EQUIZONE 50/100- phenylbutazone powder A&G Pharmaceuticals

EQUIZONE 50/100 (phenylbutazone) 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.

DESCRIPTION

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

C₁₉H₂₀N₂O₂ 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, Naughler, 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 - EQUIZONE 50[™] 50 (1.1 lb jar)

NDC 57699-001-11

EQUIZONE50™

(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



chronic equine arthritis of long duration, fair 6. Denko, CW, and Rumi, D: American Each 10 grams of powder contains: results in severely bruised mare and poor results in two cases where the condition was Pract., 6:1865 (1955). Phenylbutazone 1 gram One level scoop delivers 10 grams of Fabre, J, et al: Semain, Hop, (Paris), 31:87 7. limited to the third phalanx (1955).HOW SUPPLIED: EOUIZONE 50 Powder 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 powder. 8. Domenjoz, R, et al: Arzneimitte-Forsch, 5:488 (1955). WARNING: Do not use in horses intended for Wilhelmi G, and Pulver, R: Arzneimittel-9 human consumption. Forsch, 5:221 (1955), HUMAN WARNINGS: Keep this and all 10. Yourish, W, Paton, B, Brodie, B, and phenylbutazone. medications out of the reach of children. Burns, J: A.M.A. Arch. Ophth., 53:264 Store at room temperature, 15°-30°C (59°-86°F). Dispense in tight, child resistant containers. (1955)References: 11. Hazelton, LW, Tusing, TW, and Hollana, PRECAUTION: Concomitant use with EG: J. Pharmacol, Exper. Ther., 109:387 other anti-inflammatory drugs, such as NSAIDs or corticosteroids, should be 1. Kuzell, WC, Schaffarzick, RW, Naughler, (1953). WE, Gandia, C, and Mankle, EA: A.M.A. 12. Ogilvie, FB, and Sutter, MD: Vet. Med. Arch. Inst. Med., 92:646 (1953). avoided or closely monitored. Kuzell, WC, Schaffarzick, RW, Brown, B, and Mankle, EA: J.A.M.A., 149:729 (1952). 52:492 (1957) 2. 13. Camberos, HR: Rev. Med. Vet. (Buenos Store at room temperature, 15°-30°C Aires), 38:9 (1956). (59°-86°F). 3. Kuzell, WC, and Schaffazick, RW: Calif. 14. Sutter, MD: Vet. Med., 53:83 (1958). EQUIZONE 50[™] is a trademark of A & G Med., 77:319 (1952). Payne, RW, Shelter, MR, Farr, CH, 4, Pharmaceuticals, Inc. Hellbaum, AA, and Ishmall, WK: J. Lab. Approved by FDA under ANADA # 200-334 Clin. Med., 45:331 (1955). Manufactured for Fleming, J, and Will, G: Ann. Rheumat., 5. A & G Pharmaceuticals, Inc. Rev. 10-22 Dis., 12:95 (1953). Jackson, NJ 08527 4 5 **NDICATIONS:** Phenylbutazone is for the relief CLINICAL PHARMACOLOGY: EQUIZONE 50[™] 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 of inflammatory conditions associated with the musculoskeletal system in horses. In the (phenylbutazone) treatment of inflammatory conditions associated with infections, specific anti-infective therapy should be used concurrently. Powder 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 gout, gouty arthritis, acute arthritis, acute rheumatism and various other rheumatoid For Oral Use In Horses Only disorders in humans. Fabre (7), Domenjoz (8), Wilhelmi (9) and Yourish (10) have NON-STEROIDAL ANTHNFLAMMATORY DRUG (NSAID) established the anti-rheumatic and antiinflammatory activity of phenylbutazone. It is entirely unrelated to the steroid hormones. 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 reduce to a maintenance dose. Toxicity of phenylbutazone has been investigated in rats and mice (11) and dogs CONTRAINDICATIONS: Use with caution in product in female dairy cattle 20 months of age (12). patients who have history of drug allergy. or older Phenylbutazone has been used by Camberos WARNING: Do not use in horses intended for DESCRIPTION: Phenylbutazone chemically is 4-butyl-1,2-diphenyl-3,5-pyrazolidinedione. (13) in thoroughbred horses. Favorable results were reported in cases of traumatism, human consumption. HUMAN WARNINGS: Keep this and all medicamuscle rupture, strains and inflammations of C19H20N2O2 tions out of the reach of children. Dispense in tight, child resistant containers. favorable in the period treatment of osteoarthritis of the stifle and hip, arthrosis of Mol. Wt. 308.38 PRECAUTION: Concomitant use with other anti-Each 10 grams of powder contains 1 gram inflammatory drugs, such as NSAIDs or cortico-steroids, should be avoided or closely monitored. the trapezious muscles and general arthritis, pheny butazone Sutter (14) reported a favorable response in 1 2 3

Principal Display Panel - EQUIZONE 100™ (2.2 lb jar)

NDC 57699-001-22

EQUIZONE 100™

(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: 2.2 lb (1 kg)

Approved by FDA under ANADA # 200-334



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: EQUIZONE 100 Powder is supplied in 2.2 lb (1 kg) jars each containing a dispensing scoop. One level scoop delivers 10 grams of powder containing 1 gram of pheny butazone.

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

References

- Kuzell, WC, Schaffarzick, RW, Naughler, 1. WE, Gandia, C, and Mankle, EA: A.M.A. Arch. Inst. Med., 92:646 (1953).
- Kuzell, WC, Schaffarzick, RW, Brown, B, 2. and Mankle, EA: J.A.M.A., 149:729 (1952).
- Kuzell, WC, and Schaffazick, RW: Calif. 3 4.
- Med., 77:319 (1952). Payne, RW, Shelter, MR, Farr, CH, Hellbaum, AA, and Ishmall, WK: J. Lab. Clin, Med., 45:331 (1955). Fleming, J, and Will, G: Ann. Rheumat.,
- 5. Dis., 12:95 (1953).

- Denko, CW, and Rumi, D: American 6. Pract., 6:1865 (1955).
- 7. Fabre, J, et al: Semain, Hop. (Paris), 31:87 $(1955)_{-}$
- Domenjoz, R, et al: Arzneimitte-Forsch. 8. 5:488 (1955).
- 9. Wilhelmi G, and Pulver, R: Arzneimittel-Forsch, 5:221 (1955),
- Yourish, W, Paton, B, Brodie, B, and 10. Burns, J: A.M.A. Arch. Ophth., 53:264 (1955).
- Hazelton, LW, Tusing, TW, and Hollana, EG: J. Pharmacol, Exper. Ther., 109:387 (1953).
- Ogilvie, FB, and Sutter, MD: Vet. Med. 12. 52:492 (1957),
- 13. Camberos, HR: Rev. Med. Vet. (Buenos Aires), 38:9 (1956).
- 14. Sutter, MD: Vet. Med., 53:83 (1958).

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Rev. 10-22

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Each 10 grams 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).

EQUIZONE 100[™] is a trademark of A & G Pharmaceuticals, Inc.

> Manufactured for A & G Pharmaceuticals, Inc. Jackson, NJ 08527

EQUIZONE 100[™] (phenylbutazone)

Powder For Oral Use In Horses Only

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C19H20N2O2

Mol. Wt. 308.38

Each 10 grams of powder contains 1 gram phenylbutazone

1

NDCATIONS: 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.

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PRECAUTION: Concomitant use with other anti-inflammatory drugs, such as NSAIDs or corticosteroids, should be avoided or closely monitored. 2

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 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 estimation to the steard between the stearging the steargin is entirely unrelated to the steroid hormones.

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Pr	oduct Inform	ation							
Product Type			PRESCRIPTION ANIMAL DRUG		Item Code	m Code (Source) NDC		C:57699-001	
Route of Administration			ORAL						
Ac	tive Ingredier	nt/Active	Moiety						
	-	Ingi	redient Name			Basis of Strength Streng		Strengt	
			(K3T8S) (PHENYLBUTAZ ONE - UNII:GN5P7K3T8						
Pr	oduct Charac	teristics							
Co	lor	orange (Ligh	ange (Light orange powder)			Score			
Shape					s	Size			
Flavor		ORANGE (ORANGE FLAVOR)			lı.	Imprint Code			
Co	ntains								
Pa	ckaging								
#	ltem Code	Packa	ge Description	Marketin	g Start D	ate Mar	keting E	nd Date	
1	NDC:57699-001-11	500 g in 1	• •		•				
2	NDC:57699-001-22	1000 g in	1 JAR						
Μ	arketing In	format	ion						
Marketing Category		Application Number or Monograph Citation			Marketing Start Date		Marketing End Date		
			ANADA200334		02/18/2009				

Labeler - A&G Pharmaceuticals (182147033)

Revised: 10/2023

A&G Pharmaceuticals