Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

HY-50 Vet. 17 mg/ml solution for injection for horses

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

1 ml contains:

Active substance:
Sodium hyaluronate 17 mg

Excipients:
For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Solution for injection.
Clear, colourless, viscous solution.

4 CLINICAL PARTICULARS

4.1 Target Species

Horses.

4.2 Indications for use, specifying the target species

For intra-articular and intravenoustreatment of lameness caused by joint dysfunction associated with non-infectious synovitis.

4.3 Contraindications

Do not use in cases of joint infection.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals
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.

4.6 Adverse reactions (frequency and seriousness)

Transient mild swelling and/or heat has been reported in treated joints (2.7%). These self-limiting local signs resolve spontaneously within 48 hours, and do not negate a successful therapeutic outcome.

4.7 Use during pregnancy, lactation or lay

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

4.8 Interaction with other medicinal products and other forms of interactions

No data available.

4.9 Amounts to be administered and administration route

For intra-articular and intravenous administration.

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

For single intra-articular injection: 3 ml (51 mg) intra-articularly 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 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.
Intra-articular 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.

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

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

None known.

4.11 Withdrawal period(s)

Meat and offal: Zero days.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: sodium hyaluronate (hyaluronic acid)
ATCvet code: QM09AX01

5.1 Pharmacodynamic properties

The active substance in HY-50 Vet., 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.

Intra-articularly 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.

5.2 Pharmacokinetic particulars

Studies with radiolabelled hyaluronic acid in rabbit and sheep indicate that after intra-articular 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.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium chloride
Sodium phosphate dibasic, heptahydrate
Sodium phosphate monobasic, monohydrate
Sodium hydroxide (for pH adjustment)
Hydrochloric acid (for pH adjustment)
Water for injections

6.2 Major incompatibilities

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

6.3 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.
Any unused portion of a syringe is to be discarded.

6.4 Special precautions for storage

Store and transport refrigerated (2 °C-8 °C).
Do not freeze.

6.5 Nature and composition of immediate packaging

Pre-loaded 3 ml single-dose glass syringes. Each syringe is packaged in an individual heat-sealed tray and carton.
Carton containing 1 x 3 ml single-dose syringe.
Carton containing 12 x cartons of 1 x 3 ml single-dose syringes.
Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

Dechra Regulatory B.V.

Handelsweg 25
5531 AE Bladel
Netherlands

8 MARKETING AUTHORISATION NUMBER(S)

VPA22622/010/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 22 January 2016

10 DATE OF REVISION OF THE TEXT

January 2018