

## **SSS CLEANSER- sulfacetamide sodium and sulfur cream** **PruGen Pharmaceuticals**

*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.*

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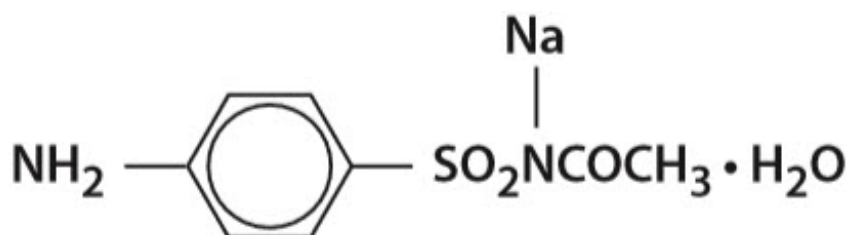
### **SSS 10-1 cleanser Sodium Sulfacetamide 10% & Sulfur 1%**

#### **Rx Only**

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#### **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 SSS 10-1 Cleanser (Sodium Sulfacetamide 10% & Sulfur 1%) contains 100 mg of Sulfacetamide Sodium, USP and 10 mg of Sulfur in a formulation consisting of: Aloe Barbadensis Leaf Juice, Butylated Hydroxy Toluene, Camellia Sinensis Leaf Extract, Cetyl Alcohol, Disodium Oleamido MEA Sulfosuccinate, Edetate Disodium, Glyceryl Stearate, Magnesium Aluminum Silicate, Methylparaben, PEG-100 Stearate, Propylene Glycol, Propylparaben, Purified Water, Sodium Cocoyl Isethionate, Sodium Methyl Cocoyl Taurate, Sodium Thiosulfate, Stearyl Alcohol, White Petrolatum, 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 para-aminobenzoic 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**

SSS 10-1 Cleanser (Sodium Sulfacetamide 10% & Sulfur 1%) is indicated for the topical control of acne vulgaris, acne rosacea and seborrheic dermatitis.

## **CONTRAINDICATIONS**

SSS 10-1 Cleanser (Sodium Sulfacetamide 10% & Sulfur 1%) is contraindicated for use by patients having known hypersensitivity to sulfonamides, sulfur or any other component of this preparation. SSS 10-1 Cleanser (Sodium Sulfacetamide 10% & Sulfur 1%) 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 SSS 10-1 Cleanser (Sodium Sulfacetamide 10% & Sulfur 1%). It is also not known whether SSS 10-1 Cleanser (Sodium Sulfacetamide 10% & Sulfur 1%) can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. SSS 10-1 Cleanser (Sodium Sulfacetamide 10% & Sulfur 1%) 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 SSS 10-1 Cleanser (Sodium Sulfacetamide 10% & Sulfur 1%). 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 SSS 10-1 Cleanser (Sodium Sulfacetamide 10% & Sulfur 1%) 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 SSS 10-1 Cleanser (Sodium Sulfacetamide 10% & Sulfur 1%) 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 SSS 10-1 Cleanser (Sodium Sulfacetamide 10% & Sulfur 1%) sooner or using less often.

## **HOW SUPPLIED**

SSS 10-1 Cleanser (Sodium Sulfacetamide 10% & Sulfur 1%) is available in a 6 oz. (170.1g) tube, NDC 42546-174-06.

Store at 20°C to 25°C (68°F to 77°F)

Protect from freezing.

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

Manufactured for:

**PruGen Pharmaceuticals**

Scottsdale, AZ 85255

Rev. 1.0

**PRINCIPAL DISPLAY PANEL - 170.1 g Tube Carton**

SSS  
10-1  
cleanser

Sodium  
Sulfacetamide 10%  
& Sulfur 1%

Rx only  
Net Wt. 6 oz (170.1g)

NDC 42546-174-06



**10-1**

cleanser

Sodium  
Sulfacetamide 10%  
& Sulfur 1%



**Rx only**

Net Wt. 6 oz (170.1g)

**NDC 42546-174-06**

**Rx only**

Net Wt. 6 oz (170.1g)

**NDC 42546-174-06**

KO P015236

**INDICATIONS FOR USE:**

For the topical control of acne vulgaris, acne rosacea and seborrheic dermatitis. See package insert for full prescribing information.

**DIRECTIONS:**

Apply SSS 10-1 Cleanser (Sodium Sulfacetamide 10% & Sulfur 1%) once or twice daily to affected areas, or as directed by your physician. Avoid contact with eyes or mucous membranes. 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 excessive drying occurs, it may be controlled by rinsing off SSS 10-1 Cleanser (Sodium Sulfacetamide 10% & Sulfur 1%) sooner or using less often.

**FOR EXTERNAL USE ONLY. NOT FOR OPHTHALMIC USE.**

Keep out of reach of children. Keep bottle tightly closed.

**CONTRAINDICATIONS:** SSS 10-1 Cleanser (Sodium Sulfacetamide 10% & Sulfur 1%) is contraindicated for use by patients having known hypersensitivity to sulfonamides, sulfur or any other component of this preparation. SSS 10-1 Cleanser (Sodium Sulfacetamide 10% & Sulfur 1%) is not to be used by patients with kidney disease.

**INGREDIENTS:** Each mL of SSS 10-1 Cleanser (Sodium Sulfacetamide 10% & Sulfur 1%) contains 100 mg of Sulfacetamide Sodium, USP and 10 mg of Sulfur in a formulation consisting of: Aloe Barbadensis Leaf Juice, Butylated Hydroxy Toluene, Camellia Sinensis Leaf Extract, Cetyl Alcohol, Disodium Oleamido MEA Sulfosuccinate, Edetate Disodium, Glyceryl Stearate, Magnesium Aluminum Silicate, Methylparaben, PEG-100 Stearate, Propylene Glycol, Propylparaben, Purified Water, Sodium Cocoyl Isethionate, Sodium Methyl Cocoyl Taurate, Sodium Thiosulfate, Stearyl Alcohol, White Petrolatum, Xanthan Gum.

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).  
Protect from freezing.

Manufactured for:  
PruGen Pharmaceuticals  
Scottsdale, AZ 85255

Rev. 1.0



**PRUGEN™**  
PHARMACEUTICALS

Sodium Sulfacetamide 10% & Sulfur 1%  
cleanser  
**SSS**  
**10-1**

**Rx only**

Net Wt. 6 oz (170.1g)

NDC 42546-174-06

**SSS CLEANSER**

sulfacetamide sodium and sulfur cream

## Product Information

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:42546-174
<b>Route of Administration</b>	TOPICAL		

## Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>SULFACETAMIDE SODIUM</b> (UNII: 4NRT660KJQ) (SULFACETAMIDE - UNII:4965G3J0F5)	SULFACETAMIDE SODIUM	100 mg in 1 g
<b>SULFUR</b> (UNII: 70FD1KFU70) (SULFUR - UNII:70FD1KFU70)	SULFUR	10 mg in 1 g

## Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
<b>ALOE VERA LEAF</b> (UNII: ZY81Z83H0X)	
<b>BUTYLATED HYDROXYTOLUENE</b> (UNII: 1P9D0Z171K)	
<b>GREEN TEA LEAF</b> (UNII: W2ZU1RY8B0)	
<b>CETYL ALCOHOL</b> (UNII: 936JST6JCN)	
<b>DISODIUM OLEAMIDO MONOETHANOLAMINE SULFOSUCCINATE</b> (UNII: 5M1101WGSY)	
<b>EDETATE DISODIUM</b> (UNII: 7FLD91C86K)	
<b>GLYCERYL MONOSTEARATE</b> (UNII: 230OU9XXE4)	
<b>MAGNESIUM ALUMINUM SILICATE</b> (UNII: 6M3P64V0NC)	
<b>METHYLPARABEN</b> (UNII: A2I8C7HI9T)	
<b>PEG-100 STEARATE</b> (UNII: YD01N1999R)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>PROPYLPARABEN</b> (UNII: Z8IX2SC1OH)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>SODIUM COCOYL ISETHIONATE</b> (UNII: 518XTE8493)	
<b>SODIUM METHYL COCOYL TAURATE</b> (UNII: JVL98CG53G)	
<b>SODIUM THIOSULFATE</b> (UNII: HX1032V43M)	
<b>STEARYL ALCOHOL</b> (UNII: 2KR89I4H1Y)	
<b>PETROLATUM</b> (UNII: 4T6H12BN9U)	
<b>XANTHAN GUM</b> (UNII: TTV12P4NEE)	

## Packaging

<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:42546-174-06	1 in 1 CARTON	11/15/2020	
1		170.1 g in 1 TUBE; Type 0: Not a Combination Product		
2	NDC:42546-174-16	1 in 1 CARTON	11/15/2020	
2		453.6 g in 1 BOTTLE; Type 0: Not a Combination Product		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Unapproved drug other		11/15/2020	

**Labeler** - PruGen Pharmaceuticals (929922750)

### Establishment

Name	Address	ID/FEI	Business Operations
Dermazone Solutions, Inc.		136116865	MANUFACTURE(42546-174)

Revised: 1/2022

PruGen Pharmaceuticals