



with OsteoCushion™ Technology

Instructions for use

Veterinary medical device for use in horses.

Veterinary Use Only

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

1. Product Description

Spryng is an intra-articular injection that is intended to aid in maintaining the mechanical homeostasis of tissues within and adjacent to the synovial lining of the joint. Spryng is composed of a protein-carbohydrate matrix made from purified, natural materials. Each viscoelastic micro-cushion of Spryng is a purified composition of two proteins (collagen, elastin) and a carbohydrate (heparin glycan) that self-assemble to form a sterile, insoluble, and pliable matrix using a proprietary, patented process. This process naturally forms a durable, sterile, hydrated biomaterial that mimics natural cartilage properties. The synovial fluid is absorbed by and passes through the porous gel-particles (Figure 1), which are insoluble and will integrate with the synovial fluid before slowly adsorbing onto the synovial membrane and subsequently being integrated into the subsynovial tissue.

How Supplied

Spryng material is sterile and supplied in aseptically filled, luer-lock syringes (Figure 1). Each package consists of one (1) syringe, which contains no less than 2 mL of Spryng in a phosphate-buffered saline carrier solution (needle not included). It is intended for single-use, intra-articular injection.

Figure 1.









Storage

Spryng should be stored at room temperature with a range of 40°-90°F (5°-30°C). Use of Spryng particles is recommended within the expiration date stated on the package.

2. Intended Use and Indications for Use

Spryng microparticles promote restoration of proper joint mechanics by adding natural, viscosolid matrices to the joint's synovial fluid. Spryng is indicated to aid in the management of noninfectious sources of joint pain including, but not limited to, degenerative joint disease, osteoarthritis, joint instability, and lameness.

3. Contraindications

Spryng is contraindicated in the following conditions:

- If there is a suspected infection in the intended joint or adjacent soft tissue or skin.
- If significant joint inflammation is present. If inflammation exists, prior effective treatment with anti-inflammatory agents is recommended.

4. Warnings

Do not inject Spryng intravascularly, as blood vessels may become occluded, infarcted, or emboli may form leading to life-threatening complications.

The use of this product in combination with other intra-articular medications has not been evaluated.

Not for use in humans

Spryng has not been evaluated when combined with other intraarticular medications in one syringe or co-administered during a single procedure.

5. Precautions

Use Spryng with caution in horses with a previous history of hypersensitivity. Injection should be performed only by a licensed veterinarian skilled in the delivery of intra-articular (IA) injections.

6. Directions for Use

Spryng material is sterilized and aseptically filled in syringes containing 2 mL of material. It is intended for single-use, intra-articular injection (Figure 1). Use clinical judgement pertaining to volume needed. Some

joints may require more or less than 2 mL of material. The amount of Spryng particles injected should represent an appropriate volume as determined by the veterinarian.

Preparation for Use

- · Animal restraint and sedation is recommended.
- Thoroughly prep the area over the joint to be injected, following aseptic techniques in accordance with standard veterinary practices.
- Only the contents of the syringe are sterile. The exterior of the syringe is not sterile. Adjust technique accordingly.

Administration of Spryng

- Agitate the syringe to resuspend the particles homogeneously, ensuring ease of administration and accurate dosing.
- · Administer intra-articularly using a sterile 19-25g needle.
- Apply even pressure on the plunger rod while injecting Spryng particles
- Volume injected may vary from 0.5 mL up to 4 mL, depending on species, joint, and joint capsule elasticity.
- Do not over-distend joints.

Additional Administration Information

- The injection technique, location, amount of synovial fluid removal, depth of injection, needle type, and the administered quantity of Spryng, may vary based on veterinarian clinical judgment and the joint selected.
- Multiple joints may be injected as a part of the same treatment.
- Additional administration of Spryng may be considered based on the veterinarian's assessment. Field experience suggests the benefits of Spryng are long lasting and may extend beyond one year.
- A maximum annual administration frequency has not been established.
- If a syringe is only partially used, discard the unused portion. Each syringe is for a single use only. Do not use if the package is open or the syringe is damaged.

Disposa

The syringe and any unused material must be discarded after a single treatment visit. Follow national, local, or institutional guidelines for use and disposal of medical sharp devices.

7. Counseling for Owners

Reasonable expectations should be discussed with the owner prior to administration of Spryng regarding time to onset, duration, and level of improvement. Owners should be informed about post-administration NSAIDs, activity restrictions, contraindications, precautions, and potential complications. They should be encouraged to contact their veterinarian if unexpected signs occur.

8. Potential Adverse Reactions

Adverse events should be reported to PetVivo at 844-PET-VIVO (738-8486) or info1@petvivo.com

Some animals experience discomfort within the first 48 hours, similar to other intra-articular therapies. Animals may develop joint heat, effusion and/or lameness approximately 7 to 14 days post-administration. If not septic in origin, these events typically resolve within a few weeks with rest, cold therapy, NSAIDs, corticosteroid injection and/or systemic antimicrobials. Veterinarians should use their clinical judgement to determine whether delayed signs should be treated as a potentially septic joint.

MADE IN THE USA

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