HYVISC- hyaluronate sodium injection
Boehringer Ingelheim Animal Health USA Inc.

Hyvisc®
(hyaluronate sodium)
Sterile Injection, 11 mg/mL

For intra-articular injection in horses only

Caution:

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

Description:

Hyvisc® (hyaluronate sodium) Injection is a clear, colorless, viscous fluid contained in a 5 mL disposable syringe, as a single 2 mL dose. Chemically, hyaluronic acid is a high molecular weight mucopolysaccharide composed of repeating disaccharide units, each unit consisting of D-glucuronic acid and N-acetyl-D-glucosamine. Each mL of Hyvisc Injection contains 11 mg of hyaluronate sodium and 8.47 mg of sodium chloride, USP, in sterile water for injection, USP, q.s.

Actions:

Hyaluronate sodium is a natural constituent of connective tissue and synovial fluid in both man and animals. In synovial fluid, hyaluronate sodium confers viscoelastic as well as lubricating properties[1,2]. In connective tissue, hyaluronate sodium specifically interacts with cartilage proteoglycans to form stable aggregates[3,4,5]. The mechanism of action by which exogenous hyaluronate sodium exerts its therapeutic effect in arthritic joints is not known at this time.

Indications:

Hyvisc (hyaluronate sodium) Injection is recommended for the treatment of joint dysfunction in horses due to non-infectious synovitis associated with equine osteoarthritis.

Dosage and Administration:

The recommended dose of Hyvisc (hyaluronate sodium) Injection is 2 mL (22 mg) given to horses intra-articularly in small and medium-sized joints (carpal, fetlock). In larger joints (hock), the dosage is 4 mL (44 mg). Treatment may be repeated at weekly intervals for a total of three treatments. As with any intra-articular injection, aseptic technique is used. The following are suggested use directions regardless of the type of joint to be treated.

1. Carefully diagnose each case using routine methods. The origin of lameness should

be pinpointed to be within a specific joint or joints (e.g., lameness is localized to a specific joint using intra-articular anesthesia). Radiographs or other diagnostic aids should not reveal recent fractures or other serious abnormalities which would suggest a poor prognosis.
2. Aseptically remove as much synovial fluid from the afflicted joint as can be easily withdrawn.
3. Remove tip cap from the Hyvisc syringe and inject through a sterile needle, 20 gauge or larger.
4. Inject a single 2 mL dose (one syringe) of Hyvisc into each joint to be treated; if the joint being treated is the hock joint, inject 4 mL (two syringes). Since Hyvisc is a viscous fluid, care should be exercised on injection so as not to dislodge the needle from the syringe.
5. Two or four days of rest or light exercise is recommended before resumption of normal activity. Improvement of joint function should be seen within one to two weeks after Hyvisc Injection.

As with any intra-articular injection, a mild inflammatory response (tenderness, heat and swelling) may be seen in the joint following the Hyvisc Injection. This 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.

Contraindications:

There are no known contraindications to the use of Hyvisc (hyaluronate sodium) Injection.

Warnings:

Do not use in horses intended for human consumption. Hyvisc (hyaluronate sodium) Injection must not be administered intravascularly.

Precautions:

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

Do not use if numerous small air bubbles are present throughout the solution.

Adverse Reactions:

In the clinical trial with Hyvisc (hyaluronate sodium) Injection, a mild, transient post-injection inflammatory response in the joint was reported in 12% of the cases treated. There were no other side effects.

Contact Information:

To report suspected adverse drug experience or for technical service questions, contact Boehringer Ingelheim Animal Health USA Inc. at 1-888-637-4251. For additional

information about reporting adverse drug experiences for animal drugs, contact FDA at 1-888-FDA-VETS (1-888-332-8387) or www.fda.gov/reportanimalae.

Safety Margin in Horses:

In toxicity studies of Hyvisc (hyaluronate sodium) Injection in horses, intra-articular doses at one, three, and five times the recommended dose once weekly for three consecutive weeks did not result in any drug related local or systemic toxic effects. The mild, transient post-injection inflammatory response observed within the joints of some horses was qualitatively and quantitatively similar to that detected in the physiologic saline injected controls. In a reproductive study in mares, 16 mL of Hyvisc (10 mg/mL) injected intramuscularly or subcutaneously once or twice during the second or third stage of pregnancy resulted in no adverse effects on the mares or newborn foals.

Storage:

Store under refrigerated conditions, 2° - 8°C (36° - 46°F). Protect from freezing and avoid excessive heat.

How Supplied:

Hyvisc (hyaluronate sodium) Injection, 11 mg/mL, is available in 2 mL prefilled, disposable syringes individually packaged.

References:

1. Radin, E.L. *et al: Annals of the Rheumatic Diseases*, 30: 322-325, (1971).
2. Swann, D.A. *et al: Annals of the Rheumatic Diseases*, 33: 318-326, (1974).
3. Hardingham, T.E. and H. Muir: *Biochemical et Biophysica Acta*, 279: 401-405, (1972).
4. Hascall, V.C. and D. Heingard: *Journal of Biological Chemistry*, 249: 423-433, (1974).
5. Brandt, K.D. *et al: Arthritis and Rheumatism*, 19: 1308-1314, (1976).

Approved by FDA under NADA #122-578

Manufactured by:

Anika Therapeutics, Inc.
Bedford, MA 01730 U.S.A.

Distributed by:

Boehringer Ingelheim Animal Health USA Inc.
Duluth, GA 30096

413003-07 AML 520-202/D

Principal Display Panel – 2 mL syringe label

Hyvisc®
(hyaluronate sodium)
Sterile Injection, 11 mg/mL
Net Contents: 2 mL
Dist. by:
Boehringer Ingelheim Animal Health USA Inc.
Duluth, GA 30096
AML # 300-176/B 413001-04 Lot: Exp:

Principal Display Panel – 2 mL display carton

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Net Contents: 2 mL

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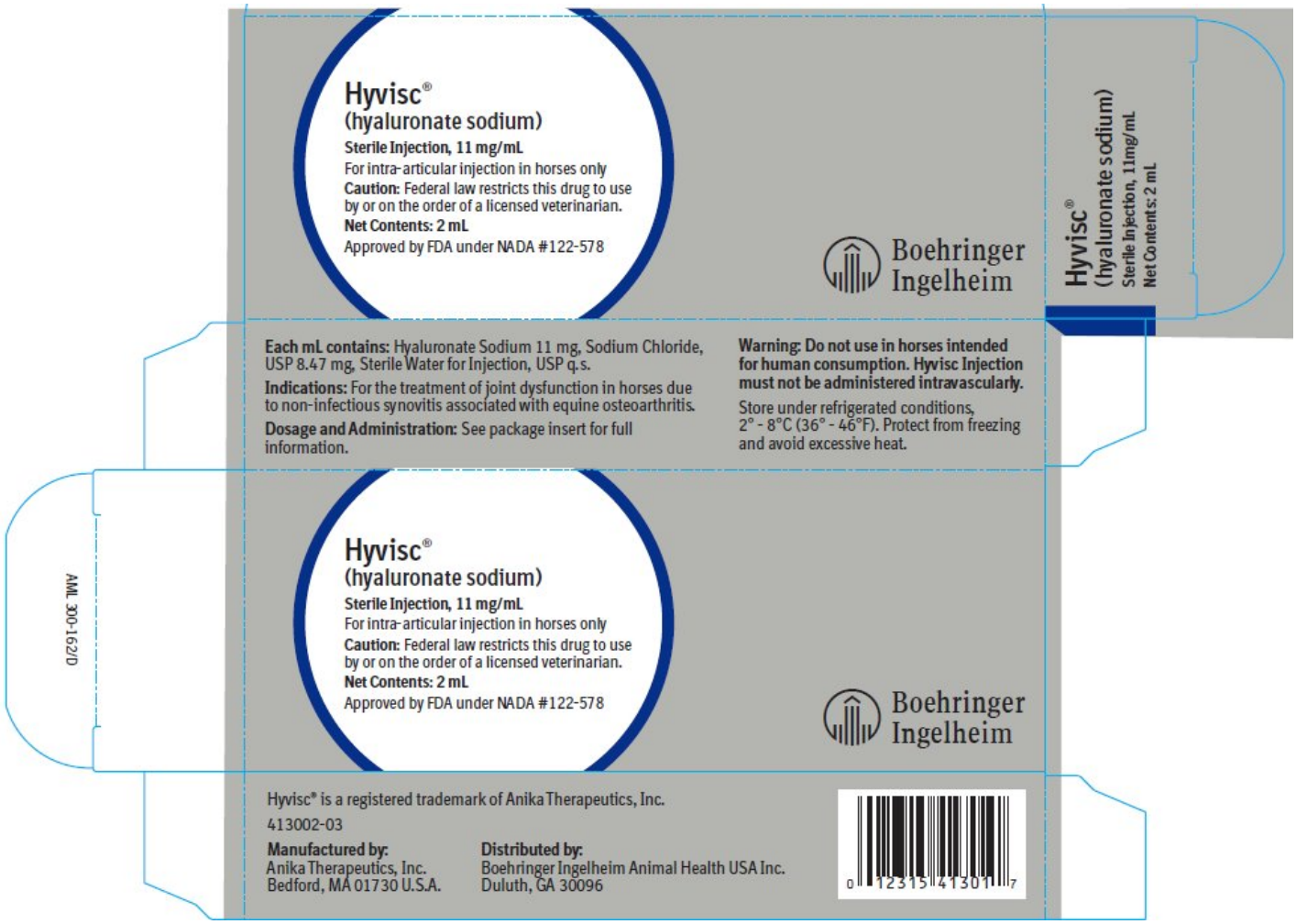

HYVISC

hyaluronate sodium injection

Product Information			
Product Type	PRESCRIPTION ANIMAL DRUG	**Item Code (Source)**	NDC:0010-4130
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	11 mg in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
WATER (UNII: 059QF0KO0R)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:0010-4130-01	1 in 1 CARTON		
1		2 mL in 1 SYRINGE, GLASS		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NADA	NADA122578	04/12/2022	

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

Revised: 4/2022

Boehringer Ingelheim Animal Health USA Inc.