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(s):	**mg**
Polysulphated Glycosaminoglycan (PSGAG)	250

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

i. 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.

ii. 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 interaction

The product may potentiate the action of anticoagulant preparations.

4.9 Amount 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)

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

Meat and offal: Zero days.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antiinflammatory and antirheumatic products, non-steroids.
ATCvet 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 μg/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 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 disposal of unused veterinary medicinal product or waste materials derived from the use of such products, if appropriate

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 36483/4001

9. DATE OF FIRST AUTHORISATION

Date: 05 January 1996

10. DATE OF REVISION OF THE TEXT

Date: January 2015

Approved: 19 January 2015