

VENELEX- dressing, wound, occlusive
STRATUS PHARMACEUTICALS INC

VENELEX™ OINTMENT
WOUND DRESSING

Rx Only

DESCRIPTION

VENELEX™ OINTMENT contains Balsam Peru, Castor Oil USP, Glyceryl Monostearate and White Petrolatum.

ACTION

VENELEX™ OINTMENT helps to deodorize and protectively cover pressure wounds (ulcers). **VENELEX™ OINTMENT** provides a moist wound environment. The moisturizing properties of **VENELEX™ OINTMENT** may also help in the prevention of cracking around the edges of sores.

INDICATIONS

VENELEX™ OINTMENT is a wound dressing for topical use in the management of chronic and acute wounds, and dermal ulcers including: pressure ulcers (Stage I-IV), venous stasis ulcers, diabetic ulcers, first and second degree burns, surgical wounds, traumatic wounds, superficial wounds, ulcers resulting from arterial insufficiency and grafted wound/donor sites.

CONTRAINDICATIONS

VENELEX™ OINTMENT is contraindicated in persons who have shown hypersensitivity to Balsam Peru, Petrolatum or any of the other ingredients used in this ointment.

USES

VENELEX™ OINTMENT is easy to apply and quickly reduces odors frequently accompanying a decubitus ulcer. The wound may be left open or appropriate dressing applied. Please note that wounds generally heal poorly in the presence of hemoglobin or zinc deficiency.

WARNING

FOR EXTERNAL USE ONLY. Do not apply to fresh arterial clots. Avoid contact with eyes. Keep this and all other medications out of reach of children. Keep tightly closed. Use only as directed by a physician. When applied to a sensitive area, a temporary stinging may occur.

USUAL DOSAGE

Apply a thin film of **VENELEX™ OINTMENT** topically a minimum of twice daily or as often as necessary. Wound may be left unbandaged or appropriate dressing can be applied. To remove, wash gently with an appropriate wound cleanser.

HOW SUPPLIED

VENELEX™ OINTMENT is supplied as follows:

SIZE	NDC NUMBER
30 GRAM TUBE	58980-780-11
60 GRAM TUBE	58980-780-21
5 GRAM PACKETTE × 60	58980-780-50

STORAGE

Store at 20°C to 25°C (68°F to 77°F), excursions permitted between 15°C and 30°C (between 59°F and 86°F). Brief exposure to temperatures up to 40°C (104°F) may be tolerated provided the mean kinetic temperature does not exceed 25°C (77°F); however, such exposure should be minimized. [See USP Controlled Room Temperature]. Protect from freezing. See crimp for lot number and expiration date.

Distributed:

Stratus Pharmaceuticals Inc.
Miami, Florida 33186

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PRINCIPAL DISPLAY PANEL - 60 gram Tube Box

STRATUS

PHARMACEUTICALS INC

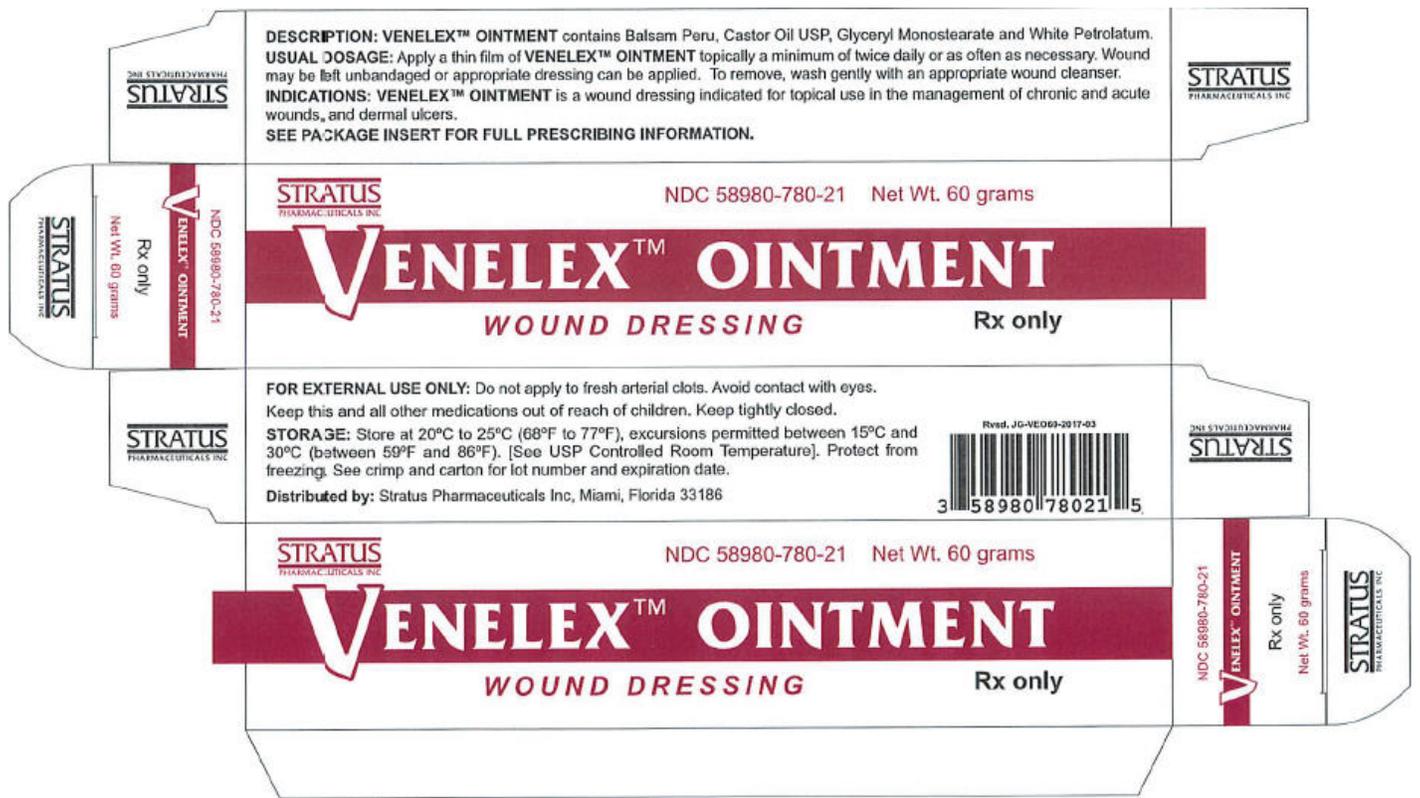
NDC 58980-780-21

Net Wt. 60 grams

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VENELEX

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Product Information

Product Type	MEDICAL DEVICE	Item Code (Source)	NHRIC:58980-780
Route of Administration	TOPICAL		

Inactive Ingredients

Ingredient Name	Strength
CASTOR OIL (UNII: D5340 Y2I9G)	
BALSAM PERU (UNII: 8P5F881OCY)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
PETROLATUM (UNII: 4T6H12BN9U)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NHRIC:58980-780-11	1 in 1 BOX		
1		30 g in 1 TUBE; Type 0: Not a Combination Product		
2	NHRIC:58980-780-21	1 in 1 BOX		
2		60 g in 1 TUBE; Type 0: Not a Combination Product		
3	NHRIC:58980-780-50	60 in 1 BOX, UNIT-DOSE		
3		5 g in 1 PACKET; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Exempt device	NAD	09/15/2017	

Labeler - STRATUS PHARMACEUTICALS INC (789001641)

Establishment

Name	Address	ID/FEI	Business Operations
TARMAC PRODUCTS INC		059890491	MANUFACTURE, LABEL, PACK

Revised: 10/2017

STRATUS PHARMACEUTICALS INC