ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARTON

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

HY-50 Vet 17 mg/ml solution for injection
Sodium hyaluronate

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

1 ml contains

Active Substance

Sodium hyaluronate	17 mg

Excipients

Sodium chloride	7.57 mg
Disodium phosphate heptahydrate	3.78 mg
Sodium dihydrogen phosphate monohydrate	0.45 mg
Water for injection	qs to 1 ml

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

3 ml single-dose syringe
12 x 3 ml single-dose syringes

5. TARGET SPECIES

Horse

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For intra-articular and intravenous use in horses

8. WITHDRAWAL PERIOD

Meat and offal – zero days

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP

11. SPECIAL STORAGE CONDITIONS

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

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read package leaflet

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only. To be supplied only on veterinary prescription.

14. THE WORDS "KEEP OUT OF THE REACH AND SIGHT OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

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

16. MARKETING AUTHORISATION NUMBER(S)

Vm: 10434/4078

17. MANUFACTURER'S BATCH NUMBER

Lot

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

LABEL FOR SINGLE-DOSE SYRINGE

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

HY-50 Vet 17 mg/ml solution for injection
Sodium hyaluronate

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

1 ml contains

Active Substance
Sodium hyaluronate 17 mg

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

3 ml

4. ROUTES OF ADMINISTRATION

Intra-articular/intravenous administration.

5. WITHDRAWAL PERIOD

Withdrawal period: Meat and offal: Zero days.

6. BATCH NUMBER

Lot

7. EXPIRY DATE

EXP

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

Target species: Horse.

B. PACKAGE LEAFLET

PACKAGE LEAFLET FOR:

HY-50 Vet 17 mg/ml solution for injection

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder:
Dechra Limited
Snaygill Industrial Estate
Keighley Road
Skipton
North Yorkshire
BD23 2RW
United Kingdom

Manufacturers responsible for the 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

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

HY-50 Vet 17 mg/ml solution for injection
Sodium hyaluronate

3. STATEMENT OF THE ACTIVE SUBSTANCE AND OTHER INGREDIENTS

1ml contains:

Active Substance:	
Sodium hyaluronate	17 mg
Excipients:	
Sodium chloride	7.57 mg
Disodium phosphate heptahydrate	3.78 mg
Sodium dihydrogen phosphate monohydrate	0.45 mg
Water for injection	qs to 1 ml

Sterile, colourless, clear solution.

4. INDICATION(S)

For intra-articular 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. ADVERSE REACTIONS

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.

If you notice any serious effects or other effects not mentioned in this package leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Horse.

8. DOSAGE FOR EACH SPECIES, ROUTE AND METHOD OF ADMINISTRATION

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 (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 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.

10. WITHDRAWAL PERIOD

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 after the expiry date stated on the label and carton.

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

12. SPECIAL WARNINGS

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.

Use during pregnancy and lactation:
Safety in pregnant and lactating mares has not been documented. 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.
Do not mix with any other product.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS

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

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

06/2019

15. OTHER INFORMATION

For animal treatment only. To be supplied only on veterinary prescription.

POM-V

Pack sizes:
3 ml single-dose syringe
12 x 3 ml single-dose syringes
Not all pack sizes may be marketed.

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

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

Approved: 18 June 2019