PARTICULARS TO APPEAR ON THE OUTER PACKAGE

1 syringe carton

20 syringe carton label

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Hylartil Vet 10 mg/ml Solution for Injection

Sodium hyaluronate

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each 2 ml syringe contains:

Active substance

Sodium hyaluronate (MrM > 3 x 10_6) 20 mg

The product does not contain an antimicrobial preservative.

3. PHARMACEUTICAL FORM

Solution for Injection

4. PACKAGE SIZE

1 x 2 ml syringe

20 x 2 ml syringes

5. TARGET SPECIES

Horses

6. INDICATION(S)

1) For the local treatment of non-infectious inflammatory joint disease in horses.

2) For the local treatment of tendinitis in horses.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For intra-articular use and direct injection into tendons.

2 ml (20 mg) of Hylartil Vet is given intra-articularly in small/medium sized joints and can also be injected directly into tendons. For larger joints the dosage can be

increased to 4 ml. The injection should be given under strict aseptic conditions. The treatment may be repeated at weekly intervals for a total of 3 treatments. Not more than two joints/tendons should be treated at the same time.

Care should be taken not to scratch the cartilage surface when given intra-articularly, as this may result in diffuse swelling lasting for 24 to 48 hours. The transient swelling will not affect the clinical result. For best results the horse should be given 2 days stall rest before gradually resuming normal activity.

8. WITHDRAWAL PERIOD(S)

Do not use in horses intended for human consumption.

Treated horses may never be used for human consumption.

The horse must have been declared as not intended for human consumption under national horse passport legislation.

9. SPECIAL WARNING(S), IF NECESSARY

Important! The syringe is sealed with a membrane which must be ruptured prior to use (see enclosed directions).

Hylartil Vet can be used during pregnancy and lactation.

The syringe must only be used once.

Transient swelling may occur at the injection site.

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

User Warnings

Directly after use of the product, hands and exposed skin should be washed thoroughly.

10. EXPIRY DATE

Expires end:

11. SPECIAL STORAGE CONDITIONS

Store in a refrigerator (2°C to 8°C). Do not freeze. Protect from light.

Keep the syringe in the outer carton.

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS

OR WASTE MATERIALS, IF ANY

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

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.

POM-V

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

Zoetis UK Limited

5th Floor, 6 St. Andrew Street

London

EC4A 3AE

Manufacturer responsible for batch release:

AMO Uppsala AB

Box 6406

751 36 Uppsala

Sweden

16. MARKETING AUTHORISATION NUMBER(S)

Vm 42058/4071

17. MANUFACTURER'S BATCH NUMBER

Batch No.:

Available in cartons containing 1 or 20 x 2 ml syringes. Not all pack sizes may be marketed.

Approved: 04/01/2018