

**HYALOVET- hyaluronate sodium liquid**  
**Boehringer Ingelheim Animal Health USA Inc.**

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**Hyalovet®**  
**(hyaluronate sodium)**  
**Veterinary Injection**

For intra-articular administration in horses only

**Caution:**

Federal law restricts this drug to use by or on the order of a licensed veterinarian.

**Description:**

Hyaluronic acid is the prototype of a wide range of saccharide biopolymers (glycosaminoglycans or mucopolysaccharides) consisting of repeating disaccharide units of N-acetyl-D-glucosamine and D-glucuronic acid linked by beta 1-3 and beta 1-4 glycosidic bonds. A component of all mammalian connective tissue, hyaluronic acid confers viscoelastic and lubricating properties to synovial fluid<sup>1</sup> and structural integrity to cartilage matrix<sup>2</sup>. As a therapeutic agent, hyaluronic acid injected into arthritic joints has been shown, in a variety of animal model systems including horses<sup>3</sup>, to improve joint function and to activate tissue repair processes in articular cartilage.

Hyalovet (hyaluronate sodium) is clear, colorless, viscous solution of a specific fraction of highly purified hyaluronic acid obtained by a molecular filtration procedure from biological material (rooster combs). The specific hyaluronic acid fraction from which Hyalovet is made has a high degree of molecular definition with an average molecular weight of 500,000-730,000 D.

Each filled 2 mL glass syringe or 2 mL glass vial contains:

Hyaluronate sodium.....	20.0 mg
Sodium chloride.....	17.0 mg
Monobasic sodium phosphate.....	0.1 mg
Dibasic sodium phosphate.....	1.2 mg
Water for injection.....	q.s., 2 mL

**Indications:**

Hyalovet is indicated for the intra-articular treatment of carpal or fetlock joint dysfunction in horses due to acute or chronic, non-infectious synovitis associated with equine osteoarthritis.

**Dosage and Administration:**

The recommended dose of Hyalovet (hyaluronate sodium) is 2 mL (20 mg hyaluronate

sodium) in small or medium sized joints (carpus, fetlock) given by intra-articular injection. More than one joint may be treated at the same time. If necessary, the injection may be repeated after one or more weeks, but not to exceed 2 injections per week for a total of 4 weeks.

Hyalovet should be injected using strict aseptic technique. Excess synovial fluid should be removed prior to injection.

For best results horses should be given two days of rest or limited exercise before resuming normal training.

### **Contraindications:**

There are no known contraindications.

### **Warning:**

Do not use in horses intended for human consumption. Not for human use. Hyalovet Injection must not be administered intravascularly.

### **Precautions:**

Used or partially used syringes should be crushed and disposed of in an approved landfill.

### **Adverse Reactions:**

As with any intra-articular injection a mild inflammatory response (tenderness, heat and swelling) may be seen in the joint following Hyalovet injection. The response is self limiting but may last from two to five days after treatment. If inflammation is excessive or severe, the possibility of infection should be considered and appropriate antibiotic therapy instituted.

To report suspected adverse events, for technical assistance, or to obtain a copy of the Safety Data Sheet, contact Boehringer Ingelheim Animal Health USA Inc. at 1-888-637-4251.

For additional information about adverse drug experience reporting for animal drugs, contact FDA at 1-888-FDA-VETS or online at [www.fda.gov/reportanimalae](http://www.fda.gov/reportanimalae).

### **Clinical Pharmacology:**

Results of gel chromatography studies demonstrate that Hyalovet (hyaluronate sodium) induces aggregation of cartilage proteoglycans sub-units as previously described for other fractions of hyaluronic acid<sup>2</sup>. In equine model studies of acute synovitis of the carpal joint, a single intra-articular injection of Hyalovet resulted in statistically significant ( $p < 0.05$ ) functional improvement with regard to lameness, swelling, pain, heat and joint flexion in a dosage dependent fashion. In chronic osteoarthritis secondary to carpal fracture in horses, a single intra-articular injection of 20 mg Hyalovet resulted in statistically significant ( $p < 0.05$ ) reduction in radiopharmaceutical uptake in subchondral

bone, as compared to saline injected controls, a finding consistent with reduced inflammation. In controlled clinical trials in horses with lameness due to arthroses of the carpal or fetlock joints, intra-articular injection of 20 mg Hyalovet resulted in marked reduction in clinical lameness, pain on palpation, pain on flexion and facilitated return to training. A measurable and statistically significant ( $p < 0.005$ ) decrease in joint circumference was detected in the horses.

### **Animal Safety:**

In subacute toxicity studies, in horses, intra-articular injection of Hyalovet at the recommended dosage (20 mg/joint) and at 3X and 5X multiples of that dosage, daily for four days followed by twice weekly injections for four additional weeks, resulted in no evidence of toxicity either locally within the joint or systemically in the horses. Slight increases in synovial fluid leucocytes and protein were attributed to the trauma associated with frequent joint injections.

Results of skin testing in horses following repeated intra-articular injections of 40 mg Hyalovet into tibiotarsal joints indicated that the product is non-antigenic in horses; no sensitization was detected.

### **Storage:**

Store at or below 25°C (77° F).

### **How Supplied:**

Hyalovet Veterinary Injection is supplied in a 2 mL syringe or vial containing 20 mg hyaluronate sodium per 2 mL.

NDC 0010-4705-01: 2 mL syringe

NDC 0010-4705-02: 2 mL vial

### **References:**

1. Swann, D.A. *et al*: Role of hyaluronic acid in joint lubrication. *Annals of the Rheumatic Diseases*, 33 (1974): 318-326.
2. Hascall, V.C. and Heinegard, D.: Aggregation of cartilage proteoglycans. I. The role of hyaluronic acid. *Journal of Biological Chemistry*, 249 (1974): 423-433.
3. Gingerich, D.A. *et al*: Effect of exogenous hyaluronic acid on joint functions in experimentally-induced equine osteoarthritis: dosage titration studies. *Research in Veterinary Science*, 30 (1981): 192-197.

Hyalovet is a registered trademark of Fidia Farmaceutici S.p.A., Abano Terme, Italy.

Approved by FDA under NADA # 140-806

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Product of Italy

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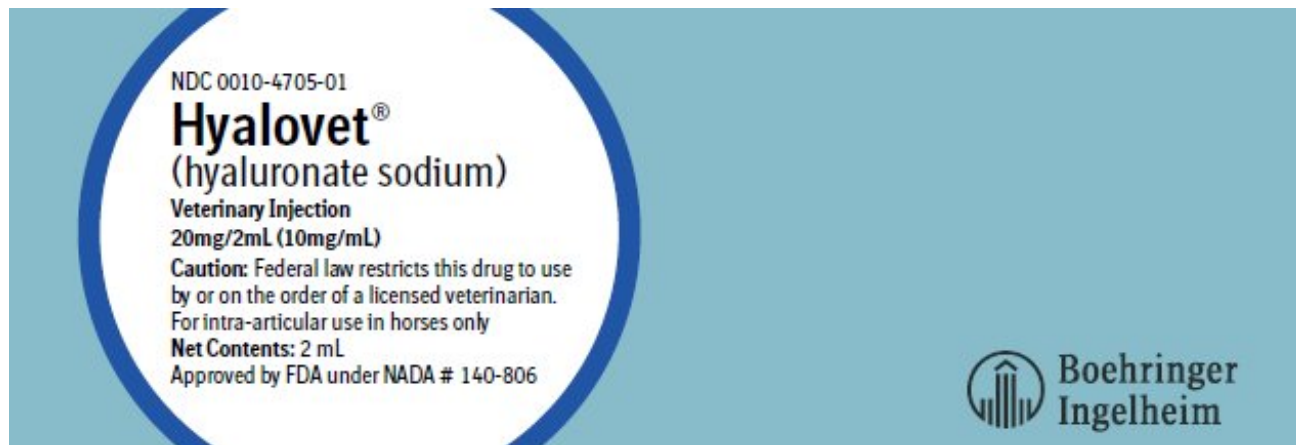
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Marketed by:

Boehringer Ingelheim Animal Health USA Inc.

Duluth, GA 30096

## Principal Display Panel - 2 mL Syringe Carton



## HYALOVET

hyaluronate sodium liquid

### Product Information

<b>Product Type</b>	PRESCRIPTION ANIMAL DRUG	<b>Item Code (Source)</b>	NDC:0010-4705
<b>Route of Administration</b>	INTRA-ARTICULAR		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>HYALURONATE SODIUM</b> (UNII: YSE9PPT4TH) (HYALURONIC ACID - UNII:S270N0TRQY)	HYALURONATE SODIUM	20 mg in 2 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>SODIUM CHLORIDE</b> (UNII: 451W47IQ8X)	17 mg in 2 mL
<b>SODIUM PHOSPHATE, MONOBASIC, DIHYDRATE</b> (UNII: 5QWK665956)	0.1 mg in 2 mL
<b>SODIUM PHOSPHATE, DIBASIC, DODECAHYDRATE</b> (UNII: E1W4N241FO)	1.2 mg in 2 mL
<b>WATER</b> (UNII: 059QF0KO0R)	

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0010-4705-01	1 in 1 CARTON		
1		2 mL in 1 SYRINGE		
2	NDC:0010-4705-02	1 in 1 CARTON		
2		2 mL in 1 VIAL		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NADA	NADA140806	05/31/1988	

**Labeler** - Boehringer Ingelheim Animal Health USA Inc. (007134091)

Revised: 11/2023

Boehringer Ingelheim Animal Health USA Inc.