

HYALOVET- hyaluronate sodium liquid
Boehringer Ingelheim Vetmedica, Inc.

HYALOVET®
(hyaluronate sodium)
Veterinary Injection

NADA 140-806, Approved by FDA

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 fluid¹ and structural integrity to cartilage matrix². As a therapeutic agent, hyaluronic acid injected into arthritic joints has been shown, in a variety of animal model systems including horses³, 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 reactions, to obtain a Material Safety Data Sheet or for technical assistance call 1-866-638-2226.

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 acid². 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.

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Product of Italy

12360

D4450C

680370/3

Manufactured for:

Boehringer Ingelheim Vetmedica, Inc.

St. Joseph, MO 64506 U.S.A.

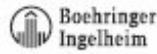
Vial Label



Syringe Label

NDC 0010-4705-01
Hyalovet[®]
 (hyaluronate sodium)
 Veterinary Injection
 20 mg/2 mL

Read Package Insert
 D4458C 680375-3
 Manufactured for:
Boehringer Ingelheim
 Vetmedica, Inc.
 St. Joseph, MO 64506
 U.S.A.



Lot No.:
 Exp. Date:

Vial Carton

Net Contents: 2 mL
 By or on the order of a licensed veterinarian.
 Caution: Federal law restricts this drug to use by
 20 mg/2 mL (10 mg/mL)
 Veterinary Injection
 (hyaluronate sodium)
Hyalovet[®]

Each vial contains:
 20 mg hyaluronate sodium, 17 mg sodium chloride, 0.1 mg mono-basic sodium phosphate, 1.2 mg dibasic sodium phosphate, 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: 2 mL per joint by intra-articular injection. See package insert for full dosage and administration information.

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Storage: Store at or below 25°C (77°F).

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AS/150 EU 3007G
 58x28x85
 Dia. 54
 11930
 D4452B
 D4452B

Lot No.:
 Exp. Date:

6804204
 Black
 6804204
 P. 2726 C
 6804204
 P. 550 C

0 12313 47052 4

Syringe Carton



HYALOVET

hyaluronate sodium liquid

Product Information

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

Active Ingredient/Active Moiety

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

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 Vetmedica, Inc. (007134091)

Registrant - Boehringer Ingelheim Vetmedica, Inc. (007134091)

Revised: 1/2017

Boehringer Ingelheim Vetmedica, Inc.