[Version 9,10/2021] corr. 11/2022

ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Hyonate 10 mg/ml solution for injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 2 ml contain:

Active substance:
20 mg Sodium hyaluronate equivalent to 18.9 mg hyaluronic acid

Excipients:

Qualitative composition of excipients and other constituents
Disodium phosphate
Sodium chloride
Sodium dihydrogen phosphate monohydrate
Water for injections

Clear, colourless solution.

3. CLINICAL INFORMATION

3.1 Target species

Horses.

3.2 Indications for use for each target species

Treatment of non-infectious synovitis of fetlock, carpal and tarsal joints.

3.3 Contraindications

Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

3.4 Special warnings

None.

3.5 Special precautions for use

Special precautions for safe use in the target species:

Not applicable.

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

In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.
People with known hypersensitivity to hyaluronic acid should avoid contact with the veterinary medicinal product.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Horses:

Very rare (<1 animal / 10 000 animals treated, including isolated reports):	Joint swelling[1], lameness[1], hypersensitivity[1,2]

[1] After intraarticular application. They subside spontaneously in most cases within a few days.
[2] Of the joint.

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 also the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

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 of sodium hyaluronate)
- Intraarticular: 2 ml (corresponding to 20 mg of 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

Not applicable.

3.12 Withdrawal periods

Meat and offal: zero days.
Milk: zero days.

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 immediate packaging: use immediately.

5.3 Special precautions for storage

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

5.4 Nature and composition of immediate packaging

2 glass bottles of 2 ml in a cardboard box.

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

[To be completed nationally]

7. MARKETING AUTHORISATION NUMBER(S)

[To be completed nationally]

8. DATE OF FIRST AUTHORISATION

{DD/MM/YYYY}

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

{MM/YYYY}

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).

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard box

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Hyonate 10 mg/ml solution for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Each 2 ml contain:
20 mg Sodium hyaluronate equivalent to 18.9 mg hyaluronic acid

3. PACKAGE SIZE

2 x 2 ml

4. TARGET SPECIES

Horses

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Intravenous or intraarticular use.

7. WITHDRAWAL PERIODS

Withdrawal period:
Meat and offal: zero days.
Milk: zero days.

8. EXPIRY DATE

Exp. {mm/yyyy}
Once opened: use immediately.

9. SPECIAL STORAGE PRECAUTIONS

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

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

To be completed nationally.

14. MARKETING AUTHORISATION NUMBERS

To be completed nationally.

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Glass bottles of 2 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Hyonate

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Sodium hyaluronate
20 mg
2 ml

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}
Once opened: use immediately.

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Hyonate 10 mg/ml solution for injection

2. Composition

Each 2 ml contain:
20 mg Sodium hyaluronate equivalent to 18.9 mg hyaluronic acid

Clear, colourless solution.

3. Target species

Horses.

4. Indications for use

Treatment of non-infectious synovitis of fetlock, carpal and tarsal joints.

5. Contraindications

Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

6. Special warnings

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician. People with known hypersensitivity to hyaluronic acid should avoid contact with the veterinary medicinal product.

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

7. Adverse events

Horses:
Very rare (<1 animal / 10,000 animals treated, including isolated reports): Joint swelling[1], lameness[1], hypersensitivity[1,2].

[1]After intraarticular application. They subside spontaneously in most cases within a few days.
[2] Of the joint.

Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder or the local representative of the marketing

authorisation holder using the contact details at the end of this leaflet, or via your national reporting system: {national system details}.

8. Dosage for each species, routes and method of administration

Intravenous or intraarticular use.

The recommended dose is:
- Intravenous: 4 ml (corresponding to 40 mgof sodium hyaluronate)
- Intraarticular: 2 ml (corresponding to 20 mg of sodium hyaluronate)

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

9. Advice on correct administration

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.

10. Withdrawal periods

Meat and offal: zero days.
Milk: zero days.

11. Special storage precautions

Keep out of the sight and reach of children.

Do not store above 25 °C.
Protect from light.
Do not use this veterinary medicinal product after the expiry date which is stated on the label after "Exp."
Shelf life after first opening the immediate packaging: use immediately.

12. Special precautions for disposal

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 applicable national collection systems. These measures should help to protect the environment.
Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

To be completed nationally.

Package size:
2 bottles of 2 ml in a cardboard box.

15. Date on which the package leaflet was last revised

{MM/YYYY}

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

16. Contact details

Marketing authorisation holder and contact details to report suspected adverse reactions:
To be completed nationally.

Manufacturer responsible for batch release:
Boehringer Ingelheim Animal Health France SCS
4, Chemin du Calquet
31000 Toulouse
France

Local representatives and contact details to report suspected adverse reactions:
To be completed nationally.

17. Other information

Substance for non-infectious joint disease.

Horses: