SULFACLEANSE 8/4 - sodium sulfacetamide and sulfur lotion
PruGen, Inc.

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

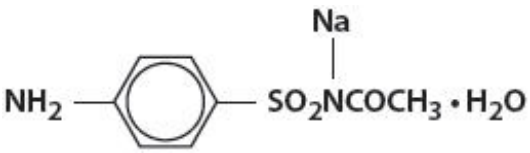
SulfaCleanse® $^{8}/_{4}$
(sodium sulfacetamide 8% & sulfur 4%)

Rx Only

Topical Suspension in a vehicle containing Green Tea and Aloe

DESCRIPTION

Sodium sulfacetamide is a sulfonamide with antibacterial activity while sulfur acts as a keratolytic agent. Chemically sodium sulfacetamide is N-[(4-aminophenyl) sulfonyl]-acetamide, monosodium salt, monohydrate. The structural formula is:



Each mL of **SulfaCleanse® 8/4 (sodium sulfacetamide 8% & sulfur 4%)** contains 80 mg of sodium sulfacetamide and 40 mg of sulfur in a formulation consisting of: aloe barbadensis gel, butylated hydroxytoluene, cetyl alcohol, disodium oleamido MEA sulfosuccinate, edetate disodium, glyceryl stearate, green tea extract, magnesium aluminum silicate, methylparaben, PEG-100 stearate, petrolatum, propylparaben, purified water, sodium cocoyl isethionate, sodium methyl cocoyl taurate, sodium thiosulfate, stearyl alcohol, xanthan gum.

CLINICAL PHARMACOLOGY

The most widely accepted mechanism of action of sulfonamides is the Woods-Fildes theory, which is based on the fact that sulfonamides act as competitive antagonists to paraaminobenzoic acid (PABA), an essential component for bacterial growth. While absorption through intact skin has not been determined, sodium sulfacetamide is readily absorbed from the gastrointestinal tract when taken orally and excreted in the urine, largely unchanged. The biological half-life has variously been reported as 7 to 12.8 hours. The exact mode of action of sulfur in the treatment of acne is unknown, but it has been reported that it inhibits the growth of Propionibacterium acnes and the formation of free fatty acids.

INDICATIONS

SulfaCleanse® 8/4 (sodium sulfacetamide 8% & sulfur 4%) is indicated for the topical control of acne vulgaris, acne rosacea and seborrheic dermatitis.

CONTRAINDICATIONS

SulfaCleanse® 8/4 (sodium sulfacetamide 8% & sulfur 4%) is contraindicated for use by patients having known hypersensitivity to sulfonamides, sulfur or any other component of this preparation. **SulfaCleanse® 8/4 (sodium sulfacetamide 8% & sulfur 4%)** is not to be used by patients with kidney disease.

WARNINGS

Although rare, sensitivity to sodium sulfacetamide may occur. Therefore, caution and careful supervision should be observed when prescribing this drug for patients who may be prone to hypersensitivity to topical sulfonamides. Systemic toxic reactions such as agranulocytosis, acute hemolytic anemia, purpura hemorrhagica, drug fever, jaundice, and contact dermatitis indicate hypersensitivity to sulfonamides. Particular caution should be employed if areas of denuded or abraded skin are involved.

FOR EXTERNAL USE ONLY. Keep away from eyes. **Keep out of reach of children.** Keep container tightly closed.

PRECAUTIONS

General

If irritation develops, use of the product should be discontinued and appropriate therapy instituted. Patients should be carefully observed for possible local irritation or sensitization during long-term therapy. The object of this therapy is to achieve desquamation without irritation, but sodium sulfacetamide and sulfur can cause reddening and scaling of the epidermis. These side effects are not unusual in the treatment of acne vulgaris, but patients should be cautioned about the possibility.

Information for Patients

Avoid contact with eyes, eyelids, lips and mucous membranes. If accidental contact occurs, rinse with water. If excessive irritation develops, discontinue use and consult your physician.

Carcinogenesis, Mutagenesis and Impairment of Fertility

Long-term studies in animals have not been performed to evaluate carcinogenic potential.

PREGNANCY

Category C

Animal reproduction studies have not been conducted with **SulfaCleanse® 8/4 (sodium sulfacetamide 8% & sulfur 4%)**. It is also not known whether **SulfaCleanse® 8/4 (sodium sulfacetamide 8% & sulfur 4%)** can cause fetal harm

when administered to a pregnant woman or can affect reproduction capacity. **SulfaCleanse® 8/4 (sodium sulfacetamide 8% & sulfur 4%)** should be given to a pregnant woman only if clearly needed.

NURSING MOTHERS

It is not known whether sodium sulfacetamide is excreted in the human milk following topical use of **SulfaCleanse® 8/4 (sodium sulfacetamide 8% & sulfur 4%)**. However, small amounts of orally administered sulfonamides have been reported to be eliminated in human milk. In view of this and because many drugs are excreted in human milk, caution should be exercised when **SulfaCleanse® 8/4 (sodium sulfacetamide 8% & sulfur 4%)** is administered to a nursing woman.

PEDIATRIC USE

Safety and effectiveness in children under the age of 12 has not been established.

ADVERSE REACTIONS

Although rare, sodium sulfacetamide may cause local irritation.

DOSAGE AND ADMINISTRATION

Apply **SulfaCleanse® 8/4 (sodium sulfacetamide 8% & sulfur 4%)** once or twice daily to affected areas, or as directed by your physician. Wet skin and liberally apply to areas to be cleansed. Massage gently into skin for 10-20 seconds, working into a full lather, rinse thoroughly and pat dry. If drying occurs, it may be controlled by rinsing off **SulfaCleanse® 8/4 (sodium sulfacetamide 8% & sulfur 4%)** sooner or using less often.

HOW SUPPLIED

SulfaCleanse® 8/4 (sodium sulfacetamide 8% & sulfur 4%) is available in a 16 fl. oz. (473 mL) bottle, NDC 42546-175-16.

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.

Protect from freezing.

KEEP THIS AND ALL MEDICATIONS OUT OF THE REACH OF CHILDREN.

Manufactured for:
PruGen Pharmaceuticals
18899 N Thompson Peak Pkwy
Scottsdale, AZ 85255

Rev.4.0

PRINCIPAL DISPLAY PANEL - 473 ml Bottle Box

NDC 42546-175-16

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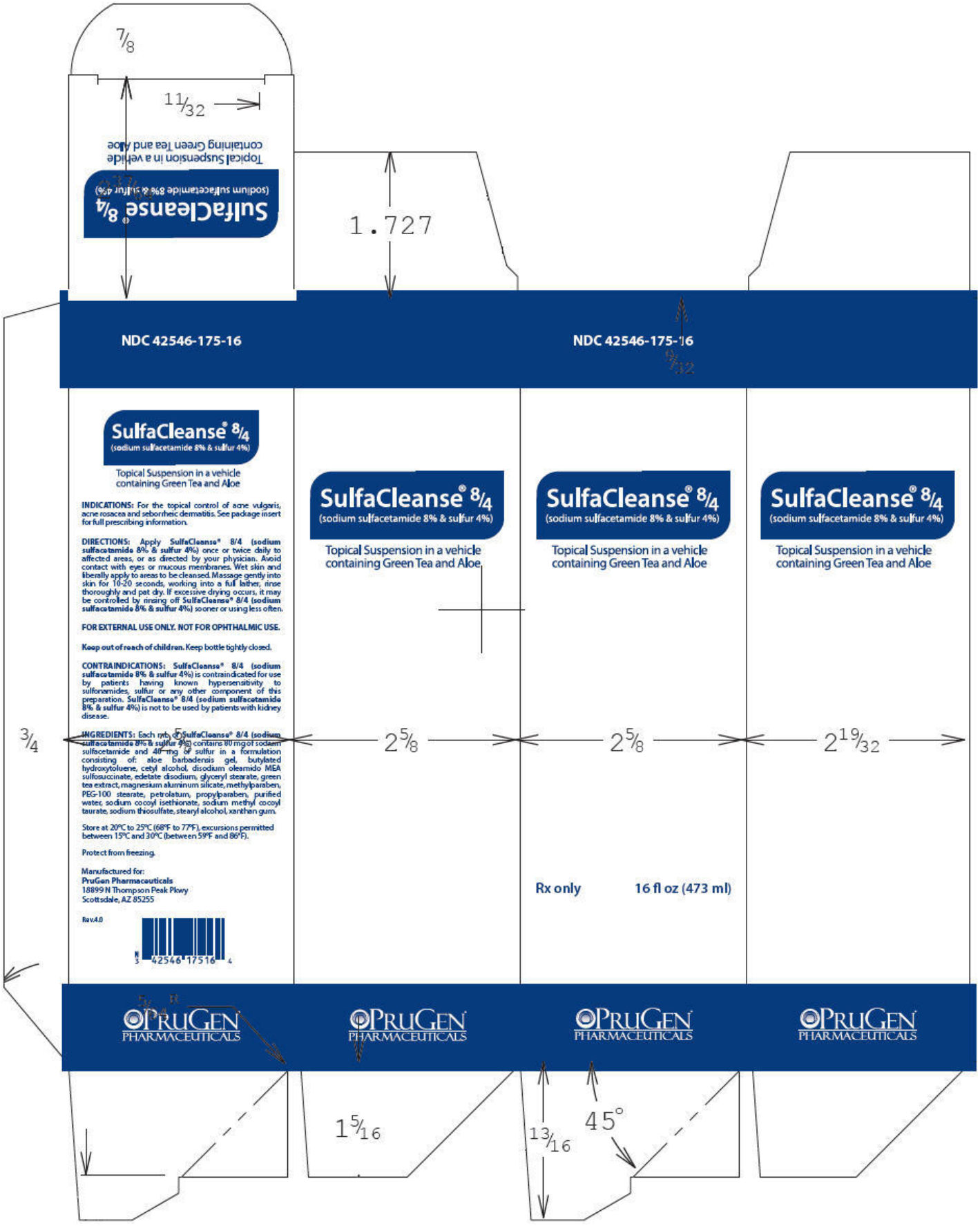
Topical Suspension in a vehicle
containing Green Tea and Aloe

Rx only
16 fl oz (473 ml)

PRUGEN®
PHARMACEUTICALS



SULFACLEANSE 8/4

sodium sulfacetamide and sulfur lotion

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:42546-175
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SULFACETAMIDE SODIUM (UNII: 4NRT660KJQ) (SULFACETAMIDE - UNII:4965G3J0F5)	SULFACETAMIDE SODIUM	80 mg in 1 mL
SULFUR (UNII: 70FD1KFU70) (SULFUR - UNII:70FD1KFU70)	SULFUR	40 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
Aloe (UNII: V5VD430YW9)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
Cetyl alcohol (UNII: 936JST6JCN)	
DISODIUM OLEAMIDO MONOETHANOLAMINE SULFOSUCCINATE (UNII: 5M1101WGSY)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
Green tea leaf (UNII: W2ZU1RY8B0)	
MAGNESIUM ALUMINUM SILICATE (UNII: 6M3P64V0NC)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PEG-100 STEARATE (UNII: YD01N1999R)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0KO0R)	
SODIUM COCOYL ISETHIONATE (UNII: 518XTE8493)	
TAURINE (UNII: 1EQV5MLY3D)	
SODIUM THIOSULFATE (UNII: HX1032V43M)	
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Product Characteristics

Color	yellow	**Score**	
Shape		**Size**	
Flavor		**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:42546-175-16	1 in 1 BOX	05/01/2011	
1		473 mL in 1 BOTTLE, PUMP; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		05/01/2011	

Labeler - PruGen, Inc. (929922750)

Establishment

Name	Address	ID/FEI	Business Operations
DERMAZONE SOLUTIONS, INC.		136116865	MANUFACTURE(42546-175)

Revised: 1/2022 PruGen, Inc.