

PARTICULARS TO APPEAR ON THE OUTER PACKAGE (CARTON)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Hyonate 10 mg/ml Solution for Injection for horses

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Contains 10 mg/ml sodium hyaluronate

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

2 x 2 mL

5. TARGET SPECIES

Horses

6. INDICATION(S)

For the treatment of lameness in horses due to non-infectious synovitis possibly associated with equine osteoarthritis.

Anti-arthritic.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Dosage:

Intra-articular (i.a.) = 2 ml

Intravenous (i.v.) = 4 ml

Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Meat withdrawal period: zero days

9. SPECIAL WARNINGS

This product does not contain an antimicrobial preservative.

10. EXPIRY DATE

EXP:

11. SPECIAL STORAGE CONDITIONS

Any solution remaining in the vial following withdrawal of the required dose should be discarded.

Do not store above 25 °C.

Protect from sunlight.

Keep the container in the outer carton.

Do not use after expiry date.

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: Read the package leaflet.

13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

For animal treatment only.

Vm 08327/4272
POM-V
To be supplied only On veterinary prescription

IE: POM

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

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Animal Health UK Ltd, Bracknell, RG12 8YS, UK

16. MARKETING AUTHORISATION NUMBER(S)

Vm 08327/4272

17. MANUFACTURER’S BATCH NUMBER

Lot:

18. FURTHER INFORMATION

Manufactured by:

Boehringer Ingelheim Animal Health France SCS,
4 chemin du Calquet,
31000 Toulouse, France

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE (VIAL LABEL)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Hyonate 10 mg/ml Solution for Injection for horses

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Contains 10 mg/ml sodium hyaluronate

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

2 ml

5. TARGET SPECIES

Horses

6. INDICATION(S)

Anti-arthritic

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For i.v. or i.a. injection

8. WITHDRAWAL PERIOD

9. SPECIAL WARNING(S), IF NECESSARY

Do not use after expiry date

10. EXPIRY DATE

EXP:

11. SPECIAL STORAGE CONDITIONS

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

For animal treatment only

UK:

IE: POM

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

Keep out of the sight and reach of children

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Animal Health UK Ltd, Bracknell, RG12 8YS, UK

16. MARKETING AUTHORISATION NUMBER(S)

Vm 08327/4272

17. MANUFACTURER’S BATCH NUMBER

Lot:

PACKAGE LEAFLET FOR:

Hyonate 10 mg/ml Solution for Injection

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Boehringer Ingelheim Animal Health UK Ltd, Bracknell, RG12 8YS, UK

Manufactured by:

Boehringer Ingelheim Animal Health France SCS,
4 chemin du Calquet,
31000 Toulouse, France

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Hyonate 10 mg/ml Solution for Injection

3. STATEMENT OF THE ACTIVE SUBSTANCE (S) AND OTHER INGREDIENTS

Each ml of Hyonate contains 10 mg of sodium hyaluronate.

4. INDICATION(S)

Hyonate is indicated in the treatment of lameness in horses due to non-infectious synovitis possibly associated with equine osteoarthritis.

Anti-arthritic.

5. CONTRAINDICATIONS

6. ADVERSE REACTIONS

In rare cases, horses may show a transient flare reaction after intra-articular injection. These may be acute but will generally resolve without sequelae within a few days.

7. TARGET SPECIES

Horses

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

For Intra-Articular or Intravenous Use in Horses Only.

The recommended dose is:

Intra-articular – 2 ml (1 vial – 20 mg)

or

Intravenous – 4 ml (2 vials – 40 mg)

depending on clinical judgement.

9. ADVICE ON CORRECT ADMINISTRATION

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 important. Excess joint fluid should be aseptically removed prior to intra-articular injection. Care should be taken not to scratch the cartilage surface with the injection needle.

Diffuse swelling lasting 24 to 48 hours may result from movement of the needle whilst in the joint space.

To achieve best results in cases of intra-articular administration, horses should be given 3 days stable rest after treatment, before gradually resuming normal activity.

10. WITHDRAWAL PERIOD

Meat withdrawal period: zero days.

11. SPECIAL STORAGE PRECAUTIONS

Do not store above 25 °C. Protect from sunlight. Keep the container in the outer carton.

12. SPECIAL WARNINGS

Use during pregnancy, lactation or lay

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

Warnings

For animal treatment only.

Keep out of the sight and reach of children.

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

Do not use after the expiry date stated on the label and carton.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Dispose of any unused product or containers in accordance with guidance from your local waste regulation authority.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

June 2022

15. OTHER INFORMATION

Description

Hyonate is a clear colourless solution for injection. It is administered by intra-articular or intravenous injection.

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.

Chemistry and Pharmacology

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

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 intercellular 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 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.

For animal treatment only.

Available in 2.5 ml and 5 ml vials. Not all pack sizes may be marketed.

Veterinary Medicinal Product authorised for use in UK and IE.

To be supplied only on veterinary prescription

UK only:

Vm 08327/4272

POM-V

Approved 21 June 2022

