PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARDBOARD BOX

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Adequan IM 500 mg/5 ml solution for injection

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Polysulphated glycosaminoglycan 500 mg/5 ml

3. PHARMACEUTICAL FORM

4. PACKAGE SIZE

Cardboard box with 7 vials.

5. TARGET SPECIES

Horses.

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.
1 IM injection every 4 days.

8. WITHDRAWAL PERIOD

Withdrawal period (meat): zero days.
Do not use in mares producing milk for human consumption.

9. SPECIAL WARNING(S), IF NECESSARY

User warnings – please read the package leaflet.

10. EXPIRY DATE

EXP {month/year}
Discard any solution remaining in the vial following the withdrawal of the required dose.

11. SPECIAL STORAGE CONDITIONS

Do not store above 25 °C
Keep the vials in the outer carton
Protect from light

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only.

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

Keep out of the reach and sight of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Daiichi Sankyo Altkirch SARL
39, rue de 3-ème Zouaves
BP 60005
68131 Altkirch Cedex
France

16. MARKETING AUTHORISATION NUMBER(S)

Vm 36483/4002

17. MANUFACTURER'S BATCH NUMBER

BN {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

VIAL

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Adequan IM 500 mg/5 ml solution for injection

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Polysulphated glycosaminoglycan 500 mg/5 ml

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

5 ml vial

4. ROUTE(S) OF ADMINISTRATION

5. WITHDRAWAL PERIOD

Withdrawal period (meat): zero days.
Do not use in mares producing milk for human consumption.

6. BATCH NUMBER

BN {number}

7. EXPIRY DATE

EXP {month/year}

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET

Adequan IM 500 mg/5 ml solution for injection

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

Marketing authorisation holder:
Daiichi Sankyo Altkirch SARL
39, rue de 3-ème Zouaves
BP 60005
68131 Altkirch Cedex
France

Manufacturer for the batch release:
Vericore Ltd
Kinnoull Road
Kingsway West
Dundee
DD2 3XR
UK

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Adequan IM 500 mg/5 ml solution for injection
Polysulphated glycoaminoclycan (PSGAG)

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

Adequan is an injectable solution containing polysulphated glycosaminoglycan 500 mg/5ml.

4. INDICATION(S)

In horses:
For treatment of lameness due to degenerative aseptic joint disease.

5. CONTRAINDICATIONS

Do not administer when a pre-existent tendency to haemorrhage or increased coagulation time is known.
Do not administer within 24 hours after surgery.
Do not use for the treatment of septic arthritis; in this case appropriate treatment such as surgery and/ or antimicrobial therapy should be instigated.
Treatment should not be given in cases of advanced renal or hepatic disease or in cases where there is a history of hypersensitivity to PSGAG.
Reference is also made to point 12.

6. ADVERSE REACTIONS

If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.
On rare occasions, transient local reactions at the injection site may occur.

7. TARGET SPECIES

Horses

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

The contents of a 5 ml vial are injected every four days for a total of seven injections.

9. ADVICE ON CORRECT ADMINISTRATION

Deep intramuscular injection.

10. WITHDRAWAL PERIOD

Withdrawal period (meat): zero days.
Do not use in mares producing milk for human consumption.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the reach and sight of children.
Do not store above 25°C.
Keep the vial in the outer carton.
Protect from light.
Do not use after EXP date stated on the carton.

12. SPECIAL WARNING(S)

Use during pregnancy, lactation:
The safety of the product was not assessed in pregnant and lactating mares. The use of the product during pregnancy and lactation is contraindicated.

Special precautions for use in animals:
This product does not contain an antimicrobial preservative. Any solution remaining in the vial following withdrawal of the required dose should be discarded.
This product must be used with caution in horses suffering with hepatic disease.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
In view of possible sensitization, contact dermatitis and skin irritation any skin contact with the product should be avoided. Wear protective gloves. Avoid self-injection. Self-injection may cause delayed blood coagulation for a few hours. In case of accidental self-injection seek medical advice immediately and show the package leaflet or the label to the doctor.

Overdose (symptoms, emergency procedures, antidotes), if necessary:
In case of overdosage, blood coagulation time, as measured by activated partial thromboplastin time, may be prolonged for 8 hours after injection.

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

August 2010

15. OTHER INFORMATION