Novobrace

A SOFT TISSUE INJECTABLE BIOADHESIVE

Novobrace™ device for tendon and ligament injury stabilization in equines

Caution: Federal law restricts this device to sale by, or on the order of, a veterinarian

DEVICE DESCRIPTION

The Novobrace™ device consists of two vials, one containing a non-toxic protein crosslinking agent and the other a proprietary buffered carrier solution. Once reconstituted and injected the device assembles by polymerization and crosslinks damaged collagen fibers within and lining lesions. The device serves as an internal brace, supporting the injured area and preventing tear propagation while the tissue heals. By providing a protected environment for healing and by its ability to reduce incidences of re-injury in the compromised tissue, the Novobrace™ device can reduce return-to-work times by up to 50%.

INDICATIONS FOR USE

Treatment of tendonitis/desmitis or lesions in equine flexor tendons and suspensory ligaments.

CONTRAINDICATIONS

For equine veterinary use only. Not for use in humans. Not recommended for older horses with lesions above carpus or possible degenerative soft tissue disease.

Do not inject into synovial structures or lesions of greater than 70% surface area. Do not treat until at least 10 days following injury.

CLINICAL PRECAUTIONS

Take care not to overfill lesion as leakage into the peri-tendonous region may result in crosslinking and inflammation.

Rare but more severe inflammatory reactions may occur, the most common being a cellulitis within 6-12 hours. If this occurs, the attending veterinarian should re-examine the horse and assess. Treatment, at the discretion of the attending veterinarian, may involve systemic anti-inflammatory drugs, antibiotics, physical therapy and bandages. Such reactions commonly resolve within 24-48 hours.

For gray horses, horses with a history of sensitivity to injection, or show/race horses where cosmetic appearance may be a particular concern, a regional limb perfusion (RLP) at the level of the carpus for foreleg, and hock for hind limb, is recommended after administration of Novobrace™. Use 4mg of dexamethasone and 250mg amikacin. The RLP should be performed over a 20 minute time period..

SAFETY

The crosslinking reaction produces a blue pigment that stains skin within one hour. Prompt washing of exposed skin after contact usually prevents staining. **Use of gloves** is therefore recommended whenever handling the product. Staining is harmless and fades within one week.

Avoid contact with eyes. **Use of safety glasses during administration is strongly recommended**. In case of contact with eyes, wash with copious amounts of water and seek medical advice.

HOW SUPPLIED

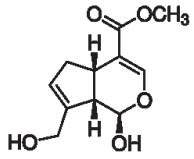
The Novobrace™ device is supplied in two sterile vials. Reconstitute immediately prior to use. The device is intended for single use only and degrades and rapidly loses efficacy upon reconstitution. Discard any unused solution. Store at or below 30°C.

Scan QR tag for educational video “Novobrace™ Technology: How It Works”

DIRECTIONS FOR USE

1. Inject horse with a weight appropriate dose of sedative.
2. Place a regional anesthesia block in the limb in order to desensitize the injection area.
3. Aseptically prepare injection site.
4. Using a sterile syringe and needle, remove 2.0ml of carrier solution in Vial 2 and inject it into Vial 1. **Vial 2 must be at least at room temperature (>65°F) prior to mixing.**
5. With the syringe needle still inserted into Vial 1, shake vigorously to dissolve the Novobrace™ Reagent.
   - Note: Once reconstituted, the Novobrace™ Reagent is unstable. Use within 1 hour.
6. Place a 22g or smaller needle using ultrasound guidance. Do not use needles of a larger gauge.
7. Attach syringe containing reconstituted solution to needle and inject slowly.
   - For lesions less than 1.5 cm in length, inject 0.3 ml of solution both 1 cm proximal and 1 cm distal to the lesion edges. Do not inject into the lesion itself.
   - For lesions between 1.5 cm and 4 cm in length, inject 0.2 ml into the lesion, and a further 0.3 ml both 1 cm proximal and 1 cm distal to the lesion edges.
   - For lesions between 4 cm and 6 cm, place two 0.2 ml injections into lesion, and two further 0.3 ml injections 1 cm proximal and 1 cm distal to the lesion. Placement of the 2 intra-lesional injections should be planned by dividing the lesion into two zones and injecting the reagent in the center of each.
   - For tendonitis place 0.3 ml at one border of affected and normal regions, and inject 0.3 ml every 3cm along the affected region. Place the last injection no more than 1cm from the other border.
   - For suspensory ligaments, begin with one 0.2 ml injection in the center of the lesion/disrupted region. If closer than 2 cm to the sesamoid bone, then place no closer than 2 cm from the bone. This should cover 1.5 cm on either side of the injection site. If insufficient for complete coverage of affected area, place further 0.2 ml injections every 3cm along ligament until final injection is no more than 1cm from edge of the affected area.
8. Apply a sterile bandage over the injection site and limb and replace daily for three days. A standing or stable bandage (non-sterile) may be used subsequently following this initial period.
9. At the discretion of the veterinarian, a weight appropriate dose of NSAIDs may be given to the horse for 3-5 days.

CROSSLINKING AGENT: GENIPIN



www.novobrace.com

LATEX = Latex Free	= Consult Instructions for Use
STERILE A = Sterilized Using Aseptic Processing Technique	= Caution, Consult Accompanying Documents
= Do Not Reuse	= Temperature Limitation
= Do Not Use if Package is Damaged	LOT = Batch Code

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