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, fragrance, 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
JG-SWDIN-I2015-04

**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
Route of Administration: TOPICAL

Item Code (Source): NHRIC:58980-960

Inactive Ingredients

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### Marketing Information

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### Labeler
- Stratus Pharmaceuticals (789001641)

### Establishment

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Revised: 10/2017