Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Hyonate 10 mg/ml solution for injection

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:
Active constituents
Sodium hyaluronate 10 mg

For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Solution for injection.
Clear, colourless liquid.

4 CLINICAL PARTICULARS

4.1 Target Species

Horses

4.2 Indications for use, specifying the target species

For the treatment of lameness in horses due to non-infectious inflammation of joints.

4.3 Contraindications

None known.

4.4 Special warnings for each target species

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

4.5 Special precautions for use

Special precautions for use in animals

See 4.9 below regarding special precautions in administration

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

None.

4.6 Adverse reactions (frequency and seriousness)

In very rare cases, horses may show a transient flare reaction after intra-articular injection.This may present as a diffuse swelling lasting 24 – 48 hours resulting from irritation by the needle while in the joint space. These may be acute but will generally resolve without sequelae within a few days.

4.7 Use during pregnancy, lactation or lay

The product may be used safely in pregnant and lactating animals.

4.8 Interaction with other medicinal products and other forms of interactions

None known.

4.9 Amounts to be administered and administration route

For intravenous or intra-articular use:

The recommended dose is:

Intravenous administration:4 ml corresponding to 40 mg sodium hyaluronate
Intra-articular administration:2 ml corresponding to 20 mg sodium hyaluronate

Treatment may be repeated at weekly intervals for a total of three treatments.

Strict aseptic technique should be observed when injecting Hyonate. As with any intra-articular procedure, proper injection site disinfection and animal restraint are very important.

Excess synovial fluid should be aseptically removed prior to injection. Care should be taken not to scratch the cartilage surface with the point of the injection needle. Diffuse swelling lasting 24-48 hours may result from irritation of the needle while in the joint space.
For best results the horse should be given three days stable rest after intra-articular treatment before gradually resuming normal activity.

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

Not applicable.

4.11 Withdrawal period(s)

Meat: zero days.
Milk: Not applicable.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Sodium hyaluronate is a saccharide biopolymer with a key role in maintaining normal joint function. It also has anti-inflammatory properties.

ATC VetCode:QM09 AX01

5.1 Pharmacodynamic properties

Hyonate is extracted from the capsule of a selected micro-organism and purified to produce an ultra pure form of sodium hyaluronate which is essentially free of protein or nucleic acids. The solution is pyrogen free and sterile. It contains no preservative.

Hyaluronic acid forms the basis of a wide range of saccharide biopolymers (glycosaminoglycans or mucopolysaccharides) consisting of repeating disaccharide units of N-acetyl-D-glucosamine and D-glucuronic acid linked by beta 1-3 and beta 1-4 glycosidic bonds. It is a component of all mammalian connective tissue and therefore widely distributed in body tissues and intracellular fluids. Sodium hyaluronate is the naturally occurring sodium salt of hyaluronic acid. In the normal joint sodium hyaluronate is synthesised by synoviocytes. The resulting long chains form a three dimensionally cross linked network and are the crucial determinant of the properties of the synovial fluid.

The high affinity of sodium hyaluronate for water, which is enclosed rather than bound within the three dimensional structure, is responsible, in particular, for the known high viscosity of the synovial fluid. Recent studies have shown that sodium hyaluronate exerts its lubricant effect primarily on the membrane separating the synovial fluid from the soft tissue (capsule) of the joint.

Sodium hyaluronate therefore has various properties:
- it improves the viscosity of the synovial fluid through its 3 dimensional structure (lubrication)
-it assists with the filtering function of the synovial membrane (regulation of composition of synovial fluid)
- it is a constituent of hyaline cartilage
- it plays a role in the supply of nutrients to the cartilage.

Sodium hyaluronate also exerts an anti-inflammatory action.

5.2 Pharmacokinetic particulars

No data available.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium chloride
Disodium phosphate anhydrous
Sodium dihydrogen phosphate monohydrate
Sodium hydroxide (for pH adjustment)
Hydrochloric acid (for pH adjustment)
Water for injections

6.2 Major incompatibilities

None known.

6.3 Shelf-life

Shelf-life of the product as packaged for sale: 3 years
Shelf-life after first opening the container:Any solution remaining in the vial following withdrawal of the required dose should be discarded.

6.4 Special precautions for storage

Do not store above 25°C. Protect from sunlight.

6.5 Nature and composition of immediate packaging

2 ml of solution in a 2.5 ml clear Type I glass vial with a chlorobutyl grey stopper or a grey butyl rubber stopper, teflon face with an aluminium overseal and plastic cap.

2 ml of solution in a 5 ml clear Type I glass vial with a chlorobutyl grey stopper or a grey butyl rubber stopper, teflon face with an aluminium overseal and plastic cap.

Not all pack sizes may be marketed.

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

Any unused product or waste material should be disposed of in accordance with national requirements.

7 MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Vetmedica GmbH
Binger Strasse 173
55216 Ingelheim am Rhein
Germany

8 MARKETING AUTHORISATION NUMBER(S)

VPA10454/062/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 23 April 1997
Date of last renewal: 23 April 2007

10 DATE OF REVISION OF THE TEXT

December 2018