

PARTICULARS TO APPEAR ON THE OUTER PACKAGE {CARTON}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

HY-50 Vet 17 mg/ml solution for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:

Sodium hyaluronate 17 mg

3. PACKAGE SIZE

3 ml single-dose syringe

12 x 3 ml single-dose syringes

4. TARGET SPECIES

Horse.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Intraarticular and intravenous use.

7. WITHDRAWAL PERIODS

Withdrawal periods: Meat and offal: zero days.

8. EXPIRY DATE

Exp. {mm/yyyy}

Single dose syringes made ready for injection shall be used immediately.

9. SPECIAL STORAGE PRECAUTIONS

Store in a refrigerator

Do not freeze.

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

Dechra Regulatory B.V.

14. MARKETING AUTHORISATION NUMBERS

Vm 50406/5037 (GB)

Vm 50406/3032 (NI)

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS
{LABEL FOR SINGLE-DOSE SYRINGE}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

HY-50 Vet

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Sodium hyaluronate 17 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

HY-50 Vet 17 mg/ml solution for injection

2. Composition

Each ml contains:

Active Substances:

Sodium hyaluronate 17 mg

Clear, colourless, viscous solution.

3. Target species

Horse.

4. Indications for use

For intraarticular and intravenous treatment of lameness caused by joint dysfunction associated with non-infectious synovitis.

5. Contraindications

Do not use in cases of joint infection.

6. Special warnings

Special precautions for safe use in the target species:

Radiographic evaluation should be carried out in cases of acute, severe lameness to ensure that the joints are free from serious fractures.

Pregnancy and lactation:

The safety of the veterinary medicinal product has not been established during pregnancy and lactation. Use only according to the benefit-risk assessment by the responsible veterinarian

Interaction with other medicinal products and other forms of interaction:

No data available.

Major incompatibilities:

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

7. Adverse events

Horse:

Common (1 to 10 animals / 100 animals treated):	Injection site joint reaction (injection site swelling, injection site warmth) ^a
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^a Transient and mild. Self-limiting swelling and/or heat in the treated joint resolve spontaneously within 48 hours, and do not negate a successful therapeutic outcome. 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:

Website: <https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine>

e-mail: adverse.events@vmd.gov.uk

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

Intraarticular and intravenous use.

Intravenous use: 3 ml intravenously repeated at weekly intervals for a total of three treatments.

For single intraarticular injection: 3 ml (51 mg) intraarticularly into medium sized and large joints. Smaller joints such as intertarsal, tarsometatarsal and interphalangeal joints can be treated with a 1.5 ml (25.5 mg) dose.

More than one joint may be treated at the same time.

9. Advice on correct administration

Excess synovial fluid should be removed whenever possible prior to injection.

Remove the veterinary medicinal product from refrigerator approximately 10 minutes before performing injection. The injection should be administered under strict aseptic conditions. Ensure removal of dirt, hair, topical medicaments and soap/antiseptic residues. Intraarticular injections should not be made through overlying skin that is infected,

blistered, scuffed or otherwise compromised. A sterile dressing and clean bandage should be applied after injection, as appropriate for the particular joint treated.

10. Withdrawal periods

Meat and offal: zero days.

11. Special storage precautions

Keep out of the sight and reach of children.

Store in a refrigerator (2 °C – 8 °C).
Do not freeze.

Do not use this veterinary medicinal product after the expiry date which is stated on the syringe label and the carton after Exp. The expiry date refers to the last day of that month.

Single dose syringes made ready for injection shall be used immediately.
Any unused portion of a syringe is to be discarded.

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

Vm 50406/5037 (GB)
Vm 50406/3032 (NI)

Pack sizes: Carton with 1 x 3 ml single-dose syringe.
Carton with 12 x 3 ml single-dose syringes.
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 www.gov.uk

16. Contact details

Marketing authorisation holder:

Dechra Regulatory B.V.
Handelsweg 25
5531 AE Bladel
The Netherlands

Manufacturer responsible for batch release:

Eurovet Animal Health B.V.
Handelsweg 25
5531 AE Bladel
The Netherlands

Dales Pharmaceuticals Limited
Snaygill Industrial Estate
Keighley Road
Skipton
North Yorkshire
BD23 2RW
United Kingdom

Local representatives and contact details to report suspected adverse reactions:

Dechra Veterinary Products Limited
Sansaw Business Park
Hadnall,
Shrewsbury
Shropshire
SY4 4AS
United Kingdom.

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

17. Other information

POM-V

Gavin Hall

Approved: 23 March 2026