SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

HYLARTIL VET 10 mg/ml Solution for Injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 2ml syringe contains:

Active substance:
Sodium Hyaluronate
(MrM, mean relative molecular mass ≥ 3.0 x106) 20.00 mg (10mg/ml)

For full list of excipients, see Section 6.1.

3. PHARMACEUTICAL FORM

Solution for injection.

4. CLINICAL PARTICULARS

4.1. Target species

Horses.

4.2. Indications for use, specifying the target species

Hylartil Vet (10mg/ml) is indicated for use in horses as follows:

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

ii) For the local treatment of tendinitis in horses.

4.3. Contraindications

None.

4.4. Special warnings for each target species

None known.

4.5. Special precautions for use

Please note the syringe is sealed with a membrane which must be ruptured prior to use (see directions in carton).

i) Special precautions for use in animals

None known.

ii) Special precautions to be taken by the person administering the veterinary medicinal product to animals

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

4.6. Adverse reactions (frequency and seriousness)

Transient swelling may occur at the injection site.

4.7. Use during pregnancy, lactation or lay

Hylartil Vet can, as far is known, be used during pregnancy and lactation.

4.8. Interaction with other medicinal products and other forms of interaction

None known.

4.9. Amounts to be administered and administration route

For intra-articular use and direct injection into tendons.

Two ml (20 mg) of Hylartil Vet is given intra-articularly in small and medium size joints and can also be injected directly into tendons. In the treatment of larger joints/tendons the dosage may be increased to 4 ml (40 mg). The injection should be given under strict aseptic conditions. The treatment may be repeated at weekly intervals for a total of three treatments. Not more than two joints/tendons should be treated at the same time.

When performing intra-articular injections care should be taken not to scratch the cartilage surface, as this may result in diffuse swelling lasting for 24 to 48 hours. The transient swelling will have no effect on the ultimate clinical result. For best results the horse should be given a two day stall rest before gradually resuming normal activity.

The syringe must only be used once.

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

None known.

4.11. Withdrawal period

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.

5. PHARMACOLOGICAL PROPERTIES

Hylartil Vet contains sodium hyaluronate. Sodium hyaluronate is a polysaccharide consisting of repeating units of N-acetylglucosamine and sodium glucuronate linked by glycosidic bonds. It is a natural substance, occurring in identical forms in all species.

ATCVet code: QM09AX01

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Sodium Chloride
Sodium Phosphate Dihydrate
Sodium Acid Phosphate Dihydrate
Sodium hydroxide (pH adjustment)
Hydrochloric acid (pH adjustment)
Water for Injections

6.2. 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.

6.4. Special precautions for storage

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

The product does not contain an antimicrobial preservative. Any product remaining in the syringe following administration of the required dose should be discarded.

6.5. Nature and composition of immediate packaging

A disposable single use 2ml prefilled parenteral syringe of colourless Type I glass, closed with a blue chlorobutyl rubber stopper. Supplied in cartons containing 1 or 20 syringes.
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, if appropriate

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

7. MARKETING AUTHORISATION HOLDER

Zoetis UK Limited
5th Floor, 6 St. Andrew Street
London
EC4A 3AE

8. MARKETING AUTHORISATION NUMBER

Vm: 42058/4071

9. RENEWAL OF THE AUTHORISATION

Date: 6 March 2006

10. DATE OF REVISION OF THE TEXT

Date: April 2014

Approved:  **30/04/2014**