



polysulfated glycosaminoglycan

Adequan® i.m. is recommended for the intramuscular treatment of non-infectious degenerative and/or traumatic joint dysfunction and associated lameness of the carpal and hock joints in horses.

Please see accompanying Full Prescribing Information.

The ONLY FDA approved equine polysulfated glycosaminoglycan (PSGAG) for the intramuscular treatment of non-infectious degenerative joint disease (DJD) of the carpal and hock joints proven to:

- DIMINISH the destructive processes of degenerative joint disease¹
- REVERSE the processes which result in the loss of cartilage components¹
- IMPROVE overall joint function and associated lameness¹

Adequan® i.m. (polysulfated glycosaminoglycan) works in a variety of ways to treat degenerative joint disease of the carpal and hock joints:

- Inhibits the loss of proteoglycan, collagen, and hyaluronic acid (HA) — key building blocks of healthy cartilage¹
- Increases hyaluronic acid (HA) levels in the synovial fluid¹
- Adequan[®] i.m. also provides relief by:
 - → decreasing inflammation of the synovial membrane (synovitis)¹
 - → improving lameness of the carpal and hock joints associated with DJD¹

IMPORTANT SAFETY INFORMATION

There are no known contraindications to the use of intramuscular Adequan® i.m. brand Polysulfated Glycosaminoglycan in horses. Studies have not been conducted to establish safety in breeding horses.

Adequan® i.m. (polysulfated glycosaminoglycan) is well-absorbed

After a single intramuscular injection of Adequan® i.m.²

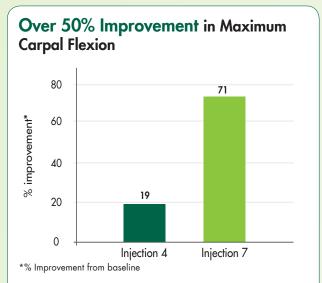


Hyaluronic Acid (HA) levels nearly doubled at 48 hours with significant increases noted from 24 up to 96 hours.²

Clinical significance of the above results is unknown.

Adequan® i.m. Dose Response Study³

The benefits of adhering to the labeled dosing regimen



A placebo-controlled, blinded dose titration study was conducted in a total of 36 healthy, mature horses that were either quarter horses or thoroughbreds. An induced adjuvant carpitis in the horse was used to assess the dose and efficacy of the intramuscular administration of Adequan® i.m. The adjuvant induced arthritis was produced with a single intraarticular injection of 0.5 mL of Freunds adjuvant. The various treatments comprised sterile saline solution as a placebo control and 50 mg, 125 mg, 250 mg, 500 mg and 1,000 mg of the active drug substance Adequan® i.m. dissolved in sterile water. Injections were given every 4 days for a total of 7 injections. Treatment followed a 10 day acclimation period and a five day model induction period.

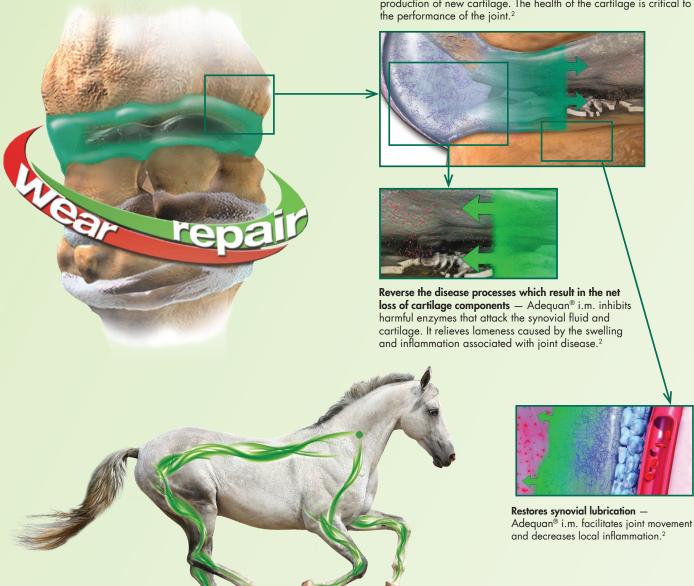
Please see accompanying Full Prescribing Information on the inside back cover.



In DJD, the natural wear and repair cycle is disrupted.

Adequan® i.m. (polysulfated glycosaminoglycan) helps restore joint function in the carpal and hock joints.1

Stimulates cartilage repair — Adequan® i.m. rapidly aids in the production of new cartilage. The health of the cartilage is critical to



WARNING: Do not use in horses intended for human consumption. Not for use in humans. Keep this and all medication out of the reach of children.

Please see accompanying Full Prescribing Information on the inside back cover.



Achieve the maximum benefits of Adequan® i.m. (polysulfated glycosaminoglycan)

Dosing and Administration

- Administer 1 intramuscular injection (500 mg)
- Every 4 days
- For 7 treatments
- Consult with your veterinarian regarding any questions on dosing

For Example:



Adequan® i.m. Indications

Adequan® i.m. is recommended for the intramuscular treatment of non-infectious degenerative and/or traumatic joint dysfunction and associated lameness of the carpal and hock joints in horses.

When assessing an FDA approved product

- Some veterinary medical devices may appear to be similar to pharmaceuticals. These devices have limited FDA oversight to assure quality controls, purity, potency, stability and sterility⁴
- According to the American Association of Equine Practitioners (AAEP), medical devices are not equivalent to FDA-approved veterinary drug products⁴
- Discuss with your veterinarian appropriate treatment options for degenerative joint disease

Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian. Each 5 mL contains 500 mg Polysulfated Glycosaminoglycan.



Adequan® i.m. Single-Dose

Brand of Polysulfated Glycosaminoglycan (PSGAG) Solution 500 mg/5 mL For Intramuscular Use In Horses

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

DESCRIPTION: Each 5 milliliters of Adequan® i.m. contains 500 mg of Polysulfated Glycosaminoglycan and Water for Injection q.s. Sodium Hydroxide and/or Hydrochloric Acid added when necessary to adjust pH. Sodium Chloride may be added to adjust tonicity.

PHARMACOLOGY: Polysulfated Glycosaminoglycan is chemically similar to the glycosaminoglycans in articular cartilage matrix. PSGAG is a potent proteolytic enzyme inhibitor and diminishes or reverses the pathologic processes of traumatic or degenerative joint disease which result in a net loss of cartilage matrix components. PSGAG improves joint function by reducing synovial fluid protein levels and increasing synovial fluid hyaluronic acid concentration in traumatized equine carpal and hock joints.

INDICATIONS: Adequan® i.m. is recommended for the intramuscular treatment of non-infectious degenerative and/or traumatic joint dysfunction and associated lameness of the carpal and hock joints in horses.

DOSAGE AND ADMINISTRATION: The recommended dose of Adequan® i.m. in horses is 500 mg every 4 days for 28 days intramuscularly. The injection site must be thoroughly cleansed prior to injection. Do not mix Adequan® i.m. with other drugs or solvents.

CONTRAINDICATIONS: There are no known contraindications to the use of intramuscular Polysulfated Glycosaminoglycan.

WARNINGS: Do not use in horses intended for human consumption. Not for use in humans. Keep this and all medications out of the reach of children.

PRECAUTIONS: The safe use of Adequan® i.m. in horses used for breeding purposes, during pregnancy, or in lactating mares has not been evaluated.

ANIMAL SAFETY: Toxicity studies were conducted in horses. Doses as high as 2,500 mg were administered intramuscularly to 6 horses twice a week for 12 weeks. This dosage is 5 times the recommended dosage and 3 times the recommended therapeutic regimen. Clinical observations revealed no soreness or swelling at the injection site or in the affected joint. No animal had any clinical or laboratory evidence of toxicity.

STORAGE CONDITIONS: Store at 20° - 25°C (68° - 77°F); excursions permitted to 15° - 30°C (59° - 86°F) (See USP Controlled Room Temperature). Discard unused portion. Dispose of spent needles in accordance with all federal, state and local environmental laws.

HOW SUPPLIED: Adequan® i.m. solution, 500 mg/5 mL is available in 5 mL glass vials, packaged in boxes of 7.

LUITPOLD PHARMACEUTICALS, INC. Animal Health Division Shirley, NY 11967, (631) 924-4000, 800-458-0163, Made in U.S.A.

NADA #140-901, Approved by FDA IN 99501, Rev. 10/08 MG #7560



Adequan® i.m. Multi-Dose

Brand of Polysulfated Glycosaminoglycan (PSGAG) Solution 100 mg/mL in 20 mL, 30 mL, and 50 mL Preserved Multi-Dose Vials For Intramuscular Use In Horses Only. Not for Intra-Articular Use.

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

DESCRIPTION: Each mL contains Polysulfated Glycosaminoglycan 100 mg, Benzyl Alcohol 0.9% v/v as a preservative, 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 glycosaminoglycans in articular cartilage matrix. PSGAG is a potent proteolytic enzyme inhibitor and diminishes or reverses the pathologic processes of traumatic or degenerative joint disease which result in a net loss of cartilage matrix components. PSGAG improves joint function by reducing synovial fluid protein levels and increasing synovial fluid hyaluronic acid concentration in traumatized equine carpal and hock joints.

INDICATIONS: Adequan® i.m. Multi-Dose is recommended for the intramuscular treatment of non-infectious degenerative and/or traumatic joint dysfunction and associated lameness of the carpal and hock joints in horses.

DOSAGE AND ADMINISTRATION: The recommended dose of Adequan® i.m. Multi-Dose in horses is 500 mg every 4 days for 28 days intramuscularly. The injection site must be thoroughly cleansed prior to injection. Do not mix Adequan® i.m. Multi-Dose with other drugs or solvents.

CONTRAINDICATIONS: There are no known contraindications to the use of intramuscular Polysulfated Glycosaminoglycan.

WARNINGS: Do not use in horses intended for human consumption. Not for use in humans. Keep this and all medications out of the reach of children.

PRECAUTIONS: The safe use of Adequan® i.m. Multi-Dose in horses used for breeding purposes, during pregnancy, or in lactating mares has not been evaluated.

SAFETY AND EFFICACY: Safety and efficacy studies utilizing Adequan® i.m. Multi-Dose were not performed. Adequan® i.m. Multi-Dose was approved based on the conclusion that the safety and effectiveness of Adequan® i.m. Multi-Dose will not differ from that demonstrated for the original formulation of Adequan® i.m.

ANIMAL SAFETY: Animal Safety studies utilizing Adequan® i.m. Multi-Dose were not performed. Safety studies were conducted in horses using the single dose formulation. Doses as high as 2,500 mg were administered intramuscularly to 6 horses twice a week for 12 weeks. This dosage is 5 times the recommended dosage and 3 times the recommended therapeutic regimen. Clinical observations revealed no soreness or swelling at the injection site or in the affected joint. No animal had any clinical or laboratory evidence of toxicity.

STORAGE CONDITIONS: Store at 20°-25°C (68°-77°F); excursions permitted to 15°-30°C (59°-86°F) (See USP Controlled Room Temperature). Dispose of spent needles in accordance with all federal, state and local environmental laws

HOW SUPPLIED: Adequan® i.m. Multi-Dose solution, 100 mg/mL is available in 20 mL, 30 mL and 50 mL glass vials, packaged in boxes of 1.

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NADA #140-901, Approved by FDA IN92901 Rev. 10/08 MG# 28493

Available sizes

- Adequan[®] i.m. (polysulfated glycosaminoglycan) 5 mL Vial Packaged 7 vials per box
- Adequan[®] i.m. (polysulfated glycosaminoglycan) 50 mL Vial Packaged 1 vial per box



Restricted to use by or on the order of a licensed veterinarian.

To learn more, visit www.adequan.com.

Ordering options for Veterinarians

• By phone: 1-800-458-0163

• Online: www.adequan.com

Please see accompanying Full Prescribing Information.





- Proven to reverse non-infectious degenerative joint disease and improve joint function of the carpal and hock joints¹
- The ONLY FDA-approved equine intramuscular Polysulfated Glycosaminoglycan on the market¹
- Backed by efficacy and safety studies reviewed by the FDA¹

Studies have not been conducted to establish safety in breeding horses. WARNING: Do not use in horses intended for human consumption. Not for use in humans. Keep this and all medication out of the reach of children.

References

1. Adequan® i.m. [package insert]. Shirley, NY: Luitpold Animal Health; 2008. 2. Burba DJ, Collier MA, Default LE, Hanson-Painton O, Thompson HC, Holder CL: In vivo kinetic study on uptake and distribution of intramuscular tritium-labeled polysulfated glycosaminoglycan in equine body fluid compartments and articulary cartilage in an osteochondral defect model. The Journal of Equine Veterinary Science 1993; 696-703. 3. Freedom of Information Summary, Adequan® i.m. NADA 140-901 http://www.fda.gov/animalveterinary/products/approvedanimaldrugproducts/foiadrugsummaries/ucm054843.htm Accessed October 26, 2010. 4. The Biological and Therapeutic Agents Committee. Medical Devices: A White Paper on Medical Devices in Equine Medicine. http://www.aaep.org/custdocs/White%20Paper%20on%20Medical%20Devices%20in%20 Equine%20Medicine.pdf Accessed February 19, 2016.



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