

PROGLYCAN

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:

PROGLYCAN is a proprietary formulation designed to replace lost or damaged synovial fluid. PROGLYCAN contains naturally occurring components of the synovia that play a central role in maintaining the homeostatic environment of the joint.

PROGLYCAN has the following benefits:

- Helps replenish lost synovial fluid with naturally occurring elements
- Assists in the normalization of synovial fluid viscosity
- Post-surgical lavage of joint cavity and surfaces
- Proprietary formulation

3. PROPERTIES:

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

Introduce PROGLYCAN into the synovial space as a post- surgical lavage, synovial fluid replacement or viscosupplement to assist in the normalization of the joint.

4. INDICATIONS:

PROGLYCAN is indicated for the replacement of lost or damaged synovial fluid. PROGLYCAN contains naturally occurring components of the synovia that play a central part in maintaining the homeostatic environment of the joint.

5. CONTRAINDICATIONS:

- Do not administer to patients with known hypersensitivity (allergy) to Polysulfated glycosaminoglycans preparations.
- Do not administer to patients with infections or skin diseases in the area of the injection site or joint.

6. COMPOSITION:

Highly viscous aqueous solution of defined fractions of purified Hyaluronic acid, Chondroitin sulfates C4 & C6 in a 10% solution of N-acetyl-D-glucosamine.

EACH VIAL CONTAINS:

Hyaluronic acid sodium salt.....60 mg
Sodium chondroitin sulfate.....1000 mg
N-acetyl-D-glucosamine.....1000 mg

7. WARNINGS:

- Do not use disinfectants containing quaternary ammonium salts for skin preparation prior to administration of PROGLYCAN as hyaluronan can precipitate in their presence.
- Keep out of reach of children.
- This device is restricted to use by or on the order of a licensed physician.

8. PRECAUTIONS: General

- Strict aseptic injection technique should be employed during the administration of PROGLYCAN.
- The safety and effectiveness of the use of PROGLYCAN concomitantly with other intra-articular (IA) injections have not been established.
- **STERILE CONTENTS.** The pre-filled vials are intended for single-use only. The contents of the vial are sterile and should be used immediately after opening. Discard any unused PROGLYCAN. Do not re-sterilize.
- Do not use PROGLYCAN if the package has been opened or damaged.
- PROGLYCAN should be stored in its original packaging in a fridge or at room temperature (below 77°F/25°C). **DO NOT FREEZE.** Do not use after expiration date indicated on packaging. Shelf life is 48 months.

9. HOW SUPPLIED:

PROGLYCAN is supplied in a single-use 10.0 mL glass vial containing 10.0mL dose of treatment. Each glass vial and package is labelled PRO-GLYCAN for ready identification. The contents of the vial are sterile and non-pyrogenic. The vial components contain no latex.

10. DIRECTIONS FOR USE:

1. Instil PROGLYCAN into the synovial space to replenish lost synovial fluid.
2. Quantity to be determined by Surgeon.
3. Discard any unused portion of vial contents.

11. MANUFACTURED FOR:

Novita Biotechnology (Pty) Ltd
28 Brommaert Avenue
Constantia
7806
www.novita-biotech.com
info@novita-biotech.com
SAHPRA: 00001494MD