SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

HY-50 Vet 17 mg/ml solution for injection in pre-filled syringe

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substances:
Sodium hyaluronate 17 mg

Excipients:

Qualitative composition of excipients and other constituents
Sodium chloride
Disodium phosphate heptahydrate
Sodium dihydrogen phosphate monohydrate
Sodium hydroxide
Hydrochloric acid
Water for injection

Clear, colourless, viscous solution.

3. CLINICAL INFORMATION

3.1 Target species

Horse.

3.2 Indications for use for each target species

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

3.3 Contraindications

Do not use in cases of joint infection.

3.4 Special warnings

None.

3.5 Special precautions for use

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.

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

Horse:

Common (1 to 10 animals / 100 animals treated):	Injection site joint reaction (injection site swelling, injection site warmth)[a]

[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 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

The safety of the veterinary medicinal product has not been established during pregnancy and lactation.

Pregnancy and lactation:
Use only according to the benefit-risk assessment by the responsible veterinarian.

3.8 Interaction with other medicinal products and other forms of interaction

No data available.

3.9 Administration routes and dosage

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 dose (25.5 mg).

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

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

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

Not reported.

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.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QM09AX01.

4.2 Pharmacodynamics

The active substance in the veterinary medicinal product, sodium hyaluronate, is produced by a bacterial fermentation process. Sodium hyaluronate is the sodium salt of hyaluronic acid, a non-sulphated acid mucopolysaccharide or glycosaminoglycan of high molecular weight composed of equimolar amounts of D-glucuronic acid and N-acetylglucosamine linked together by glycosidic bonds.

Hyaluronic acid is a natural constituent of connective tissues in all mammals and its chemical structure is the same in all species. Vitreous humour, umbilical cord and synovial fluid are especially rich in hyaluronic acid. Hyaluronic acid is also found in the articular cartilage matrix.

Hyaluronic acid has biochemical activities which are distinct from its physical and rheological properties. It is an effective free radical scavenger, a potent inhibitor of leucocyte and macrophage migration and aggregation, and enhances healing of connective tissue.

Intraarticularly administered sodium hyaluronate alleviates aseptic joint inflammation and enhances joint function. The mechanism of action involved in the beneficial effects of sodium hyaluronate is not fully understood.

4.3 Pharmacokinetics

Studies with radiolabelled hyaluronic acid in rabbit and sheep indicate that after intraarticular injection, hyaluronic acid is cleared from the joint within 4 to 5 days. Uptake is primarily via the lymphatics. Hyaluronate is metabolised in the liver.
Pharmacokinetic properties of intravenously administered sodium hyaluronate have not been studied.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

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

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years
Single dose syringe made ready for injection shall be used immediately.
Any unused portion of a syringe is to be discarded.

5.3 Special precautions for storage

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

5.4 Nature and composition of immediate packaging

Pre-loaded single-dose syringe (type I glass syringe barrel with rubber tip cap and rubber stopper) and a plunger rod in an individual heat-sealed tray.

Pack sizes:
Carton with 1 x 3 ml pre-filled single-dose syringe
Carton with 12 x 3 ml pre-filled single-dose syringes

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

Dechra Regulatory B.V.

7. MARKETING AUTHORISATION NUMBERS

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

8. DATE OF FIRST AUTHORISATION

12 June 1998

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

March 2026

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCT

Veterinary medicinal product subject to prescription.

Find more product information by searching for the ‘Product Information Database’ on www.gov.uk.

Gavin Hall
Approved: 29 October 2026