

ADEQUAN I.A.- polysulfated glycosaminoglycan injection, solution
American Regent, Inc.

Adequan® I.A.
(Polysulfated Glycosaminoglycan) (PSGAG)

Solution 250 mg/mL

For intra-articular (I.A.) use in horses

DESCRIPTION

Each milliliter of Adequan contains 250 mg of Polysulfated Glycosaminoglycan and Water for Injection q.s. Sodium Hydroxide and/or Hydrochloric Acid added when necessary to adjust pH.

PHARMACOLOGY

Polysulfated Glycosaminoglycan is chemically similar to the mucopolysaccharides of cartilaginous tissue. It is a potent proteolytic enzyme inhibitor and diminishes or reverses the processes which result in the loss of cartilaginous mucopolysaccharides. PSGAG improves joint function by stimulating synovial membrane activity, reducing synovial protein levels and increasing synovial fluid viscosity in traumatized equine carpal joints.

TOXICITY

Toxicity studies were conducted in horses. Doses as high as 1,250 mg were administered intracarpally to 6 horses once a week for 18 weeks. This dosage is 5 times the recommended dosage and 3.6 times the recommended therapeutic regimen. Clinical observations revealed soreness and swelling in 1.8% (2 of 109 animals) at the injection site which was mild, self limiting and lasted less than one day. There was a dose related evaluation on partial thromboplastin time, creatinine and glucose. No animal had any clinical illness during the trial and none showed clinical evidence of toxicity except transient swelling at the injection site, possibly due to mechanical invasion of the joint.

INDICATIONS

Adequan is recommended for the treatment of non-infectious degenerative and/or traumatic joint dysfunction and associated lameness of the carpal joint in horses.

CONTRAINDICATIONS

Do not use in horses showing hypersensitivity to Polysulfated Glycosaminoglycan. Do not administer Adequan in the face of joint sepsis.

WARNING

Do not use in horses intended for human consumption.

DOSAGE AND ADMINISTRATION

The recommended dose of Adequan in horses is 250 mg (1 vial) once a week for five weeks, intra-articularly. The joint area must be shaved, cleansed and sterilized as in a surgical procedure prior to

injection. Do not mix Adequan with other drugs or solvents.

ADVERSE REACTIONS

Two major categories of adverse reactions have been reported following the intra-articular administration of Adequan:

1. Inflammatory joint reactions consisting of joint pain, effusion, and swelling with associated lameness.
2. Septic arthritis.

Less frequently, nonseptic arthritis, hemarthrosis, and cellulitis at the injection site and surrounding tissues have been reported.

PRECAUTIONS

Adequan is indicated for use only in the carpal joint of horses. Do not mix Adequan with other drugs or solvents.

Reaction in the joint may occasionally occur within 48 hours after intra-articular treatment. If the reaction involves excessive inflammation, cease therapy with Adequan.

Post-injection inflammation may result from possible sensitivity to Adequan; traumatic injection technique; exceeding the recommended dose, frequency of administration or number of Adequan injections; and from combining Adequan with other drugs. Excessive joint inflammation may be manifested by rapid onset, tenderness, swelling and warmth over the injection carpus. Inflammatory joint reactions may successfully be treated by systemic anti-inflammatory drugs, cold hydrotherapy and rest. Serious reactions of this type may indicate the presence of joint sepsis.

Joint sepsis is a rare but potentially life-threatening complication of the intra-articular injection. It usually results from the deposition of skin organisms into the joint space by the needle tip. Gustafson et al., (1989) have demonstrated that Adequan may potentiate a subinfective dose of contaminant bacteria. (2, 3). Hence, strict aseptic injection technique is of utmost importance.

Successful resolution of joint sepsis depends on prompt recognition and rigorous antimicrobial treatment. (1, 4, 5, 6). Early diagnosis of septic arthritis may be complicated by the similar appearance of joint inflammation. Excessive inflammation accompanied by lameness, swelling, and edema extending beyond the joint limits should alert the practitioner to the possibility of sepsis. Synovial fluid analysis with cytology and bacterial culture of the fluid or a section of synovial membrane are valuable diagnostic aids. Upon suspicion of joint sepsis, broad spectrum antibiotic therapy should be instituted without delay and joint lavage considered. It is recommended that samples used for bacterial culture be taken prior to initiating antibiotic therapy.

The concomitant use of Adequan with steroidal or non-steroidal anti-inflammatory agents may mask the symptoms of joint sepsis, thereby delaying the diagnosis and reducing the likelihood of a satisfactory resolution.

Intra-articular injections should not be performed when the overlying skin is scurfed or blistered, as this precluded adherence to aseptic injection technique.

Veterinarians are directed to the Reference Section below for additional information concerning septic arthritis and its treatment.

IMPAIRMENT OF FERTILITY

Fertility impairment studies in mares and stallions have not been conducted. Do not use in horses intended for breeding.

CAUTION

Federal law restricts this drug to use by or on the order of a licensed veterinarian.

HOW SUPPLIED

Adequan solution, 250 mg/mL is available as:

NDC 10797-991-72 1 mL single dose vials Packaged in boxes of 6

Store at controlled room temperature up to 25°C (77°F) (See USP).

REFERENCES

1. Bertone, A; McIlwraith, CW et al: Comparison of various treatments for experimentally induced equine infectious arthritis. *Am J. Vet Res.* (48): 519, 1987.
2. Gustafson, SB; McIlwraith, CW; Jones, RL: Comparison of the effect of polysulfated glycosaminoglycan, corticosteroids and sodium hyaluronate in the potentiation of a subinfective dose of *Staphylococcus aureus* in the midcarpal joint of horses. *Am J. Vet Res.* (50): 2014-2017, 1989.
3. Gustafson, SB; McIlwraith, CW; Jones, RL; Dixon-White, HE: Further investigations into the potentiation of infection by intra-articular injection of polysulfated glycosaminoglycan and the effect of filtration and intra-articular injection of amikacin in horses. *Am J. Vet Res.* (50): 2018-2022, 1989.
4. Koch, DB: Management of infectious arthritis in the horse. *Comp. Cont. Educ.* (1): 546, 1979.
5. McIlwraith, CW: Treatment of infectious arthritis. *Vet. Clin. N. Am., Lg. Anim. Prat.* (5): 363, 1983.
6. Morris, PG: The clinical management of septic arthritis in the horse. *Comp. Cont. Educ.* (2): 5207, 1980.
7. Von Essen, R. and Holtt, A: Improved method of isolating bacteria from joint fluids by the use of blood culture bottles. *Ann. Rheum. Dis.* (45): 454, 1986.

LUITPOLD PHARMACEUTICALS, INC.

Animal Health Division

Shirley, NY 11967

(631) 924-4000

1-800-458-0163

Made in the U.S.A.

IN 99171

Rev. 6/07

MG #8148

NADA #136-383, Approved by FDA

PRINCIPAL DISPLAY PANEL – 1 mL Carton

Adequan® I.A.

(Polysulfated Glycosaminoglycan)

PSGAG injection

For intra-articular use in horses

- For the treatment of non-infectious degenerative and/or traumatic joint dysfunction and associated lameness of the carpal joint in horses.

ANIMAL HEALTH

A Division of Luitpold Pharmaceuticals, Inc.

NADA # 136-383, Approved by FDA

Single Dose Vials

Contains 6 Vials (1 mL each)

CAUTION:
Federal law restricts this drug to use by or on the order of a licensed veterinarian.

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

Discard unused portion. Store at controlled room temperature up to 25°C (77°F) (See USP).

Keep this and all medications out of the reach of children.

Rev. 10/07

NDC 10797-991-72

Adequan® I.A.
(POLYSULFATED GLYCOSAMINOGLYCAN)
PSGAG injection
For intra-articular use in horses

- For the treatment of non-infectious degenerative and/or traumatic joint dysfunction and associated lameness of the carpal joint in horses.

Animal Health™
LUITPOLD
A Division of Luitpold Pharmaceuticals, Inc.

NADA # 136-383, Approved by FDA Single Dose Vials • Contains 6 Vials (1 mL each)

coating free area

3 10797 99172 7

Single Dose Vials • Contains 6 Vials (1 mL each)

See bottom for lot # and expiration date.

Adequan® I.A.
(POLYSULFATED GLYCOSAMINOGLYCAN)
PSGAG injection
For intra-articular use in horses

- Each vial contains 250 mg PSGAG in Water for Injection USP.
- Sodium Hydroxide and/or Hydrochloric Acid added when necessary to adjust pH.

• See package insert for full directions.

Luitpold Pharmaceuticals, Inc.
Animal Health Division
Shrewsbury, NJ 07874
(800) 458-0163

NDC 10797-991-72

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ADEQUAN I.A.

polysulfated glycosaminoglycan injection, solution

Product Information

Product Type	PRESCRIPTION ANIMAL DRUG	Item Code (Source)	NDC:10797-991
Route of Administration	INTRA-ARTICULAR		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
POLYSULFATED GLYCOSAMINOGLYCAN (UNII: 268AW7000T) (POLYSULFATED GLYCOSAMINOGLYCAN - UNII:268AW7000T)	POLYSULFATED GLYCOSAMINOGLYCAN	250 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:10797-991-72	6 in 1 CARTON		
1		1 mL in 1 VIAL, SINGLE-USE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NADA	NADA136383	12/01/1984	

Labeler - American Regent, Inc. (002033710)**Establishment**

Name	Address	ID/FEI	Business Operations
American Regent, Inc.		002033710	ANALYSIS, MANUFACTURE

Establishment

Name	Address	ID/FEI	Business Operations
Daiichi Sankyo Altrich Sari		262417595	API MANUFACTURE

Revised: 12/2019

American Regent, Inc.