HYLARTIN® V is a sterile pyrogen-free solution of a highly purified, sodium hyaluronate in 2.0 mL physiological sodium chloride-phosphate buffer with a pH of 7.0-7.5.

CHEMISTRY:
Sodium hyaluronate is a natural, physiological substance which occurs extracellularly in connective tissue in both animals and man and is chemically identical in different species. High concentrations (>0.2 mg/mL) of hyaluronate are found in the synovial fluid, the vitreous of the eye and the umbilical cord. Sodium hyaluronate is a normal component of connective tissue matrix and it is injected therapeutically only in compartments where it constitutes a normal component, specifically the joint cavity.

TOXICOLOGY:
Acute, sub-acute and chronic toxicity studies in mice, rats, rabbits, dogs, monkeys and horses have not demonstrated any significant adverse reactions or sensitization. In an acute toxicity study in horses, HYLARTIN® V was injected intra-articularly at dosages corresponding to five times the recommended dose per animal (200 mg total). In a sub-acute study, horses were injected intra-articularly with the recommended dose per joint (20 mg) at weekly intervals for nine weeks. The results of both investigations showed that hematological and blood chemistry values remained within normal ranges. In mice, the intravenous LD₅₀, was found to be the order of 50 mg/kg body weight. There is always a potential immunological risk with repeated parenteral administration of biological material. However, as shown by Richter (1974), sodium hyaluronate, of both human and avian origin, did not produce any antibodies after repeated immunization, nor did intense stimulation of the immunization process by coupling protein to the hyaluronate and simultaneous administration of Freund’s adjutant give rise to antibodies.

CLINICAL STUDIES:
Clinical field trials with thoroughly-bred and standardized race horses were undertaken at four separate clinics. A total of 252 joints were injected with HYLARTIN® V in these investigations. In one study, only horses which were conventional treatment failures were included and the overall improvement rate following HYLARTIN® V treatment approached 90 percent. In the other studies, the improvement rate surpassed this figure.

In another case, electrogoniometry was used to objectively show that HYLARTIN® V can improve the function of arthritic carpal and fetlock joints. HYLARTIN® V brought return to symmetry with respect to timing and duration of various angular motions of the joints. In cases where HYLARTIN® V was not able to achieve contralateral symmetry of the joint motion pattern, blocking of the joint with anesthetic also had no effect, indicating that most probably mechanical damage was responsible for the joint dysfunction.

REFERENCES:
NADA 112-048, Approved by FDA
Made in Sweden by:
AMO Uppsala AB, Rapsgatan 7
Box 6406, SE-751 36 Uppsala, Sweden

DOSAGE AND ADMINISTRATION:
2 mL (20 mg) of HYLARTIN® V given to horses intra-articularly in small and medium size joints (carpal, fetlock). In the treatment of larger joints (hock), the dosage is 4 mL (40 mg). The treatment may be repeated at weekly intervals for a total of three treatments. HYLARTIN® V should be injected in horses intra-articularly under strict aseptic conditions. Effusion should be removed prior to injection. When performing the injections, care should be taken not to scratch the cartilage surface, as this may result in diffuse swelling lasting for 24 to 48 hours. This transient swelling, however, will have no effect on the ultimate clinical result. For best results, the horse should be given two days stall rest before gradually resuming normal activity.

STORAGE CONDITIONS:
Store at 2° to 8°C. The expiration date is stated on the package. Protect from freezing. Protect from light.

HOW SUPPLIED:
HYLARTIN® V, is supplied sterile in disposable glass syringes, each containing 20 mg (10 mg/mL) of sodium hyaluronate in 2.0 mL physiological sodium chloride-phosphate buffer. Each mL contains: Sodium hyaluronate 10.0 mg, sodium chloride 8.5 mg, disodium hydrogen phosphate dihydrate 0.28 mg, sodium dihydrogen phosphate 0.04 mg, water for injection USP q.s.

REFERENCE:
Zoetis Inc.
Kalamazoo, MI 49007 Revised: February 2013

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**INSTRUCTIONS**

**OPENING TECHNIQUE**

Tear off the paper covering.

Bend the plastic backwards at the central indentation so as to fully expose the white plastic cap.

Dislodge syringe.

**ASSEMBLY**

Press the vial completely into the holder until the needle perforates the membrane.

Remove the plastic cap.

Screw the plastic cap into the blue plunger.

Connect the cannula and check for proper function.

Store at 2° to 8°C. For single use only.

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**Description:** HYLARTIN-V 2 ML  
**Market:** US  
**Supplier:** AMO - Uppsala  
**Perigord No.:** 023016  
**Barcode No.:** N/A  
**Pages:** 2 of 2  
**Dimensions:** 210 x 297 mm - Image Prints 50%  
**Notes:** N/A  
**Colours:** Black

**REASON FOR REVISION:**  
Zoetis Artwork Changes

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