

# HY-50™

(Hyaluronate sodium Injection)

## FOR HORSES

### Featuring



### EFFICACY

In Clinical studies, 41 horses (21 Standardbreds, 5 Thoroughbreds, 7 Saddlebreds, 1 Warmblood and 7 Grade) with lameness in 74 joints (confirmed by diagnostic intra-articular anesthesia) were treated with a single dose of HY-50™ (3ml into carpal, fetlock and tibiotarsal joints and 1.5ml into intertarsal and phalangeal joints). One week treatment, 34 of the horses were completely sound, with another 5 showing considerable improvement, for an overall efficacy rate of 95%. Thirty-eight of the horses were completely sound two weeks post-treatment and remained sound through the six week evaluation period.

### SAFETY

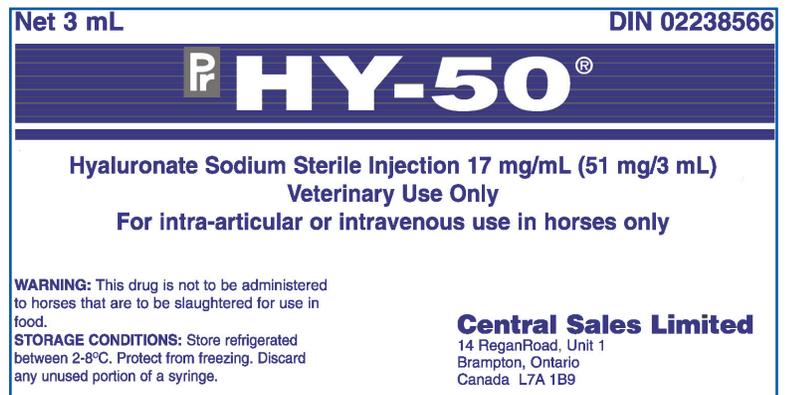
There are no systemic side effects and local side effects are uncommon. Only 2.7% of treated horses exhibited mild local side effects such as heat and edema following treatment. These resolved spontaneously within 48 hours. The risk of hypersensitivity reactions to HY-50™ is much lower than with animal-origin hyaluronate preparations.

### CONCENTRATION & VOLUME

HY-50™ delivers 17 mg/ml hyaluronate sodium, or 51mg per 3ml dose. A high dose is achieved with a small volume injection, making HY-50™ ideal for the treatment of small joints and large joints with a narrowed joint space due to progressive destruction.

### PURITY

HY-50™ is produced from a patented fermentation process utilizing state of the art purification techniques. As a result HY-50™ is protein-free and pyrogen-free.



To Order:  
Tel: 1-800-387-2522 Fax: 1-888-437-9999

See Over

# HY-50®

## Central Sales Antiarthritic agent Hyaluronate Sodium Sterile Injection For intra-articular or intravenous use in horses only

**DESCRIPTION:** HY-50® is a highly purified, sterile, pyrogen-free aqueous solution of hyaluronate sodium derived by a fermentation process using *Streptococcus* spp. and then purified to yield a product which is essentially free of protein and nucleic acids. Each mL contains: Hyaluronate Sodium 17 mg; Sodium Chloride 7.57 mg; Sodium Phosphate Dibasic 3.78 mg; Sodium Phosphate Monobasic 0.45 mg; and Water for Injection q.s.

**CHEMISTRY:** Hyaluronate sodium is the sodium salt of hyaluronic acid, a highly polymerized, non-sulphated acid mucopolysaccharide or glycosaminoglycan composed of equimolar amounts of D-glucuronic acid and N-acetylglucosamine linked together by glycosidic bonds. Hyaluronate possesses a negative charge which enables it to bind readily to other substances such as water, ions, proteins and solutes. The hyaluronate produced by bacteria is structurally and chemically indistinguishable from mammalian hyaluronate.

**PHARMACOLOGY:** Hyaluronate is a naturally occurring substance present in connective tissue, skin, vitreous humour, synovial fluid and umbilical cord in all mammals. Hyaluronate is synthesized by synoviocytes and is responsible for the viscoelastic characteristic of synovial fluid. Synovial fluid hyaluronate functions as a lubricant of the intra-articular soft tissues, aids in providing nourishment and removing waste products from the avascular cartilage, and is an important constituent of the synovial membrane barrier. The surface of articular cartilage is coated by a thin amorphous layer of a protein-hyaluronate complex. Hyaluronate is also found in the superficial layers of the cartilage matrix where it exerts resistance to cartilage compression while retaining plasticity. Hyaluronate has biochemical activities which are distinct from its physical properties. It is a potent inhibitor of cell migration, a direct inhibitor of leukocyte activity, and it prevents the formation of excess fibrous tissue.

**INDICATIONS:** HY-50® is indicated for the intra-articular or intravenous treatment of carpal and fetlock joint dysfunction in horses due to acute or chronic, non-infectious synovitis associated with equine osteoarthritis.

**CONTRAINDICATIONS:** Do not administer to horses with a history of hypersensitivity to hyaluronate sodium. Do not administer when joint sepsis and/or fractures are suspected.

**DOSAGE AND ADMINISTRATION:** Intravenous route: The recommended dose of HY-50® is 51 mg hyaluronate sodium (contents of one syringe) once a week for three consecutive weeks. Intra-articular route: The recommended dose of HY-50® is 51 mg hyaluronate sodium (contents of one syringe) in small or medium sized joints (i.e. carpus, fetlock) by intra-articular injection. More than one joint may be treated at the same time. Treatment may be repeated after one or more weeks if necessary, but not to exceed four consecutive weekly injections in the same joint.

HY-50® should be administered using strict aseptic technique. The site should be surgically prepared to ensure removal of all dirt, hair, topical medicaments, and soapy residues. Intra-articular injections should not be made through skin that has been recently fired or blistered or that has been scurfed by the use of counterirritants. After introducing the needle into the joint, excess synovial fluid should be allowed to drain, or should be removed when possible, prior to attaching the syringe and injecting HY-50®. Discard any unused portion of a syringe. A sterile dressing and clean bandage should be applied after injection, as appropriate for the particular joint treated. Hand walk for at least 2 days after treatment. Return to strenuous exercise will depend on the severity of each case and the regression of clinical signs.

**CAUTION:** In cases of severe acute lameness, radiographic evaluation should be carried out prior to intra-articular or intravenous HY-50® treatment to ensure that the joints are free from serious fractures. Observe strict aseptic technique. Intra-articular injections should not be made through skin that has been recently fired or blistered, or that has been scurfed by the use of counterirritants. The safety of HY-50® has not been established in breeding animals or in pregnant or lactating mares.

**ADVERSE REACTIONS:** In an open field trial, transient, localized post-injection swelling, edema and/or heat were observed in 2.7% of the joints treated with HY-50®. These were usually mild and self-limiting, resolving spontaneously within 48 hours, and did not interfere with a successful therapeutic outcome. No adverse reactions and no systemic effects have been observed or reported as a result of treatment with intra-articular HY-50®. No local or systemic adverse reactions were observed in experimental animals during safety and efficacy studies when HY-50® was administered intravenously.

**MOLECULAR RANGE:** 635,000 - 785,000 (700,000 is mid-range)

**WARNING:** This drug should not be administered to horses that are to be slaughtered for use in food.

**STORAGE CONDITIONS:** Store refrigerated between 2-8°C. Protect from freezing. Discard any unused portion of a syringe.

DIN 02238566

® HY-50 is a registered trademark of BEXCO PHARMA INC.

**Presentation:** HY-50® is supplied in 3 mL (51 mg) single dose glass syringes individually packaged in sealed plastic trays and outer cartons, and available in single units.

**NAC No.:** 11700291

