

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

Adequan® i.m.

polysulfated glycosaminoglycan

SINGLE DOSE

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 Packaged 7 vials per box

AMERICAN REGENT, INC.
ANIMAL HEALTH
Shirley, NY 11967
(1-888-354-4857)

Approved by FDA under NADA #140-901

Made in U.S.A.

IN 99501
Rev. 9/2021
MG # 44455

Container Label

NDC 10797-995-01

Adequan® i.m.
polysulfated glycosaminoglycan

500 mg/5 mL (100 mg/mL)

For Intramuscular Use In Horses

Store at 20°-25°C (68°-77°F) (See USP Controlled Room Temperature).

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NDC 10797-995-01

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500 mg/5 mL (100 mg/mL)
5 mL Single Dose Vial

For Intramuscular Use In Horses
AMERICAN REGENT, INC. ANIMAL HEALTH
Shirley, NY 11967

Store at 20° to 25°C
(68° to 77°F).
(See USP Controlled
Room Temperature).

See package insert
for full directions.

Approved by FDA
under NADA # 140-901
Rev. 09/2021

Lot / Exp.

Carton Labeling

NDC 10797-995-70

Adequani.m.®
polysulfated glycosaminoglycan

PSGAG Injection

500 mg/5 mL (100 mg/mL)

For the intramuscular use in horses.

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

SINGLE DOSE VIALS

7 Vials (5 mL each)

AMERICAN REGENT, INC., ANIMAL HEALTH
Shirley, NY 11967
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COATING FREE AREA

NDC 10797-995-70





Adequan i.m.[®]
 polysulfated glycosaminoglycan
PSGAG Injection
500 mg/5 mL (100 mg/mL)

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

SINGLE DOSE VIALS
 7 Vials (5 mL) 

AMERICAN REGENT, INC., ANIMAL HEALTH
 Shirley, NY 11967
 1-888-354-4637

Approved by FDA
 under NADA # 140-901

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

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.

STORAGE CONDITIONS: Store at 20° to 25°C (68° to 77°F). (See USP Controlled Room Temperature).

Discard unused portion.

See bottom for lot # and expiration date.



Adequan i.m.[®]
 polysulfated glycosaminoglycan

500 mg/5 mL (100 mg/mL)



NDC 10797-995-70



Adequan i.m.[®]
 polysulfated glycosaminoglycan
PSGAG Injection
500 mg/5 mL (100 mg/mL)

For intramuscular use in horses
 For the treatment of non-infectious degenerative
 and/or traumatic joint dysfunction and associated
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 7 Vials (5 mL) 

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 Shirley, NY 11967
 1-888-354-4637

Approved by FDA
 under NADA # 140-901

DESCRIPTION: Each vial contains 500 mg polysulfated glycosaminoglycan (PSGAG) in Water for Injection, Sodium Hydroxide and/or Hydrochloric Acid added when necessary to adjust pH. Sodium Chloride may be added to adjust tonicity.

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 cleaned prior to injection. Do not mix Adequan[®] i.m. with other drugs or solvents.

See package insert for full directions.

Rev. 09/2021

See bottom for lot # and expiration date.

Serialization Label



LOT 0000
EXP 01-2999

GTIN 00310797995701
SN 100000344586

ADEQUAN I.M.

polysulfated glycosaminoglycan injection, solution

Product Information

Product Type	PRESCRIPTION ANIMAL DRUG	Item Code (Source)	NDC:10797-995
Route of Administration	INTRAMUSCULAR		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
POLYSULFATED GLYCOSAMINOGLYCAN (UNII: 268AW7000T) (POLYSULFATED GLYCOSAMINOGLYCAN - UNII:268AW7000T)	POLYSULFATED GLYCOSAMINOGLYCAN	100 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:10797-995-70	7 in 1 CARTON		
1	NDC:10797-995-01	5 mL in 1 VIAL, SINGLE-USE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NADA	NADA140901	11/01/1989	

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: 10/2023

American Regent, Inc.