

## **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. PHARMACOLOGICAL PROPERTIES**

**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**

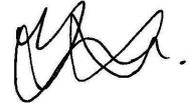
**Vm** 36483/4002

**9. DATE OF FIRST AUTHORISATION**

**Date:** 20 June 1997

**10. DATE OF REVISION OF THE TEXT**

**Date:** January 2015



Approved: 19 January 2015