SODIUM SULFACETAMIDE 8% AND SULFUR 4% CLEANSER- sulfacetamide sodium, sulfur liquid
Method 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.

Sodium Sulfacetamide Sulfur Cleanser

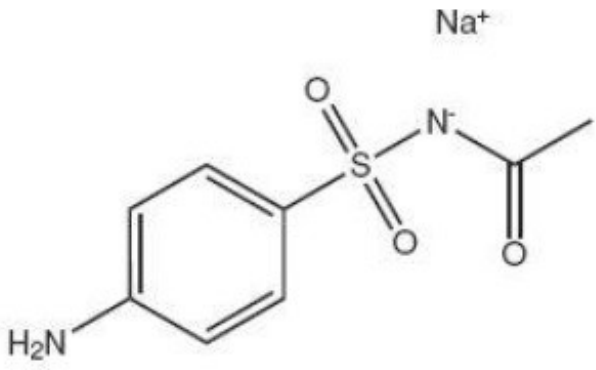
Rx Only

DESCRIPTION

Each gram of sodium sulfacetamide 8% and sulfur 4% cleanser contains 80 mg of sodium sulfacetamide and 40 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, Green Tea Extract, PEG-100 Stearate, Phenoxyethanol, Purified Water, Sodium laureth sulfate, Sodium Thiosulfate, Stearyl alcohol, Triacetin, Xanthan Gum.

Sodium sulfacetamide is a sulfonamide with antibacterial activity while sulfur acts as a keratolytic agent. Sodium sulfacetamide is $C_8H_9N_2NaO\ 3S{\cdot}H2O$ with molecular weight of 254.24. Chemically, it is N-[(4-aminophenyl)sulfonyl]-acetamide, monosodium salt, monohydrate.

The structural formula is:



Clinical Pharmacology

Sodium sulfacetamide exerts a bacteriostatic effect against sulfonamide sensitive Gram-positive and Gram-negative microorganisms commonly isolated from secondary cutaneous pyogenic infections. It acts by restricting the synthesis of folic acid required by bacteria for growth, by its competition with para-aminobenzoic acid. There is no

clinical data available on the degree and rate of systemic absorption of this product when applied to the skin or scalp. However, significant absorption of sodium sulfacetamide through the skin has been reported.

The following in vitro data is available but the clinical significance is unknown. Organisms that show susceptibility to sodium sulfacetamide are: Streptococci, Staphylococci, E. coli, Klebsiella pneumoniae, Pseudomonas pyocyanea, Salmonella species, Proteus vulgaris, Nocardia and Actinomyces.

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

SODIUM SULFACETAMIDE 8% - SULFUR 4% CLEANSER is indicated for use in the topical control of acne vulgaris, acne rosacea and seborrheic dermatitis.

CONTRAINDICATIONS:

SODIUM SULFACETAMIDE 8% - SULFUR 4% CLEANSER is contraindicated for use by patients having known hypersensitivity to sulfonamides, sulfur or any other component of this preparation. SODIUM SULFACETAMIDE 8% - SULFUR 4% CLEANSER is not to be used by patients with kidney disease.

WARNINGS

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.

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

KEEP OUT OF REACH OF CHILDREN.

In case of accidental ingestion contact a poison control center immediately. Keepcontainer tightly closed.

Precaution

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 Sodium Sulfacetamide 8% & Sulfur 4% Cleanser. It is also not known whether Sodium Sulfacetamide 8% & Sulfur 4% Cleanser can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Sodium Sulfacetamide 8% & Sulfur 4% Cleanser 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% & Sulfur 4% 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 8% & Sulfur 4% Cleanser is administered to a nursing woman.

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

Adverse Reaction

Although rare, sodium sulfacetamide may cause local irritation.

Call your doctor for medical advice about side effects.

To report a serious adverse event or obtain product information, call 1-877-250-3427.

DOSAGE AND ADMINISTRATION

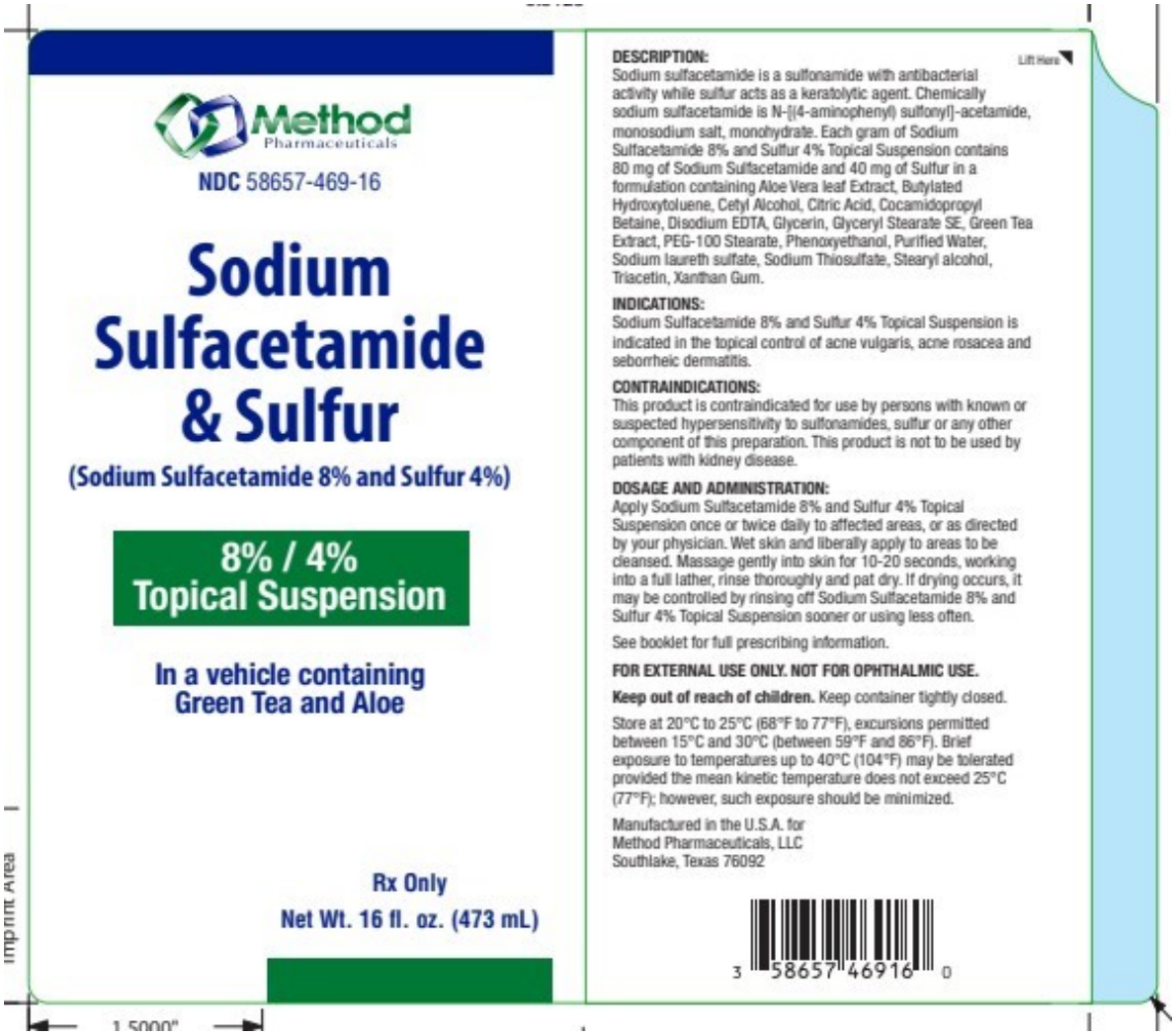
Apply Sodium Sulfacetamide 8% and Sulfur 4% Topical Suspension once or twice daily to affected areas, or as directed by your physician. Wet skin and liberally apply to areas to be cleansed. Massage gently into skin for 10-20 seconds, working into a full lather, rinse thoroughly and pat dry. If drying occurs, it may be controlled by rinsing off Sodium Sulfacetamide 8% and Sulfur 4% Topical Suspension sooner or using less often. See booklet for full prescribing information.

HOW SUPPLIED

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.

NOTICE: Protect from freezing and excessive heat. The product may tend to darken slightly on storage. Slight discoloration does not impair the efficacy or safety of the product. Keep bottle tightly closed. Occasionally, a slight discoloration of fabric may occur when an excessive amount of the product is used and comes in contact with white fabrics. This discoloration, however, presents no problem, as it is readily removed by ordinary laundering without bleaches.

This bottle is not filled to the top but does contain 16 fl oz of product as identified on the front panel of the bottle.



SODIUM SULFACETAMIDE 8% AND SULFUR 4% CLEANSER

sulfacetamide sodium, sulfur liquid

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:58657-469
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
TRIACETIN (UNII: XHX3C3X673)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
GLYCERYL STEARATE SE (UNII: FCZ5MH785I)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
PEG-100 STEARATE (UNII: YD01N1999R)	
WATER (UNII: 059QF0KO0R)	
SODIUM THIOSULFATE (UNII: HX1032V43M)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)	
XANTHAN GUM (UNII: TTV12P4NEE)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
GLYCERIN (UNII: PDC6A3C0OX)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58657-469-16	473 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	02/15/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		02/01/2022	

Labeler - Method Pharmaceuticals (060216698)

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