

**SODIUM SULFACETAMIDE, SULFUR- sodium sulfacetamide 9.8% sulfur 4.8% liquid**

**Aspen Medical LLC**

*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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**Sodium Sulfacetamide 9.8% Sulfur 4.8%**

Rx Only

FOR EXTERNAL USE ONLY. NOT FOR INTRA VAGINAL OR OPHTHALMIC USE. (KEEP AWAY FROM EYES)

Aloe Vera Leaf Extract, Butylated Hydroxytoluene, Cetyl Alcohol, Citric Acid, Cocamidopropyl Betaine, Disodium EDTA, Glycerin, Glyceryl Stearate SE, PEG-100 Stearate, Phenoclyethanol, Purified Water, Sodium Laureth Sulfate, Sodium Thiosulfate, Stearyl Alcohol, Triacetin, Xanthan Gum.

Sodium Sulfacetamide 9.8% & Sulfur 4.8% Cleanser is indicated in the topical control of acne vulgaris, acne rosacea and seborrheic dermatitis.

**CAUTION**

If redness or irritation occurs, discontinue use.

**Call your doctor for medical advice about side effect.**

Wash affected areas once or twice daily, 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 leather, rinse thoroughly and pat dry. If drying occurs, it may be controlled by rinsing cleanser off sooner or using less often.

**FOR EXTERNAL USE ONLY. NOT FOR INTRAVAGINAL OR OPHTHALMIC USE. (KEEP AWAY FROM EYES).**

**KEEP OUT OF REACH OF CHILDREN**

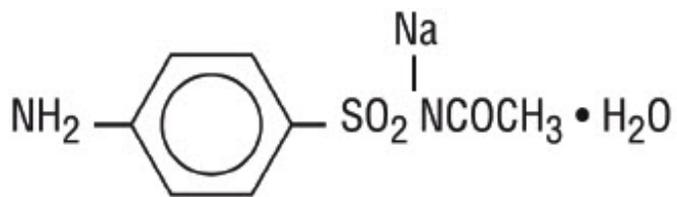
**(Shake well before use)**

Store at 20°C to 25°C (68°F to 77°F). See USP controlled room temperature. Protect from freezing.

In case of accidental ingestion contact a Poison Control Center immediately. Keep container tightly closed.

You may report side effects by calling the FDA at 1-800-FDA-1088

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:



The most widely accepted mechanism of action of sulfonamides is the woods-fields 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.

Sodium Sulfacetamide 9.8% & Sulfur 4.8% Cleanser is contraindicated for use by patients having known hypersensitivity to sulfonamides, sulfur or any other component of this preparation. Sodium Sulfacetamide 9.8% & Sulfur 4.8% Cleanser is not to be used by patients with kidney disease.

Although it is 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.

## **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 & 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 Sodium Sulfacetamide 9.8%

& Sulfur 4.8% Cleanser. It is also not known whether Sodium Sulfacetamide 9.8% & Sulfur 4.8% Cleanser can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Sodium Sulfacetamide 9.8% & Sulfur 4.8% Cleanser should be given to a pregnant woman only if clearly needed.

### **PEDIATRIC USE**

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

### **NURSING MOTHERS**

It is not known whether sodium sulfacetamide is excreted in the human milk following topical use of Sodium Sulfacetamide 9.8% & Sulfur 4.8% Cleanser. However, small amounts of orally administered sulfonamides have milk. In view of this and because many drugs are excreted in human milk, caution should be exercised when Sodium Sulfacetamide 9.8% & Sulfur 4.8% Cleanser is administered to a nursing woman.

Although rare, sodium sulfacetamide may cause local irritation.

Sodium Sulfacetamide 9.8% & Sulfur 4.8 % Cleanser is available in

10 oz (285 g) bottle, NDC 87026-205-10.

This bottle is not filled to the top but does contain 10 oz of product as identified on the front panel of the bottle.

### **USA Manufactured For:**

Aspen Medical LLC

8 The Green Ste. B

Dover, DE 19901

Rev. 10/25

Aspen Medical

NDC 87026-205-10

Rx Only

Sodium

Sulfacetamide

& Sulfur

Sodium Sulfacetamide 9.8%

Sulfur 4.8%

9.8%/4.8%

Cleanser

For External Use only

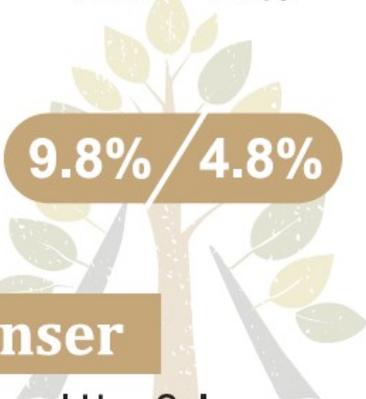
NET WT. 10 OZ. (285 g)



NDC 87026-205-10 Rx Only

# Sodium Sulfacetamide & Sulfur

Sodium Sulfacetamide 9.8%  
Sulfur 4.8%



Cleanser

For External Use Only

NET WT. 10 OZ. (285 g)

**INGREDIENTS**

Each gram of Sodium Sulfacetamide 9.8% and Sulfur 4.8% cleanser contain 98 mg of sodium sulfacetamide and 48 mg of sulfur in a cleanser containing Aloe Vera Leaf Extract, Butylated Hydroxytoluene, Cetyl Alcohol, Citric Acid, Cocamidopropyl Betaine, Disodium EDTA, Glycerin, Glyceryl Stearate SE, PEG-100 Stearate, Phenocycethanol, Purified Water, Sodium Laureth Sulfate, Sodium Thiosulfate, Stearyl Alcohol, Triacetin, Xanthan Gum.

**INDICATIONS**

Sodium Sulfacetamide 9.8% & Sulfur 4.8% Cleanser is indicated in the topical control of acne vulgaris, acne rosacea and seborrheic dermatitis.

**CAUTION**

If redness or irritation occurs, discontinue use.  
Call your doctor for medical advice about side effects.

**DOSAGE AND ADMINISTRATION**

Wash affected areas once or twice daily, 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 drying occurs, it may be controlled by rinsing cleanser off sooner or using less often.

FOR EXTERNAL USE ONLY. NOT FOR INTRA VAGINAL OR OPHTHALMIC USE. (KEEP AWAY FROM EYES).

KEEP OUT OF REACH OF CHILDREN.  
Shake well before use

**STORAGE**

Store at 20°C to 25°C (68°F to 77°F). See USP controlled room temperature. Protect from freezing.

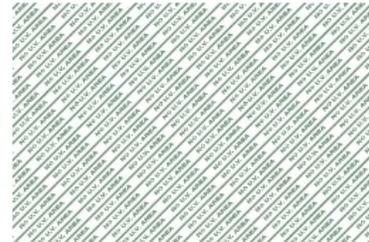
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**USA Manufactured For:**

Aspen Medical LLC  
8 The Green Ste. B  
Dover, DE 19901  
Rev. 10/25



PEEL HERE

**SODIUM SULFACETAMIDE, SULFUR**

sodium sulfacetamide 9.8% sulfur 4.8% liquid

**Product Information**

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:87026-205
<b>Route of Administration</b>	TOPICAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
<b>SULFACETAMIDE SODIUM</b> (UNII: 4NRT660KJQ) (SULFACETAMIDE - UNII:4965G3J0F5)	SULFACETAMIDE SODIUM	98 mg in 1 g

SULFUR (UNII: 70FD1KFU70) (SULFUR - UNII:70FD1KFU70)

SULFUR

48 mg  
in 1 g

### Inactive Ingredients

Ingredient Name	Strength
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
TRIACETIN (UNII: XHX3C3X673)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
SODIUM THIOSULFATE (UNII: HX1032V43M)	
ALOE BARBADENSIS LEAF POWDER (UNII: ZY81Z83H0X)	
GLYCERYL STEARATE SE (UNII: FCZ5MH785I)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)	
WATER (UNII: 059QF0KO0R)	
CITRIC ACID (UNII: 2968PHW8QP)	
GLYCERIN (UNII: PDC6A3C0OX)	
PEG-100 STEARATE (UNII: YD01N1999R)	
SODIUM LAURETH SULFATE (UNII: BPV390UAP0)	
XANTHAN GUM (UNII: TTV12P4NEE)	

### Product Characteristics

Color	white	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:87026-205-10	285 g in 1 BOTTLE; Type 0: Not a Combination Product	02/01/2026	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		02/01/2026	

**Labeler** - Aspen Medical LLC (119562869)

**Registrant** - Aspen Medical LLC (119562869)