

Pr **Adequan® I.M.** DIN 01910051

**PSGAG 100 mg/mL**

5 mL Single Dose Vial *Fiole à dose unique*  
For Veterinary Use Only *Usage vétérinaire seulement*

Dist. by: *par:* Distributor Name  
Distributor Address  
for: *pour:* AMERICAN REGENT, INC.  
ANIMAL HEALTH  
Shirley, NY 11967

995-01C  
Rev. 8/19C



LOT  
EXP

Label Size: 2.5" x 0.75" Part Number: VL995-01CRev8-19C Code: RSS (01) 103 10797995319

### Label

**Please review this proof and clearly mark any modifications and corrections required.**

Color Key

Customer: American Regent, Inc.

- DieCut
- Pantone 348
- Black
- Datalase1
- Datalase2

**Please Check One:**  Proof Approved. Proceed with Order.  Change as Noted. New Proof Required.

Customer Sign Off \_\_\_\_\_ Date \_\_\_\_\_

Internal QC Approval: \_\_\_\_\_

Please Check a Rewind Direction



- Test adhesive substrate on container?  Yes  No
- Test label fit to container?  Yes  No
- Is the job sheeted?  Yes  No
- Is waste matrix stripped?  Yes  No
- Is perforation required?  Yes  No
- Is a backslit required?  Yes  No

- Is unvarnished area OK?  Yes  No
- Varnish type?  Gloss  Matte  Other
- Lamination type?  Gloss  Matte
- Are labels imprinted?  Yes  No
- Did you approve UPC position?  Yes  No
- Plastic core required?  Yes  No

**Matte coatings can be prone to scratching or scuffing. Gloss coatings are more durable. We will gladly supply samples of a specified coating for your testing.**

**Please refer to a Pantone Swatch Guide for accurate color match.** This color will not match your final printed piece.

This **MatchPrint Proof** will be used at press to match any CMYK process artwork to the final printed piece.

**This Proof may show the Trapping of colors.** Trapping is the overlapping of colors where objects meet.

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Proof by: **Gintzler International**, A Resource Label Group Co. / 100 Lawrence Bell Drive, Buffalo, NY 14221

COATING FREE AREA

DIN 01910051  
**Pr Adequan® I.M.**  
**PSGAG Sterile Injection 100 mg/mL**



**FOR VETERINARY USE ONLY**  
**FOR INTRAMUSCULAR ADMINISTRATION (I.M.)**  
**Contains 7 Vials (5 mL each)**

**SINGLE DOSE VIALS**

**WARNINGS:** This drug is not to be administered to horses that are to be slaughtered for use in food. Keep out of the reach of children.

**CAUTION:** Not intended for use in breeding animals as effects on fertility and reproductive function in mares and stallions have not been studied. Avoid inadvertent intravascular administration.

**AMERICAN REGENT, INC.**  
**ANIMAL HEALTH**  
 Shirley, NY 11967  
 (1-800-458-0163)

Distributed by:  
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Each vial contains 500 mg PSGAG in Water for Injection. Sodium hydroxide and/or hydrochloric acid added as necessary to adjust pH. Sodium chloride may be added to adjust tonicity.

**INDICATIONS:** For the treatment of non-infectious degenerative and/or traumatic joint dysfunction and associated lameness in horses. See package insert for full directions.

Store at controlled room temperature 18-25°C (64-77°F). Single dose vial—Discard unused portion.

995-70C  
 Rev. 8/19C



COATING FREE AREA



DIN 01910051  
**Pr Adequan® I.M.**  
**Injection stérile de PSGAG 100 mg/mL**

**POUR USAGE VÉTÉRINAIRE SEULEMENT**  
**INTRAMUSCULAIRE (I.M.)**  
**POUR ADMINISTRATION**  
**INTRAMUSCULAIRE (I.M.)**  
**Contient 7 Flacons (5 mL chacun)**  
**FLACON UNIDOSE**

**MISES EN GARDE:** Cette drogue ne doit pas être administrée aux chevaux devant être abattus à des fins alimentaires. Garder hors de la portée des enfants. **PRÉCAUTIONS:** Ne pas utiliser chez les animaux de reproduction; les effets sur la fertilité et les fonctions reproductrices n'ayant pas été étudiés chez la jument et l'étalon. Éviter une administration intravasculaire accidentelle.

Distribué par:  
 Distributor Name  
 Distributor Address

Entreposer à une température contrôlée de 18-25°C (64-77°F). Jeter la portion non-utilisée.

**INDICATIONS:** Pour le traitement des dysfonctionnements traumatiques et/ou dégénératifs, non infectieux, des articulations, et autres boiteries associées chez le cheval. Voir le dépliant interne pour de plus amples informations.

Chaque flacon contient 500 mg de PSGAG et de l'eau pour injection. Peut aussi contenir de l'hydroxyde de sodium et/ou de l'acide chlorhydrique pour ajuster le pH; le chlorure de sodium peut être ajouté pour ajuster la tonicité.



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**job information**

**Customer:** AMERICAN REGENT, INC.  
**Customer #:** XXXXX  
**Item:** AmericanReg\_PC995-70C\_AdqIM\_Canada\_7vials\_Carton AT  
**Epp #:** 124757 AT  
**Cad# / Size:** 3.8437 x 1.875 x 5.25"

**ink colors and finishes**

- DIELINE
- COATING FREE
- CMYK
- ICS 342
- PMS 1797

**history**

**Version#**  
**Printed** XXXXXX  
**Rev-1:** 8-6-2019  
**Rev-2:** 8-7-2019  
**Rev-3:**  
**Rev-4:**  
**Rev-5:**  
**Rev-6:**  
**Rev-7:**  
**Rev-8:**  
**Rev-9:**  
**Rev-10:**  
**Rev-11:**  
**Rev-12:**

**proof reading**

QC: \_\_\_\_\_ date: \_\_\_\_\_

**client approvals**

**THIS PROOF MUST BE SIGNED AND RETURNED**  
 Job will not be released for production unless signed off by client

approval: \_\_\_\_\_  
 approval: \_\_\_\_\_  
 date: \_\_\_\_\_  
 Approved  With Corrections



Pr

DIN 01910051

# Adequan® I.M.

Polysulfated Glycosaminoglycan Injection  
100 mg/mL



## FOR VETERINARY USE ONLY

### FOR INTRAMUSCULAR USE IN HORSES

**Description:** Each mL of Adequan® I.M. contains 100 mg Polysulfated Glycosaminoglycan (PSGAG) and Water for Injection q.s. Sodium hydroxide and/or hydrochloric acid added as necessary to adjust pH. Sodium chloride may be added to adjust tonicity.

**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 joints.

**Toxicity:** 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 or a total of 21 injections. This dosage is 5 times the recommended dosage and approximately 3 times the recommended therapeutic regimen. Clinical observations revealed no soreness or swelling at the injection site or in the affected joint. No animal showed any evidence of abnormality that was related to Adequan® I.M. treatment as determined by clinical observation and a battery of laboratory tests.

From 100,000 doses used clinically, the reported incidence of side effects is 0.001% (1 case). This reaction consisted of a transient joint flare, occurring within 24 hours of injection, and resolving within 24 hours with anti-inflammatory therapy.

**Indications:** Adequan® I.M. is recommended for the treatment of non-infectious degenerative and/or traumatic joint dysfunction and associated lameness in horses.

**Contraindications:** Do not use Adequan® I.M. in horses demonstrating hypersensitivity to PSGAG.

**Warnings:** This drug is not to be administered to horses that are to be slaughtered for use in food. Keep out of the reach of children.

**Dosage and Administration:** The recommended dose of Adequan® I.M. is 500 mg (1 vial) per 1000 lbs. body weight, given intramuscularly every 4 days for a total of 8 injections over a 28 day period. The injection site must be thoroughly cleansed prior to injection. Do not mix Adequan® I.M. with other drugs or solvents. For intramuscular use only — avoid inadvertent intravascular administration.

**Adverse Reactions:** There are no known adverse reactions associated with the use of Adequan® I.M.

**Caution:** Avoid inadvertent intravascular administration. Not intended for use in breeding animals as effects on fertility and reproductive function in mares and stallions have not been studied.

**How Supplied:** Adequan® I.M., PSGAG 100 mg/mL, is available in 5 mL single dose vials packaged in boxes of 7.

**Storage Conditions:** Store at controlled room temperature 18-25°C (64-77°F). Discard unused portion.

AMERICAN REGENT, INC.

ANIMAL HEALTH

Shirley, N.Y. 11967

(1-800-458-0163)

Distributed by: **Distributor Name**

**Distributor Address**

**City, Province, Postal Code**

IN99501C  
Rev. 8/19C  
MG #15651



Pr

DIN 01910051

# Adequan® I.M.

Injection de Polysulfate de Glycosaminoglycan  
100 mg/mL



## POUR USAGE VETERINAIRE SEULEMENT

### POUR INJECTION INTRAMUSCULAIRE CHEZ LE CHEVAL

**Description:** Chaque mL d'Adequan contient 100 mg de Polysulfate de Glycosaminoglycan (PSGAG) et de l'eau pour injection q.s. Si nécessaire, le pH est ajusté avec de l'hydroxyde de sodium et/ou de l'acide chlorhydrique. Le chlorure de sodium peut être ajouté pour ajuster la tonicité.

**Pharmacologie:** Le Polysulfate de Glycosaminoglycan est chimiquement similaire aux mucopolysaccharides du tissu cartilagineux. Il est un puissant inhibiteur de la protéolyse enzymatique et diminue ou renverse le processus résultant en la perte des mucopolysaccharides cartilagineux. Le PSGAG améliore la fonction articulaire en stimulant l'activité de la membrane synoviale, en réduisant le niveau des protéines synoviales et en augmentant la viscosité du liquide synovial dans les articulations traumatisées du cheval.

**Toxicité:** Des études de toxicité furent effectuées chez des chevaux. Des doses aussi élevées que 2,500 mg furent administrées à 6 chevaux par voie intramusculaire, deux fois par semaine, pendant 12 semaines ou un total de 21 injections (une à tous les 4 jours). Ce dosage constitue 5 fois la dose recommandée et approximativement 3 fois la durée du traitement recommandée. Lors d'examens cliniques, on n'a observé aucune douleur ou enflure au site d'injection ou dans l'articulation affectée. Les examens cliniques et les tests de laboratoire n'ont révélé aucune anomalie liée à l'administration d'Adequan I.M. Suite à l'utilisation clinique de 100,000 doses, des effets secondaires furent rapportés dans un seul cas (0.001%) et ils furent caractérisés par l'apparition dans les 24 heures suivants l'injection, d'une inflammation transitoire de l'articulation. Suite à un traitement anti-inflammatoire, la condition revint à la normale dans les 24 heures.

**Indications:** Adequan I.M. est recommandé pour le traitement des dysfonctionnements traumatiques et/ou dégénératifs, non infectieux, des articulations, et autres boiteries associées chez le cheval.

**Contre-indications:** Ne pas utiliser chez les chevaux hypersensibles au PSGAG.

**Mises en garde:** Cette drogue ne doit pas être administrée aux chevaux devant être abattus à des fins alimentaires. Garder hors de la portée des enfants.

**Dosage et administration:** Le dosage recommandé d'Adequan I.M. est de 500 mg (1 flacon) par 1000 lbs de poids vif, par voie intramusculaire, à tous les 4 jours pour un total de 8 injections sur une période de 28 jours. Le site d'injection doit être nettoyé avec précaution avant l'injection. Ne pas mélanger l'Adequan I.M. avec d'autres drogues ou solvants. Pour usage intramusculaire seulement — éviter une administration intravasculaire accidentelle.

**Réactions adverses:** On n'a rapporté aucune réactions adverse suite à l'usage de l'Adequan I.M.

**Précautions:** Ne pas utiliser chez les animaux de reproduction; les effets sur la fertilité et les fonctions reproductrices n'ayant pas été étudiés chez la jument et l'étalon. Éviter une administration intravasculaire accidentelle.

**Présentation:** Adequan® I.M., PSGAG 100 mg/mL, est disponible en flacons à dose unique de 5 mL vendu en boîtes de 7.

**Conditions d'entreposage:** Entreposer à une température contrôlée de 18-25 °C (64-77 °F). Jeter la portion non-utilisée.

AMERICAN REGENT, INC.

SANTÉ ANIMALE

Shirley, N.Y. 11967

(1-800-458-0163)

Distribué par: **Nom du distributeur**  
**Adresse du distributeur**  
**ville, province, code postal**