

CHONDRO-1000

Rx Only

1. INFORMATION FOR PRESCRIBERS:

CAUTION:

Federal law restricts this device to sale by or on the order of a veterinarian (or properly licensed practitioner).

2. DESCRIPTION:

CHONDRO-1000 is a polysulfated glycosaminoglycan (PSGAG) solution of concentration 100 mg/ml (500mg/5ml). CHONDRO-1000 is provided in a sterile 5ml glass vial and is indicated as a sterile post-surgical lavage. Each vial contains a sterile solution of Polysulfated glycosaminoglycans of concentration 100mg/ml.

3. PROPERTIES:

Glycosaminoglycans are important components of all extracellular tissue structures including cartilage and synovial fluid. The active components in CHONDRO-1000 exhibit viscoelastic and polyionic properties similar in nature to synovial fluid.

4. INDICATIONS:

CHONDRO-1000 is indicated as an intra-peritoneal prophylactic agent for prevention of adhesions. It is also indicated as a sterile post-surgical lavage to prevent adhesions in gynaecological procedures and to strengthen post surgical scar.

5. CONTRAINDICATIONS:

- Do not administer to patients with known hypersensitivity (allergy) to Polysulfated glycosaminoglycans preparations.

6. COMPOSITION: EACH VIAL CONTAINS:

Polysulfated glycosaminoglycans (PSGAG)..... 500mg

7. WARNINGS:

- Not for food animal use.
- Keep out of reach of children.
- For veterinary use only.

8. PRECAUTIONS: General:

- Strict aseptic injection technique should be employed during the administration of CHONDRO-1000.
- The safety and effectiveness of repeat treatment cycles of CHONDRO-1000 has not been established.
- **STERILE CONTENTS.** The pre-filled vials are intended for single-use only. The contents of the vials are sterile and should be used immediately after opening. Discard any unused CHONDRO-1000. Do not re-sterilize.
- Do not use CHONDRO-1000 if the package has been opened or damaged.
- CHONDRO-1000 should be refrigerated where possible. **DO NOT FREEZE.** Do not use after expiration date indicated on packaging. Shelf life is 48 months.

- Only properly licensed medical professionals and veterinarians trained in accepted injection techniques should inject CHONDRO-1000 for the indicated use.

9. HOW SUPPLIED:

CHONDRO-1000 is supplied in a single-use 5.0 mL vial containing 5.0mL dose of treatment. Each vial is labelled CHONDRO-1000 for ready identification. The contents of the vial are sterile and non-pyrogenic. The vial components contain no latex.

10. DIRECTIONS FOR USE:

- Install the medical device as the final lavage prior to surgical closure of the joint space.
- Volume to be determined by veterinary surgeon.
- Discard any unused portion of vial contents.

11. MANUFACTURED FOR:

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