SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

HY-50 Vet 17 mg/ml solution for injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance:

Sodium Hyaluronate 17 mg/ml

Excipients:

For a 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

Horse.

4.2 Indications for use, specifying the target species

For intra-articular and intravenous treatment 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

i. 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.

ii. 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

Safety in pregnant and lactating mares has not been documented. Use only according to the benefit/risk assessment by the responsible veterinarian.

4.8 Interaction with other medicinal products and other forms of interaction

No data available.

4.9 Amounts to be administered and administration route

Intravenous use: 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 shall be used immediately. Any unused portion of a syringe is to be discarded.

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

Not reported.

4.11 Withdrawal period(s)

Meat and offal – zero days.

5. PHARMACOLOGICAL 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	7.57 mg/ml
Disodium Phosphate Heptahydrate	3.78 mg/ml
Sodium Dihydrogen Phosphate Monohydrate	0.45 mg/ml
Water for Injection	qs to 1 ml

6.2 Incompatibilities

Do not mix with any other product.

6.3 Shelf life

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

6.4 Special precautions for storage

Store in a refrigerator (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. Available in single cartons or boxes containing 12 cartons.

Not all pack sizes may be marketed.

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

Any unused product or waste material should be disposed in accordance with national requirements.

7. MARKETING AUTHORISATION HOLDER

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

8. MARKETING AUTHORISATION NUMBER

Vm 10434/4078

9. DATE OF FIRST AUTHORISATION

12 June 1998

10. DATE OF REVISION OF THE TEXT

March 2016

PROHIBITION OF SALE, SUPPLY AND/OR USE

Not applicable.

Approved: 02 March 2016