SODIUM SULFACETAMIDE, SULFUR- sodium sulfacetamide 8% sulfur 4% 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.

Sodium Sulfacetamide 8% Sulfur 4%

Rx Only

FOR EXTERNAL USE ONLY. NOT FOR OPHTHALMIC USE.
Keep out of reach of children. Keep container tightly closed.
Keep away from eyes. Shake well before use.

In case of accidental ingestion contact a Poison Control Center immediately.

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

Aloe vera leaf extract, butylated hydroxytoluene, cetyl alcohol, citric acid, cocamidopropyl betaine, disodium EDTA, glycerin, glyceryl stearate SE, green tea extract, PEG-100 stearate, phenoxyethanol, purified water, sodium laureth sulfate, sodium thiosulfate, stearyl alcohol, triacetin, xanthan gum.

Sodium Sulfacetamide 8% and Sulfur 4% Topical Suspension is indicated in the topical control of acne vulgaris, acne rosacea and seborrheic dermatitis.

CAUTION

In case of itching or redness discontinue the use.

Apply Sodium Sulfacetamide 8% and Sulfur 4% Topical Suspension 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 Sodium Sulfacetamide 8% and Sulfur 4% Topical Suspension sooner or using less often.

Store at 20℃ to 25C (68°F to 77°F), excursions permitted between 15C and 30C (between 59°F and 86°F). Brief exposure to temperatures up to 40C (104°F) may be tolerated provided the mean kinetic temperature does not exceed 25C (77°F) however, such exposure should be minimized. Protect from freezing.

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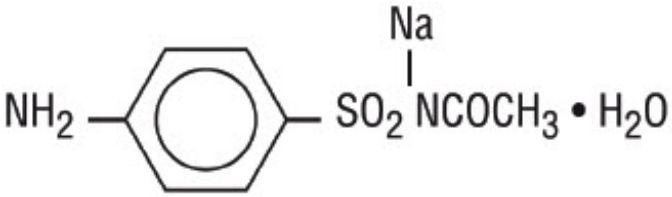
Sodium sulfacetamide is a sulfonamide with antibacterial activity while sulfur acts as a keratolytic agent. Chemically sodium sulfacetamide is N-[(4-aminophenyl)sulfonyl]-acetamide monosodium salt, monohydrate. The structural formula is:



This product is contraindicated for use by persons with known or suspected hypersensitivity to sulfonamides, sulfur or any other component of this preparation. This product is not to be used by patients with kidney disease.

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 not known, but it has been reported that it inhibits the growth of Propionibacterium acnes and the formation of free fatty acids.

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.

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 8% and Sulfur 4% Topical Suspension. It is not known whether Sodium Sulfacetamide 8%

and Sulfur 4% Topical Suspension can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Sodium Sulfacetamide 8% and Sulfur 4% Topical Suspension 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 Sodium Sulfacetamide 8% and Sulfur 4% Topical Suspension. 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 Sodium Sulfacetamide 8% and Sulfur 4% Topical Suspension is administered to a nursing woman.

PEDIATRIC USE

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

Although rare, sodium sulfacetamide may cause local irritation. Call your doctor for medical advice about side effects.

Sodium Sulfacetamide 8% and Sulfur 4% Topical Suspension is available in
16 fl oz (473 mL) bottles NDC 87026-203-16

This bottle is not filled to the top but does contain 16 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 87026-203-16

Rx Only

Sodium

Sulfacetamide

& Sulfur

Sodium Sulfacetamide 8%

Sulfur 4%

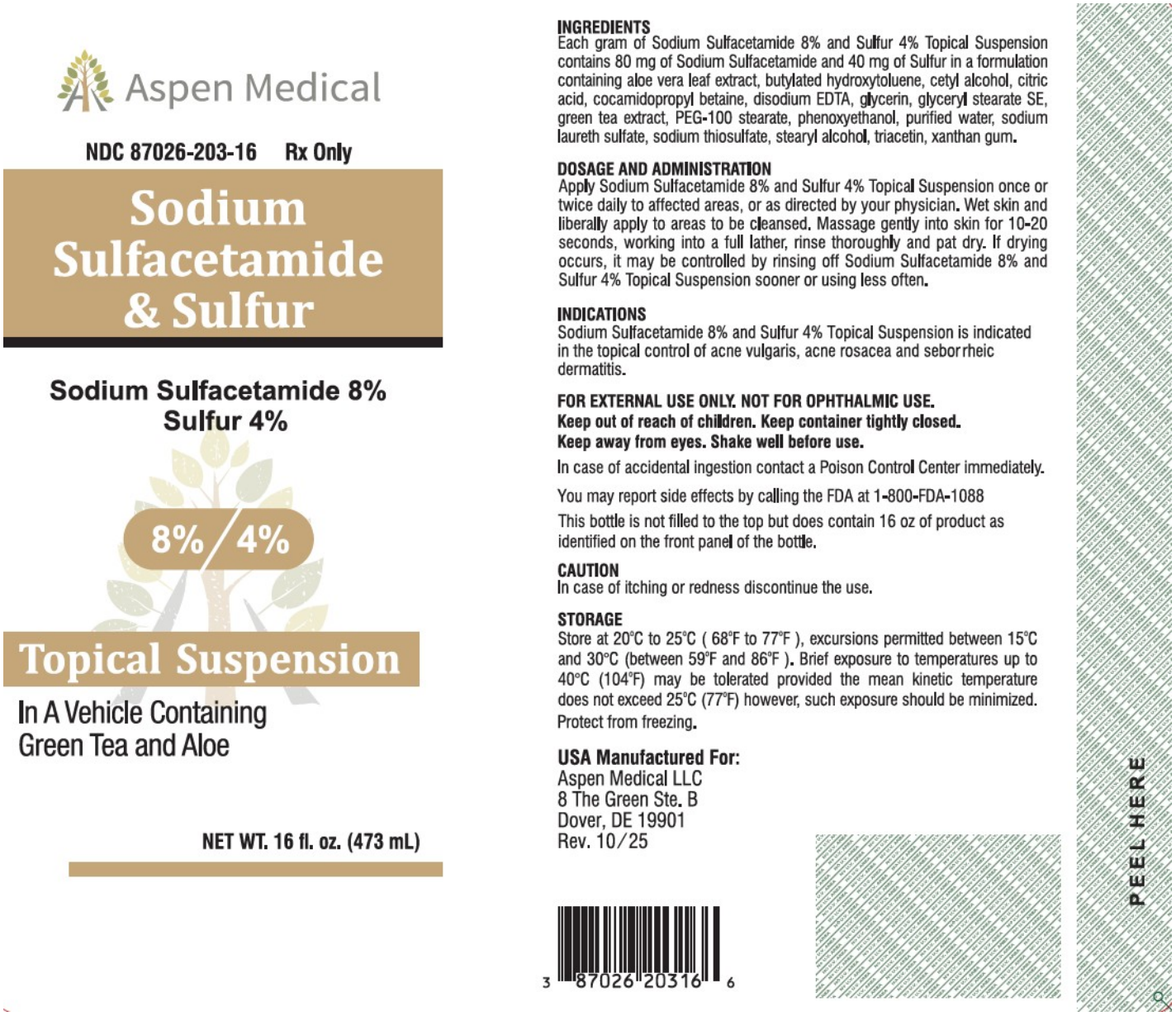
8%/4%

Topical Suspension

In A Vehicle Containing

Green Tea and Aloe

NET WT. 16 fl. oz. (473 mL)



SODIUM SULFACETAMIDE, SULFUR

sodium sulfacetamide 8% sulfur 4% liquid

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:87026-203
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 g
SULFUR (UNII: 70FD1KFU70) (SULFUR - UNII:70FD1KFU70)	SULFUR	40 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
TRIACETIN (UNII: XHX3C3X673)	
XANTHAN GUM (UNII: TTV12P4NEE)	
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)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	

Product Characteristics

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:87026-203-16	473 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)

Revised: 2/2026 Aspen Medical LLC