

Not all products are created equally

FDA-approved

FDA-approved drug requirements

Clinical safety & efficacy Consistent formulation

Advertising submission



Only one FDA-approved polysulfated glycosaminoglycan

No generic equivalent











Equine Hyaluronate Sodium (HAs)

Equine Hyaluronate Sodium (HAs)

Brand name and generic Rx products
A few examples: HYVISC® (hyaluronate sodium)
LEGEND® (hyaluronate sodium)
HYALOVET® (hyaluronate sodium)











Medical Devices

Medical Devices

None are FDA-cleared joint treatments

A few examples: ICHON™ • Chondroprotec® • HYCOAT®

TRANSCEND™ • Map™ 5 • Pentosan Polysulfate • Polyglycan®



Not FDA-required, but recommended









Compounded Injectables

Compounded Injectables

Special-case formulations

A few examples: Compounded acetyl-d-glucosamine injection • Compounded HA injection "Cocktail" injections of HA, chondroitin, glucosamine











Supplements

Supplements

For general health, not disease treatment

A few examples: Summit Joint Performance®
MoveX® • Platinum® • Conquer® • VitaFlex®
SmartFlex® • And many more









INDICATIONS: For the intramuscular treatment of non-infectious degenerative and/or traumatic joint dysfunction and associated lameness of the carpal and hock joints in horses. 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. WARNING: 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. CAUTION: Federal law restricts this drug to use by or on the order of a licensed veterinarian.

Ask your veterinarian about the difference

	Clinical safety & efficacy	FDA-approved drug requirements Consistent formulation	Advertising submission
Adequan i.m.® polysulfated glycosaminoglycan	Must be proven in clinical trials and studies before going to market. No generic PSGAGs are approved by the FDA, so there is no other product just like Adequan® but cheaper.	Manufacturer must acquire active ingredient from an FDA-inspected source, adhere to Good Manufacturing Practices , verify drug quality and purity, and maintain detailed consistency records for each batch.	Must submit all marketing , promotional and educational pieces to the FDA upon publication or dissemination.
Equine Hyaluronate Sodium (HAs)	Brand name and generic products must be proven in clinical trials and studies before going to market.	Manufacturer must acquire active ingredient from an FDA-inspected source, adhere to Good Manufacturing Practices, verify drug quality and purity, and maintain detailed consistency records for each batch.	Must submit all marketing, promotional and educational pieces to the FDA upon publication or dissemination.
Medical Devices	Regulated differently by the FDA than prescription drugs, with different types requiring different levels of approval. Because devices may not have been clinically tested, they cannot be considered as "off-label" or "generic" replacements for drugs.	Manufacturer must adhere to Quality System Regulations, but the requirements for verifying ingredient sources and batch consistency are different from FDA-approved drugs.	Not required to submit marketing, promotional or educational materials. Should not be promoted as drugs.
Compounded Injectables	Not FDA-approved, although FDA-approved drugs should be used in formulation. Not considered generic drugs.	Use a compounding pharmacist who follows FDA Guidelines for Good Compounding Practices.	Not required to submit marketing, promotional or educational materials.
Supplements	Not regulated by the FDA. No pre-market approval required. Not intended to treat, prevent or cure disease and cannot make direct medical claims, such as "reduces pain."	No requirement for manufacturers to verify ingredient source, processes, product quality or batch consistency.	Not required to submit marketing, promotional or educational materials. Cannot make medical claims.

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

Please see accompanying Full Prescribing Information or visit www.adequan.com. Trademarks are the property of their respective owners.



Nothing else compares

The only FDA-approved PSGAG for arthritis in horses, also known as degenerative joint disease, Adequan® i.m. has been proven to:1,2

REDUCE inflammation RESTORE synovial joint lubrication REPAIR joint cartilage the disease process

Discover if Adequan® i.m. is the right choice. Learn more at **Adequan.com**.

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

- 1. Adequan® i.m. (polysulfated glycosaminoglycan), Package Insert. American Regent, Inc.
- 2. Burba DJ, Collier MA, DeBault 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 articular cartilage in an osteochondral defect model. *J Equine Vet Sci* 1993; 13: 696-703.

What the experts are saying

"I try to talk to clients, telling them I feel it's a bigger bang for your buck if you go with the intramuscular Adequan [than unproven supplements]."—Dr. Robin Dabareiner, Texas A&M professor before working at Waller Equine Hospital.

"If I'm going to recommend that you spend your money, I want to have some research or solid proof that I'm not just throwing your money away."—Dr. Zach Loppnow, an equine surgery resident at Steinbeck Country Equine Clinics in California.

Each of these experts is a paid consultant of American Regent, Inc. The opinions expressed by the consultants may not be the opinions of American Regent Animal Health or American Regent, Inc.

So what?

FDA-approved animal drugs are required to provide proof of safety and efficacy, consistent formulation, and truthful advertising and labeling. Turn the page to see how this may affect product choice.

Product label



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 (PSGAG) 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); (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 (100 mg/mL) in a 5 mL single dose glass vial.

NDC 10797-995-70

5 mL Single Dose Vials

AMERICAN REGENT, INC. ANIMAL HEALTH Shirley, NY 11967 (1-888-354-4857) Made in U.S.A. IN99501 Rev. 9/2021 MG #44455

Packaged 7 vials per box

Approved by FDA under NADA # 140-901



MULTI-DOSE

Solution 100 mg/mL in a 50 mL Preserved Multi-Dose Vial 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 (PSGAG) 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. The solution is clear, colorless to slightly yellow.

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 hook 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: Practice aseptic techniques in withdrawing each dose to decrease the possibility of post-injection bacterial infections. Adequately clean and disinfect the stopper prior to entry with a sterile needle and syringe. Use only sterile needles, and use each needle only once.

The vial stopper may be punctured a maximum of 10 times.

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). Avoid prolonged exposure to temperatures \geq 40°C (104°F).

Use within 28 days of first puncture and puncture a maximum of 10 times. Dispose of spent needles in accordance with all federal, state and local environmental laws.

HOW SUPPLIED: Adequan® i.m. Multi-Dose solution, 5,000 mg/50 mL (100 mg/mL) in 50 mL multi-dose glass vials.

NDC 10797-959-01 50 mL Multi-Dose Vials Packaged 1 vial per box

 AMERICAN REGENT, INC.
 Made in U.S.A.

 ANIMAL HEALTH
 IN959

 Shirley, NY 11967
 Rev. 9/2021

 (1-888-354-4857)
 MG #44453