Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Adequan 100 mg/ml Solution for Injection

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Substance:

Polysulphated Glycosaminoglycan (PSGAG) 100 mg/ml

For a full list of excipients see section 6.1.

3 PHARMACEUTICAL FORM

Solution for injection.
Clear, colourless to 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 and acute superficial digital flexor tendonitis.

4.3 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.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals

For intramuscular administration only
If signs or symptoms of hypersensitivity occur, the treatment must be discontinued

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)

None known

4.7 Use during pregnancy, lactation or lay

Adequan should not be used in pregnant animals.

4.8 Interaction with other medicinal products and other forms of interaction

Adequan may potentiate the action of anticoagulant preparations.

4.9 Amounts to be administered and administration route

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

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

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 – zero days

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

ATCVet code: QM01AX12 Glucosaminoglycan polysulfate

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.

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.

5.2 Pharmacokinetic properties

Pharmacokinetic studies were carried out in animals (rats and rabbits) and humans with radioactively labelled PSGAG. After 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 for cartilage. The levels in cartilage were higher than the values measured in serum or the synovia. 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 for 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 hydroxide
Sodium chloride
Hydrochloric acid (dilute)
Water for injection

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 the veterinary medicinal product as packaged for sale: 3 years.

6.4 Special precautions for storage

Do not store above 25ºC.
Protect from light.

6.5 Nature and composition of immediate packaging

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

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials

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(S)

VPA 10404/001/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Renewal of the last authorisation: 30th September 2010

10 DATE OF REVISION OF THE TEXT

May 2015