PARTICULARS TO APPEAR ON THE OUTER PACKAGE {Cardboard box of 2 vials}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Hyonate 10 mg/ml solution for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains: Sodium hyaluronate 10 mg

3. PACKAGE SIZE

2 x 2 ml

4. TARGET SPECIES

Horses.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Intravenous or intra-articular use.

7. WITHDRAWAL PERIODS

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

8. EXPIRY DATE

Exp. {mm/yyyy}

Shelf life after first opening the container: Any solution remaining in the vial following withdrawal of the required dose should be discarded.

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

Boehringer Ingelheim Animal Health UK Limited

14. MARKETING AUTHORISATION NUMBERS

Vm 08327/4272

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS {Glass vials of 2 ml}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT



2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Sodium hyaluronate

10 mg/ml

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Hyonate 10 mg/ml solution for injection

2. Composition

Each ml contains: Sodium hyaluronate......10 mg

Clear, colourless liquid.

3. Target species

Horses.

4. Indications for use

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

5. Contraindications

None known.

6. Special warnings

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.

<u>Special precautions for safe use in the target species:</u> See section 9 below regarding special precautions in administration.

<u>Pregnancy and lactation:</u> Can be used during pregnancy and lactation.

<u>Special restrictions for use and special conditions for use:</u> For administration by a veterinarian or under their direct supervision

7. Adverse events

Horses:

Very rare (<1 animal / 10,000 animals treated): Injection site joint reaction¹ (e.g. swelling²).

¹After 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 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 at https://www.gov.uk/report-veterinary-medicine-problem.

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

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.

9. Advice on correct administration

Strict aseptic technique should be observed when injecting the veterinary medicinal product. 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.

For best results, the horse should be given three days stable rest after intra-articular treatment before gradually resuming normal activity.

10. Withdrawal periods

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

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 or carton after "Exp". The expiry date refers to the last day of that month.

Shelf life after first opening the container: Any solution remaining in the vial following withdrawal of the required dose should be discarded.

12. Special precautions for disposal

Medicines should not be disposed of via wastewater.

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

Vm 08327/4272

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

Not all pack sizes may be marketed.

15. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the 'Product Information Database' on <u>www.gov.uk</u>.

16. Contact details

Marketing authorisation holder and contact details to report suspected adverse reactions: Boehringer Ingelheim Animal Health UK Ltd, Bracknell, RG12 8YS, UK Tel: + 44 1344 746957

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

17. Other information

Substance for non-infectious joint disease.

POM-V Veterinary medicinal product subject to prescription

Gavín Hall

Approved: 22 May 2025