SODIUM SULFACETAMIDE, SULFUR- sulfacetamide sodium and sulfur liquid
Westminster Pharmaceuticals, 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 9.8%
and Sulfur 4.8% Cleanser

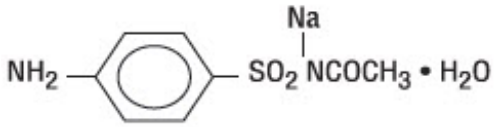
Rx Only

FOR EXTERNAL USE ONLY. NOT FOR OPHTHALMIC USE.

DESCRIPTION

Each gram of Sodium Sulfacetamide 9.8% and Sulfur 4.8% Cleanser contains 98 mg of sodium sulfacetamide and 48 mg of colloidal sulfur in a vehicle consisting of Aloe Vera leaf Extract, Butylated Hydroxytoluene, Cetyl Alcohol, Citric Acid, Cocamidopropyl Betaine, Disodium EDTA, Glycerin, Glyceryl Stearate SE, 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 $C_8H_9N_2NaO_3S \cdot H_2O$ with molecular weight of 254.24. Chemically sodium sulfacetamide is N-[(4-aminophenyl) sulfonyl]-acetamide, monosodium salt, monohydrate. The structural formula is:



Sodium sulfacetamide is an odorless, white, crystalline powder with a bitter taste. It is freely soluble in water, sparingly soluble in alcohol, while practically insoluble in benzene, in chloroform and in ether.

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

This product is indicated for use in the topical control of acne vulgaris, acne rosacea and seborrheic dermatitis.

CONTRAINDICATIONS

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

WARNINGS

Sulfonamides are known to cause Stevens-Johnson syndrome in hypersensitive individuals. Stevens-Johnson syndrome also has been reported following the use of sodium sulfacetamide topically. Cases of drug-induced systemic lupus erythematosus from topical sulfacetamide also have been reported. In one of these cases, there was a fatal outcome.

KEEP OUT OF REACH OF CHILDREN.

PRECAUTIONS

FOR EXTERNAL USE ONLY. NOT FOR OPHTHALMIC USE. Avoid contact with eyes, lips and mucous membranes.

General

Nonsusceptible organisms, including fungi, may proliferate with the use of this preparation.

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. If the use of this product produces signs of hypersensitivity or other untoward reactions, discontinued use of the preparation. Patients should be carefully observed for possible local irritation or sensitization during long-term therapy. Systemic toxic reactions such as granulocytosis, 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. Systemic absorption of topical sulfonamides is greater following application to large, infected, abraded, denuded or severely burned areas. Under these circumstances, any of the adverse effects produced by the systemic administration of these agents could potentially occur, and appropriate observations and laboratory determinations should be performed. 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

Patients should discontinue the use of this product if the condition becomes worse or if a rash develops in the area being treated or elsewhere. The use of this product also should be discontinued promptly and the physician notified if any arthritis, fever or sores in the mouth develop. Avoid contact with eyes, eyelids, lips and mucous membranes.

Drug Interactions

This product is incompatible with silver preparations.

Carcinogenesis, Mutagenesis and Impairment of Fertility

Long-term animal studies for carcinogenic potential have not been performed on this product to date. Studies on reproduction and fertility also have not been performed. Chromosomal nondisjunction has been reported in the yeast, Saccharomyces cerevisiae, following application of sodium sulfacetamide. The significance of this finding to the topical use of sodium sulfacetamide in the human is unknown.

Pregnancy

Category C

Animal reproduction studies have not been conducted with this product. It is also not known whether this product can affect reproduction capacity or cause fetal harm when administered to a pregnant woman. This product should be used by a pregnant woman only if clearly needed or when potential benefits outweigh potential hazards to the fetus.

Nursing Mothers

It is not known whether this drug is excreted in the human milk. Because many drugs are excreted in human milk, caution should be exercised when this product is administered to a nursing woman.

Pediatric Use

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

DOSAGE AND ADMINISTRATION

Wash affected areas once or twice daily, or as directed by your physician. Wet skin and liberally apply to areas to be cleansed. Massage gently into skin for 10 to 20 seconds working into a full lather, rinse thoroughly and pat dry. If skin dryness occurs, it may be controlled by rinsing cleanser off sooner or using less frequently.

See booklet for full prescribing information.

STORAGE

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 and excessive heat. Keep bottle tightly closed.

To report a serious adverse event or obtain product information, please contact Westminster Pharmaceuticals at 1-844-221-7294.

Manufactured for:
Westminster Pharmaceuticals, LLC
Nashville, TN 37217

Rev. 12/22

PRINCIPAL DISPLAY PANEL - 285 g Bottle Label

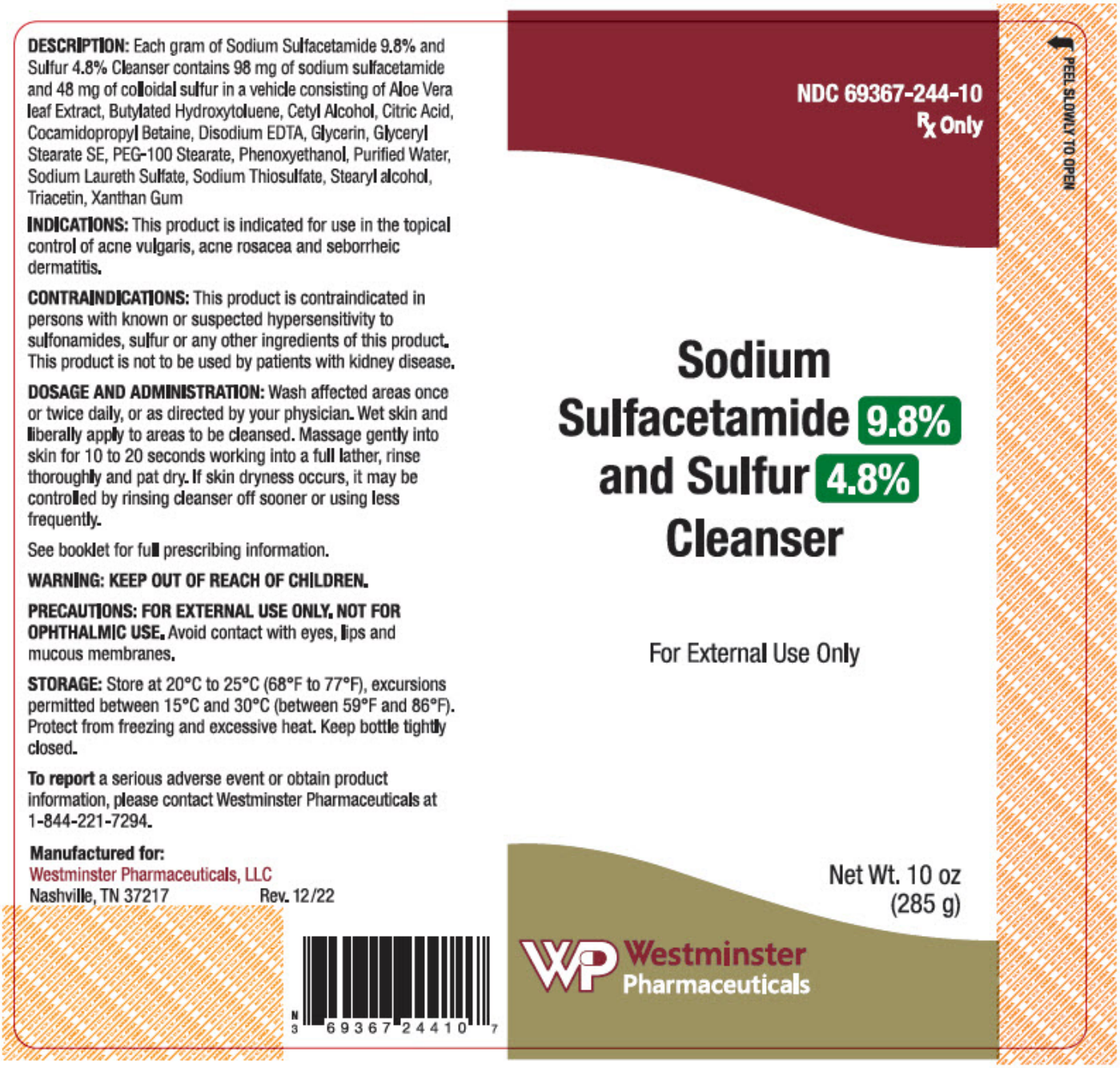
NDC 69367-244-10
Rx Only

Sodium
Sulfacetamide 9.8%
and Sulfur 4.8%
Cleanser

For External Use Only

Net Wt. 10 oz
(285 g)

Westminster
Pharmaceuticals



SODIUM SULFACETAMIDE, SULFUR

sulfacetamide sodium and sulfur liquid

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:69367-244
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
SULFACETAMIDE SODIUM (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
AMMONIUM LAURYL SULFATE (UNII: Q7AO2R1M0B)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)	
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	
GLYCERIN (UNII: PDC6A3C0OX)	
GLYCERYL STEARATE SE (UNII: FCZ5MH785I)	
GUAR GUM (UNII: E89I1637KE)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PEG-100 STEARATE (UNII: YD01N1999R)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0KO0R)	
SODIUM THIOSULFATE (UNII: HX1032V43M)	
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)	
TRIACETIN (UNII: XHX3C3X673)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69367-244-10	285 g in 1 BOTTLE; Type 0: Not a Combination Product	05/05/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
UNAPPROVED DRUG OTHER		05/05/2020	

Labeler - Westminster Pharmaceuticals, LLC (079516651)

Revised: 4/2023 Westminster Pharmaceuticals, LLC