SONAFINE WOUND DRESSING- dressing, wound, drug emulsion
Stratus Pharmaceuticals

SONAFINE™ WOUND DRESSING

TOPICAL EMULSION DRESSING

Description

SONAFINE™ WOUND DRESSING is a water-based emulsion formulated for the dressing and management of superficial wounds, minor abrasions, dermal ulcers, donor sites, 1st and 2nd degree burns, including sunburns, and radiation dermatitis. When applied properly to a wound **SONAFINE™ WOUND DRESSING** provides an optimum moist environment for the healing process and isolates the wound from harmful germs and other external contamination.

Indications and Usage

SONAFINE™ WOUND DRESSING is indicated for use in: Full Thickness Wounds, Pressure Sores, Dermal Ulcers including Lower Leg Ulcers, Superficial Wounds, 1st and 2nd Degree Burns, Including Sunburns, Dermal Donor and Graft Site Management, Radiation Dermatitis and Minor Abrasions

Contraindications

SONAFINE™ WOUND DRESSING is contraindicated for use on bleeding wounds, skin rashes related to food or medicine allergies and when an allergy to one of the ingredients is known.

Warnings

In radiation therapy **SONAFINE™ WOUND DRESSING** may be applied as directed by the treating physician. Do not apply 4 hours prior to a radiation session.

Do not apply **SONAFINE™ WOUND DRESSING** to dermal grafts until after the graft has successfully taken.

Keep out of the reach of children.

Precautions and Observations

For the treatment of any dermal wound, consult a physician. Use **SONAFINE™ WOUND DRESSING** only as directed.

SONAFINE™ WOUND DRESSING is nontoxic, it is for topical use only and should not be ingested or taken internally.

SONAFINE™ WOUND DRESSING does not contain a sunscreen and should not be used prior to extended exposure to the sun.

The use of **SONAFINE™ WOUND DRESSING** on skin rashes due to allergies has not been studied sufficiently and therefore is not recommended.

Following the application of **SONAFINE™ WOUND DRESSING** a temporary tingling sensation may occur (10 to 15 minutes). If clinically indicated, use of **SONAFINE™ WOUND DRESSING** may be continued during the anti-infective therapy.

If the condition does not improve within 10-14 days, consult a physician.

SONAFINE™ WOUND DRESSING may dissolve fuchsin when this dye is used to define the margins of the radiation fields to be treated.

Instructions for Use

SONAFINE™ WOUND DRESSING is for topical use only as directed by a healthcare professional.

Wounds, Abrasions, Full Thickness Wounds, Dermal Graft Site Management and Donor Site Management

Wash the affected area(s) with saline, clean water or suitable wound cleanser.

Apply **SONAFINE™ WOUND DRESSING** on and around the affected area(s) in thick layers ¼ to ½ inch thick.

If applying gauze dressing, moisten the dressing lightly before application.

Reapply **SONAFINE™ WOUND DRESSING** as described above every 24 to 48 hours or as directed until the wound or lesion has healed fully.

For donor site management, apply **SONAFINE™ WOUND DRESSING** after skin removal and cover with a moist dressing. Reapply as directed.

For dermal graft site management apply **SONAFINE™ WOUND DRESSING** to the graft site only after the graft has taken successfully. **SONAFINE™ WOUND DRESSING** can be washed away with a saline solution or clean water without causing damage to the newly formed tissues.

1st and 2nd Degree Burns Including Sunburns

Before any application of **SONAFINE™ WOUND DRESSING** to burns take precaution in removing any clothing in the affected area(s).

Apply **SONAFINE™ WOUND DRESSING** as soon as possible on and around the affected area(s) in a thick ¼ to ½ inch layer until the skin no longer absorbs the product. A white waxy residue may remain. If pain from the burn persists, apply thinner layers of **SONAFINE™ WOUND DRESSING** until the pain has ceased.

Continue to apply **SONAFINE™ WOUND DRESSING** until the affected area(s) has healed completely.

Application of **SONAFINE™ WOUND DRESSING** to the affected area(s) should continue during any subsequent physical therapy treatments.

Radiation Dermatitis

Apply a generous amount of **SONAFINE™ WOUND DRESSING** three times per day, seven days a week to the treated area(s), gently massaging the area(s) until **SONAFINE™ WOUND DRESSING** is completely absorbed.

SONAFINE™ WOUND DRESSING may be applied as indicated by the treating physician **(see Warnings)**.

Continue to apply **SONAFINE™ WOUND DRESSING** as described above until the skin has fully recovered.

Do not interrupt applications during the course of radiation therapy, even for one day.

Do not apply **SONAFINE™ WOUND DRESSING** 4 hours prior to a radiation session.

Ingredients

SONAFINE™ WOUND DRESSING contains avocado oil, cetyl palmitate, ethylene glycol

monostearate, fragance, liquid paraffin, methyl paraben, paraffin wax, propylene glycol, propyl paraben, purified water, sodium alginate, sodium hydroxide, sorbic acid (potassium salt), squalane, stearic acid and trolamine.

How Supplied

SONAFINE™ WOUND DRESSING is supplied in tubes in the following sizes:

45gram tube, NDC# 58980-960-12
90gram tube, NDC# 58980-960-31

Store at room temperature, do not freeze.

Rx ONLY- Prescription Medical Device: Federal Law restricts this device to sale by or on the order of a physician (or properly licensed practitioner).

Manufactured by:
Tarmac Products Inc
Miami Gardens, FL 33014

Distributed by:
Stratus Pharmaceuticals Inc
12379 SW 130th Street
Miami, FL 33186

For additional information:
Contact Customer Service at:
Toll Free - 1-800-442-7882

www.stratuspharmaceuticals.com

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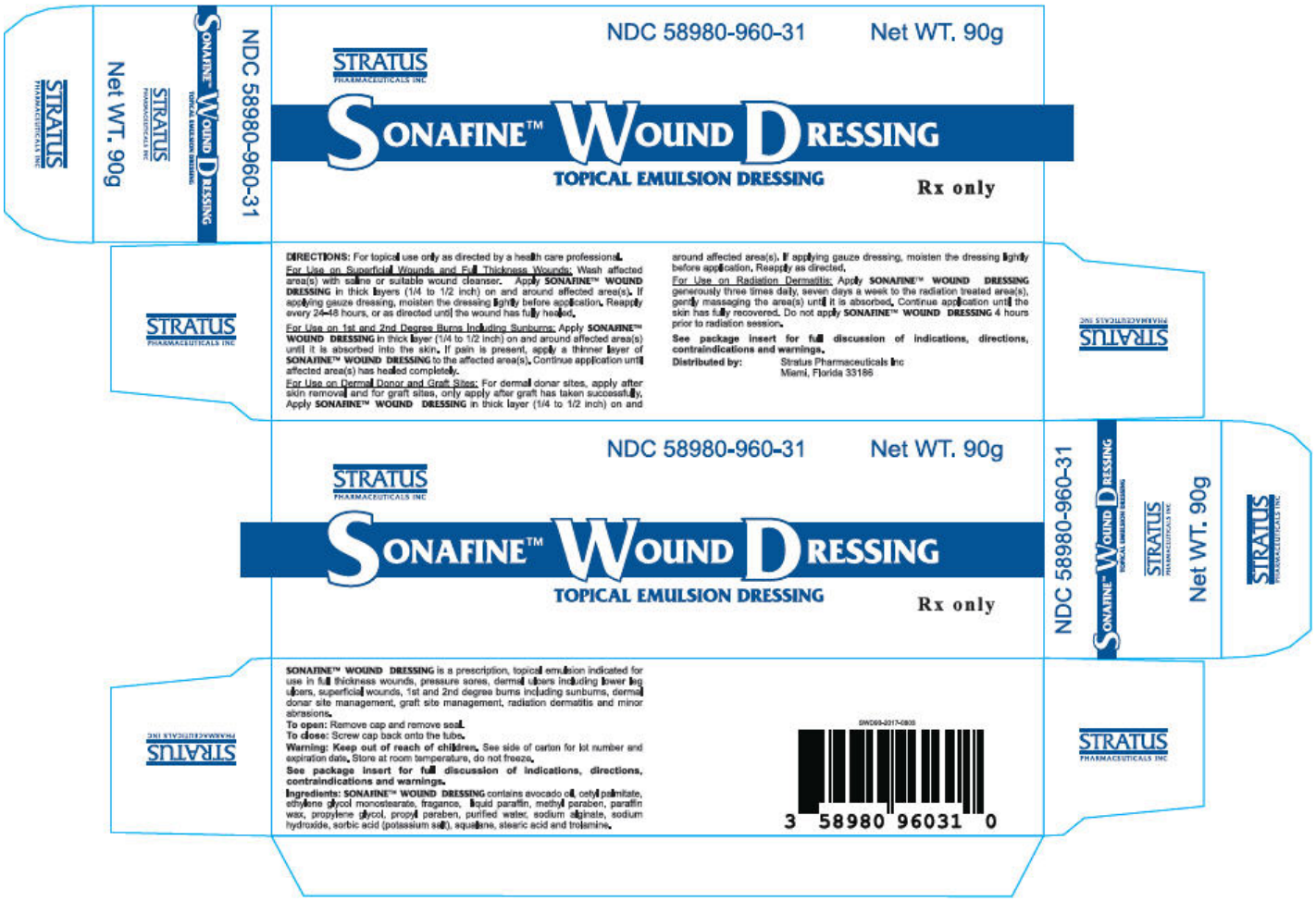
PRINCIPAL DISPLAY PANEL - 90 g Tube Box

STRATUS
PHARMACEUTICALS INC

NDC 58980-960-31
NET WT. 90g

SONAFINE™ WOUND DRESSING
TOPICAL EMULSION DRESSING

Rx only



SONAFINE WOUND DRESSING

dressing, wound, drug emulsion

Product Information			
Product Type	MEDICAL DEVICE	**Item Code (Source)**	NHRIC:58980-960
Route of Administration	TOPICAL		

Inactive Ingredients	
Ingredient Name	**Strength**
Mineral Oil (UNII: T5L8T28FGP)	
Stearic Acid (UNII: 4ELV7Z65AP)	
Paraffin (UNII: I9O0E3H2ZE)	
Squalane (UNII: GW89575KF9)	
Avocado Oil (UNII: 6VNO72PFC1)	
Cetyl Palmitate (UNII: 5ZA2S6B08X)	
Glycol Stearate (UNII: 0324G66D0E)	
Methylparaben (UNII: A2I8C7HI9T)	
Propylparaben (UNII: Z8IX2SC1OH)	
Water (UNII: 059QF0KO0R)	
Propylene Glycol (UNII: 6DC9Q167V3)	
Sodium Alginate (UNII: C269C4G2ZQ)	

Trolamine (UNII: 9O3K93S3TK)	
Sodium Hydroxide (UNII: 55X04QC32I)	
Potassium Sorbate (UNII: 1VPU26JZZ4)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NHRIC:58980-960-12	1 in 1 BOX		
1		45 g in 1 TUBE; Type 0: Not a Combination Product		
2	NHRIC:58980-960-31	1 in 1 BOX		
2		90 g in 1 TUBE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
PREMARKET NOTIFICATION	K110172	08/19/2011	

Labeler - Stratus Pharmaceuticals (789001641)

Establishment

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

Revised: 10/2017 Stratus Pharmaceuticals