1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Hyonate 10 mg/ml solution for injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:
Sodium hyaluronate ..... 10 mg

Excipients:

Qualitative composition of excipients and other constituents
Disodium phosphate anhydrous
Sodium chloride
Sodium dihydrogen phosphate monohydrate
Sodium hydroxide (for pH adjustment)
Hydrochloric acid (for pH adjustment)
Water for injections

Clear, colourless liquid.

3. CLINICAL INFORMATION

3.1 Target species

Horses.

3.2 Indications for use for each target species

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

3.3 Contraindications

None known.

3.4 Special warnings

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

3.5 Special precautions for use

Special precautions for safe use in the target species:

See 3.9 below regarding special precautions in administration.

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

Not applicable.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Horses:

Very rare (<1 animal / 10 000 animals treated):	Injection site joint reaction[1] (e.g. injection site swelling[2])

[1]After intraarticular injection.
[2] Diffuse swelling lasting 23-48 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.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:
Can be used during pregnancy and lactation.

3.8 Interaction with other medicinal products and other forms of interaction

None known.

3.9 Administration routes and dosage

Intravenous or intraarticular use.

The recommended dose is:

- Intravenous: 4 ml (corresponding to 40 mg sodium hyaluronate)
- Intraarticular: 2 ml (corresponding to 20 mg sodium hyaluronate)

Three treatments at weekly intervals. Fewer treatments may be required if early improvement is observed.

Strict aseptic technique should be observed when injecting the veterinary medicinal product. As with any intraarticular 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.
For best results, the horse should be given three days stable rest after intraarticular treatment before gradually resuming normal activity.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

None.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance.

For administration by a veterinarian or under their direct supervision.

3.12 Withdrawal periods

Meat and offal:	zero days.
Milk:	Not authorised for use in animals producing milk for human consumption.

4. PHARMACOLOGICAL INFORMATION

4.1 ATC-vet code: QM09AX01

4.2 Pharmacodynamics

Hyaluronic acid is extracted from the capsule of selected micro-organism and purified as a sodium salt. Hyaluronic acid is a component of all mammalian connective tissue and is widely distributed in body tissues and intracellular fluids.

4.3 Pharmacokinetics

Sodium hyaluronate is the naturally occurring sodium salt of hyaluronic acid. In the normal joint sodium hyaluronate is synthesised in the synoviocytes.
The high affinity of sodium hyaluronate for water is responsible for the known high viscosity of the synovial fluid.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Not applicable.

5.2 Shelf life

Shelf life of the veterinary medicinal 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.

5.3 Special precautions for storage

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

5.4 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.

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

Medicines should not be disposed of via wastewater or household waste.
Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Vetmedica GmbH

7. MARKETING AUTHORISATION NUMBER(S)

VPA10454/062/001

8. DATE OF FIRST AUTHORISATION

10/07/2015

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

15/11/2024

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).