

# Summary of Product Characteristics

## 1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Adequan 250 mg/ml Solution for Injection

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

### Active Substance

Polysulphated glycosaminoglycan (PSGAG) 250 mg

For a full list of excipients see section 6.1.

## 3 PHARMACEUTICAL FORM

Solution for injection.

Clear, pale yellow aqueous solution.

## 4 CLINICAL PARTICULARS

### 4.1 Target Species

Horse.

### 4.2 Indications for use, specifying the target species

For treatment of lameness in horses due to traumatic or degenerative aseptic joint disease.

### 4.3 Contraindications

Do not use in animals with infected or actively inflamed joints or with severe degradation of joint cartilage.

Do not use in animals with known sensitivity to the active ingredient.

Do not use in cases of advanced renal or hepatic disease.

Do not use in pregnant animals.

### 4.4 Special warnings for each target species

None.

### 4.5 Special precautions for use

#### **Special precautions for use in animals**

In the presence of an active joint inflammation, therapy with a suitable anti-inflammatory agent should be given prior to intra-articular treatment with Adequan. The anti-inflammatory treatment should be discontinued as soon as possible since steroidal and non-steroidal agents may contribute to the degeneration of cartilage.

#### **Special precautions to be taken by the person administering the veterinary medicinal product to animals**

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.

#### **4.6 Adverse reactions (frequency and seriousness)**

After intra-articular injection, reactions in the joint, including joint oedema, may occur after the first injection and occasionally after further injections.

Should an acute inflammation occur, postpone further injections.

If signs or symptoms of hypersensitivity occur, the treatment must be discontinued.

#### **4.7 Use during pregnancy, lactation or lay**

Do not use during pregnancy.

#### **4.8 Interaction with other medicinal products and other forms of interactions**

The product may potentiate the action of anticoagulant preparations.

#### **4.9 Amounts to be administered and administration route**

For intra-articular use only.

Avoid the introduction of contamination during use.

Inject the contents of 1ml ampoule (250 mg/ml) into the affected joint once a week for 5 weeks. The joint area must be shaved, cleansed and sterilized, as for a surgical procedure, to prevent joint infection.

#### **4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary**

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.

#### **4.11 Withdrawal period(s)**

Meat and offal: zero days

### **5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES**

Pharmacotherapeutic group: Antiinflammatory and antirheumatic products, non-steroids. ATC vet code: QM01AX12

#### **5.1 Pharmacodynamic properties**

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.

The product inhibits cartilage degrading enzymes (various glycanohydrolases and glycosidases), stimulates the proteoglycan synthesis and hyaluronic acid synthesis and thus increases the viscosity of the synovial fluid.

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.

#### **5.2 Pharmacokinetic particulars**

Pharmacokinetic studies were carried out in animals (rats and rabbits) and humans with radioactively labelled PSGAG. After intra-articular and intramuscular administration to humans, maximum plasma levels were reached within 30 minutes and decreased by half after 3 to 5 hours.

The intramuscular administration of 125 mg/ml PSGAG to humans indicates that PSGAG has an affinity to cartilage. These levels in cartilage were higher than the values measured in serum or the synovial fluid. While the serum levels decreased within 12 hours, the concentration in cartilage increased up to 24 hours and remained on a plateau at about 5 microgram/g up to 48 hours. Organ distribution and metabolism were investigated in rats and rabbits. In the tissues (kidney, liver, spleen, bone marrow), unchanged PSGAG was detected together with partially depolymerised and desulphated metabolites, which were also eliminated in the urine. Less than 1 per cent of PSGAG was eliminated in the faeces.

## **6 PHARMACEUTICAL PARTICULARS**

### **6.1 List of excipients**

Sodium chloride  
Sodium hydroxide  
Hydrochloric acid  
Water for injection

### **6.2 Major 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 the veterinary medicinal product as packaged for sale: 3 years.  
Shelf-life after first opening the immediate packaging: Use immediately.

### **6.4 Special precautions for storage**

Do not store above 25°C.  
Protect from light.  
Keep the container in the outer carton.  
This product does not contain any anti-microbial preservative. Any solution remaining in the vial after withdrawal of the required dose should be discarded.

### **6.5 Nature and composition of immediate packaging**

Cardboard box with 5 neutral Type I glass ampoules with break ring containing 1 ml.

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

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

## **7 MARKETING AUTHORISATION HOLDER**

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39 rue de 3-eme Zouaves, BP 60005  
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68131  
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## **8 MARKETING AUTHORISATION NUMBER(S)**

VPA10404/001/002

## **9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

Date of first authorisation: 01 October 1990  
Date of last renewal: 15 October 2010

## **10 DATE OF REVISION OF THE TEXT**

May 2015