PACKAGE LEAFLET
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:
<To be completed nationally>

Manufacturer for the batch release:
Eurovet Animal Health B.V.
Handelsweg 25
5531 AE Bladel
The Netherlands

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

HY-50 Vet is a sterile, colourless, clear solution containing:

Active Substance	
Sodium Hyaluronate	17 mg/ml
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

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 leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Horse.

8. DOSAGE FOR EACH SPECIES, ROUTE(S) 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 reach and sight 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 WARNING(S)

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, IF ANY

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

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

2021-05-12

15. OTHER INFORMATION