

COLLANEX COLLAGEN PARTICLES - dressing, wound, collagen powder

STRATUS PHARMACEUTICALS INC

COLLANEX™

Collagen Particles

Five Vials, 1g each

Collagen Particles

Triple Helical Matix

Conforms to FDA Quality System Requirements.

Manufactured as per cGMP standards.

Product Information

- This device is intended for single use only.
- All open and unused portions must be discarded.
- Sterility guaranteed in unopened, undamaged package only.
- Store in a cool and dry place.

Product Application

1. Cleanse the wound.
2. Apply medication to the wound if indicated.
3. Apply Collanex™ Particles 1/4 inch thick to the wound surface. Do not pack tightly; allow for expansion of particles.
4. Cover with non-stick dressing.
5. Use Collanex™ Particles until wound is fully healed.
6. Maintain a moist wound environment.

Product Removal

1. Change as indicated by the amount of drainage and instructions provided with the absorbent cover dressing.
2. After removal of the cover dressing, repeat steps under Product Application as needed.

Precautions

- Wounds may appear to be larger during the first several days of treatment due to the reduction of swelling.
- An increase in drainage may be seen in the first several days of treatment.
- The product is made from bovine materials. **Do not use if you have an allergy to bovine derived materials (milk, beef products, leather, etc.)**
- **Warnings:** Discontinue use of Collanex™ Particles and notify your doctor if excessive redness, pain, swelling or blistering occurs.
- All open and unused portions must be discarded.
- **Warnings:** Potential risk of loss of sterility and infection if opened and reused.

RX Only

Distributed by:

Stratus Pharmaceuticals Inc.
Miami, FL 33186

Made in the USA

800-442-7882

STRATUS
PHARMACEUTICALS INC

Reorder 5898075405

Rev1, 062021

PRINCIPAL DISPLAY PANEL - 1 g Vial Carton

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COLLANEX COLLAGEN PARTICLES

dressing, wound, collagen powder

Product Information

Product Type	MEDICAL DEVICE	Item Code (Source)	NHRIC:58980-754
Route of Administration	TRANS DERMAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BOVINE TYPE I COLLAGEN (UNII: FHJ3ATL51C) (BOVINE TYPE I COLLAGEN - UNII:FHJ3ATL51C)	BOVINE TYPE I COLLAGEN	1 g

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NHRIC:58980-754-05	5 in 1 BOX		
1		1 in 1 VIAL, SINGLE-DOSE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Premarket Notification	K910944	05/01/1991	

Labeler - STRATUS PHARMACEUTICALS INC (789001641)**Establishment**

Name	Address	ID/FEI	Business Operations
Human BioSciences Inc		014511541	MANUFACTURE, LABEL

Revised: 11/2021

STRATUS PHARMACEUTICALS INC