SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Adequan IM 500 mg/5 ml solution for injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance: Polysulphated glycosaminoglycan (PSGAG) 500 mg per 5 ml vial

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Solution for injection.
Clear colourless to slightly yellow aqueous solution.

4. CLINICAL PARTICULARS

4.1 Target species

Horses.

4.2 Indications for use, specifying the target species

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

4.3 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 section 4.7.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

i. 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 dysfunction.

ii. 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.

4.6 Adverse reactions (frequency and seriousness)

On rare occasions, transient local reactions at the injection site may occur.

4.7 Use during pregnancy, lactation or lay

The safety of the product was not assessed in pregnant and lactating mares.
The use of the product during pregnancy and lactation is contra-indicated.

4.8 Interaction with other medicinal products and other forms of interaction

Simultaneous use of PSGAG and anticoagulants increases the risk of haemorrhage.
Simultaneous use of PSGAG and nonsteroidal anti-inflammatory drugs (NSAIDs) increases the risk of bleeding in the gastro-intestinal tract.

4.9 Amounts to be administered and administration route

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

4.10 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.

4.11 Withdrawal period(s)

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

5. PHARMACOLOGICALPROPERTIES

Pharmacotherapeutic group: Antiinflammatory and antirheumatic products,
ATCvet code: QM01AX12

5.1 Pharmacodynamic properties

The active ingredient is a semisynthetic substance, similar to the physiological mucopolysaccharides which are the basic components of cartilage.

Polysulphated glycosaminoglycan (PSGAG) inhibits cartilage degrading enzymes (various glycanohydrolases and glycosidases), stimulates the proteoglycan synthesis and hyaluronic acid synthesis and thus increases the viscosity of the synovia.

5.2 Pharmacokinetic particulars

Following a single intramuscular dose of 500 mg per horse, PSGAG is very rapidly absorbed. At 2 hours after administration, maximum serum concentrations of on average 1.9 mg/litre were attained. Thereafter, the concentrations declined with a half-life of 3.9 hours. From 24 to 96 hours after administration, serum levels remained constant around 0.1 mg/litre PSGAG is readily excreted in urine In the synovial fluids, C_{max}-values of about 0.3 to 0.4 mg/litre are observed at a T_{max} of between 2 and 4 hours after dosing. These concentrations decline rapidly.

From data in other animal species it is deduced that PSGAG has affinity for cartilage. Concentrations in cartilage are higher than in synovial fluids or serum. PSGAG is metabolised by removal of the sulphate groups and depolymerisation of the mucopolysaccharide chain. It is excreted with the urine. Less than 1 % is eliminated in the faeces.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Water for injections
Sodium hydroxide or hydrochloric acid (for pH adjustment)
Sodium chloride (for osmolality adjustment)

6.2 Incompatibilities

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

6.3 Shelf life

Shelf-life of veterinary medicinal product as packaged for sale: 3 years.
Shelf-life after first opening the immediate package: discard any solution remaining in the vial following the withdrawal of the required dose.

6.4. Special precautions for storage

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

6.5 Nature and composition of immediate packaging

Cardboard box with 7 neutral glass vials of 5 ml with EPDM rubber stopper.

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

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

7. MARKETING AUTHORISATION HOLDER

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

8. MARKETING AUTHORISATION NUMBER

Vm 36483/4002

9. DATE OF FIRST AUTHORISATION

Date: 20 June 1997

10. DATE OF REVISION OF THE TEXT

Date: January 2015

Approved: 19 January 2015