYL BUTAZONE - UNII:GN5P7K3T8S)</b>	PHENYL BUTAZONE	200 mg in 1 mL

## Inactive Ingredients

Ingredient Name	Strength
BENZYL ALCOHOL (UNII: LKG8494WBH)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	

## Packaging

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

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANADA	ANADA200371	07/31/2007	

**Labeler** - Aspen Veterinary Resources, Ltd. (627265361)

**Registrant** - Sparhawk Laboratories, Inc. (147979082)

## Establishment

Name	Address	ID/FEI	Business Operations
Sparhawk Laboratories, Inc.		147979082	analysis, manufacture

## Establishment

Name	Address	ID/FEI	Business Operations
SINTENOVO SA DE CV		812039808	api manufacture

Revised: 5/2024

Aspen Veterinary Resources, Ltd.