PARTICULARS TO APPEAR ON THE OUTER PACKAGE

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Adequan 100 mg/ml Solution for Injection

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Polysulphated Glycosaminoglycan (PSGAG)

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

7 x 5ml

5. TARGET SPECIES

Horse

6. INDICATION(S)

For treatment of lameness in horses due to traumatic or degenerative aseptic joint disease and acute superficial digital flexor tendonitis.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Dosage: Inject 5 ml by deep intra-muscular injection every four days for a total of seven injections.
Read the package leaflet before use.
Does not contain an antimicrobial preservative. For single use only

8. WITHDRAWAL PERIOD

Meat and offal - Zero days

9. SPECIAL WARNING(S), IF NECESSARY

If signs or symptoms of hypersensitivity occur, the treatment must be discontinued.
Do not use in pregnant animals.
The product may potentiate the action of anticoagulant preparations
Do not mix with other drugs due to possible incompatibilities.

In the case of overdosage, blood coagulation time, as measured by activated partial thromboplastin time, may be prolonged for a few hours after the injection.
Do not use in cases of advanced renal or hepatic disease.

User Warnings
Care should be taken to avoid accidental self-injection.
In the case of accidental eye or skin contact, wash the affected area thoroughly with copious amounts of water. If irritation persists, seek medical attention.

10. EXPIRY DATE

The expiry date refers to the last date of that month

11. SPECIAL STORAGE CONDITIONS

Keep the container in the outer carton.
Do not store above 25 ºC.
Protect from light.

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Dispose of any unused product and empty containers in accoradance with guidance from your local waste regulation authority. **13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE** *[Distribution category]*

FOR ANIMAL TREATMENT ONLY

UK	Ireland
POM-V To be supplied only on veterinary prescription	POM Prescription only medicine

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

KEEP OUT OF THE REACH AND SIGHT OF CHILDREN

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

UK	Ireland
Aniserve GmbH Geyerspergerstr. 27 80689 Muenchen Germany	Daiichi Sankyo Altkirch SARL 39, rue de 3-ème Zouaves BP 60005 68131 Altkirch Cedex France

Veterinary Medicinal product authorised for use in the UK and Ireland

16. MARKETING AUTHORISATION NUMBER(S)

UK	Ireland
Vm 48469/4001	VPA10404/001/001

17. MANUFACTURER'S BATCH NUMBER

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS {NATURE/TYPE}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Adequan 100 mg/ml Solution for Injection

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Polysulphated Glycosaminoglycan (PSGAG) 100 mg/ml

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

5ml

4. ROUTE(S) OF ADMINISTRATION

For intramuscular injection in horses **5. WITHDRAWAL PERIOD**

Meat and offal - Zero days

6. BATCH NUMBER

7. EXPIRY DATE

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

FOR ANIMAL TREATMENT ONLY

Do not store above 25°C. Protect from light.
Keep the container in the outer carton. Read the package leaflet before use.

Veterinary medicinal product authorised for use in the UK and Ireland.

POM-V
Vm 48469/4001
To be supplied only on veterinary prescription

[Include information under these headings as it appears in the SPC]

PACKAGE LEAFLET FOR:

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing Authorisation Holder
Aniserve GmbH
Geyerspergerstr. 27
80689 Muenchen
Germany

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Adequan 100 mg/ml Solution for Injection

3. STATEMENT OF THE ACTIVE SUBSTANCE (S) AND OTHER INGREDIENTS

Polysulphated Glycosaminoglycan (PSGAG) 100 mg/ml
Clear, colourless to pale yellow aqueous solution.

4. INDICATION(S)

For treatment of lameness in horses due to traumatic or degenerative aseptic joint disease and acute superficial digital flexor tendonitis.

5. CONTRAINDICATIONS

Do not use in animals with known hypersensitivity to the active ingredient.
Do not use in cases of advanced renal or hepatic disease.
Do not use in pregnant animals.
Any solution remaining in the vial after withdrawal of the required dose should be discarded.
If you notice any serious effect or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

6. ADVERSE REACTIONS

None known

7. TARGET SPECIES

Horses
For animal treatment only

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

The contents of a 5 ml vial are injected by deep intra-muscular injection every four days for a total of seven injections.

9. ADVICE ON CORRECT ADMINISTRATION

This product does not contain an antimicrobial preservative. Any solution remaining in the vial after withdrawal of the required dose should be discarded.
For single use only

10. WITHDRAWAL PERIOD(S)

Meat and offal - Zero days

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the reach and sight of childrenDo not store above 25 ºC.
Protect from light.
Keep the vial in the carton
Do not use after the expiry date which is stated on the label and carton
The expiry date refers to the last date of that month

12. SPECIAL WARNING(S)

Special precautions for use in animals
For intramuscular administration only.
If signs or symptoms of hypersensitivity occur, the treatment must be discontinued.

User Warnings
Care should be taken to avoid accidental self-injection.
In the case of accidental eye or skin contact, wash the affected area thoroughly with copious amounts of water. If irritation persists, seek medical attention.

Interaction with other medicinal products and other forms of interaction
Adequan may potentiate the action of anticoagulant preparations.

Overdose (symptoms, emergency procedures, antidotes)
In the case of overdosage, blood coagulation time, as measured by activated partial thromboplastin time, may be prolonged for a few hours after the injection.
For Animal Treatment Only

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Dispose of any unused product and empty containers in accoradance with guidance from your local waste regulation authority.

14. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

15. OTHER INFORMATION

The active ingredient is a semisynthetic substance, similar to the physiological mucopolysaccharides which are the basic component of cartilage. In healthy joints, the synthesis and degradation of cartilage is in equilibrium. In traumatic and degenerative joint disease, the natural equilibrium between synthesis and degradation of the cartilage is disturbed. This results in an increased degradation which further results in a loss of glycosaminoglycans.

Adequan inhibits cartilage degrading enzymes (various glycanohydrolases and glycosidases), stimulates the proteoglycan synthesis and hyaluronic acid synthesis and thus increases the viscosity of the synovia.
Various *in-vitro* studies and animal models have been employed to investigate the anti-osteoarthritis activities of PSGAG.

The finding, that the development and progression of degenerative joint diseases were inhibited in all species and models tested, indicates that PSGAG will also therapeutically influence degenerative or traumatic joint diseases in horses.

MA Numbers	ILegal Catergories
UK: **Vm** 48469/4001	POM-V To be supplied only on veterinary prescription
IE: VPA10404/001/001	POM Prescription only medicine

Veterinary Medicinal product authorised for use in the UK and Ireland

Gavin Hall
Approved: 06 July 2024