SODIUM SULFACETAMIDE 9.8% AND SULFUR 4.8% CLEANSER- sulfacetamide sodium, sulfur liquid
Acella 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% - Sulfur 4.8% Cleanser

Rx Only

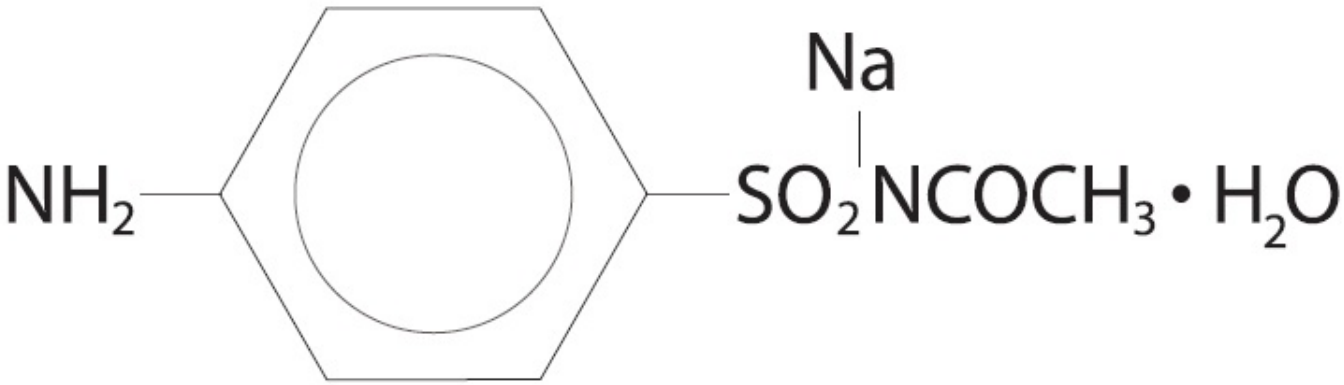
DESCRIPTION

Each gram of Sodium Sulfacetamide 9.8% - Sulfur 4.8% Cleanser contains 98 mg of Sodium Sulfacetamide and 48 mg of Sulfur in a formulation containing Aloe Barbadensis (Aloe Vera) Leaf Extract, Butylated Hydroxytoluene, Camellia Oleifera (Green Tea) Leaf Extract, Cetyl Alcohol, Disodium Oleamido MEA Sulfosuccinate, Edetate Disodium, Fragrance, Glycerin, Glyceryl Monostearate, Magnesium Aluminum Silicate, Methylparaben, PEG-100 Stearate, Propylparaben, Purified Water, Sodium Cocoyl Isethionate, Sodium Methyl Cocoyl Taurate, Sodium Thiosulfate, Stearyl Alcohol and Xanthan Gum.

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:



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

INDICATIONS

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

CONTRAINDICATIONS:

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.

WARNINGS

Although rare, sensitivity to sodium sulfonamide 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 Sodium Sulfacetamide 9.8% - Sulfur 4.8% Cleanser. It is 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.

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 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 9.8% - Sulfur 4.8% Cleanser is administered to a nursing woman.

Pediatric Use

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

ADVERSE REACTIONS

Although rare, sodium sulfacetamide may cause local irritation.

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 to 20 seconds, working into a full lather, rinse thoroughly and pat dry. If skin dryness occurs, it may be controlled by rinsing off sooner or using less frequently.

HOW SUPPLIED

Sodium Sulfacetamide 9.8% - Sulfur 4.8% Cleanser is supplied in a 10 oz (285 g) bottle (NDC 42192-156-10).

STORAGE

Store at 20º to 25ºC (68º to 77ºF), excursions permitted between 15º and 30ºC (between 59º and 86ºF). [See USP, “Controlled Room Temperature.”] Protect from freezing and excessive heat.

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

All prescription substitutions using this product shall be made subject to state and federal statutes as applicable. **NOTE: This is not an Orange Book product and has not been subjected to FDA therapeutic equivalency or other equivalency testing.** No representation is made as to generic status or bioequivalency. Each person recommending a prescription substitution using this product shall make such

recommendations based on each such person’s professional opinion and knowledge, upon evaluating the active ingredients, excipients, inactive ingredients and chemical formulation information provided herein.

MANUFACTURED FOR:
Acella Pharmaceuticals, LLC
Alpharetta, GA 30022
1-800-541-4802
Rev. 0916-04

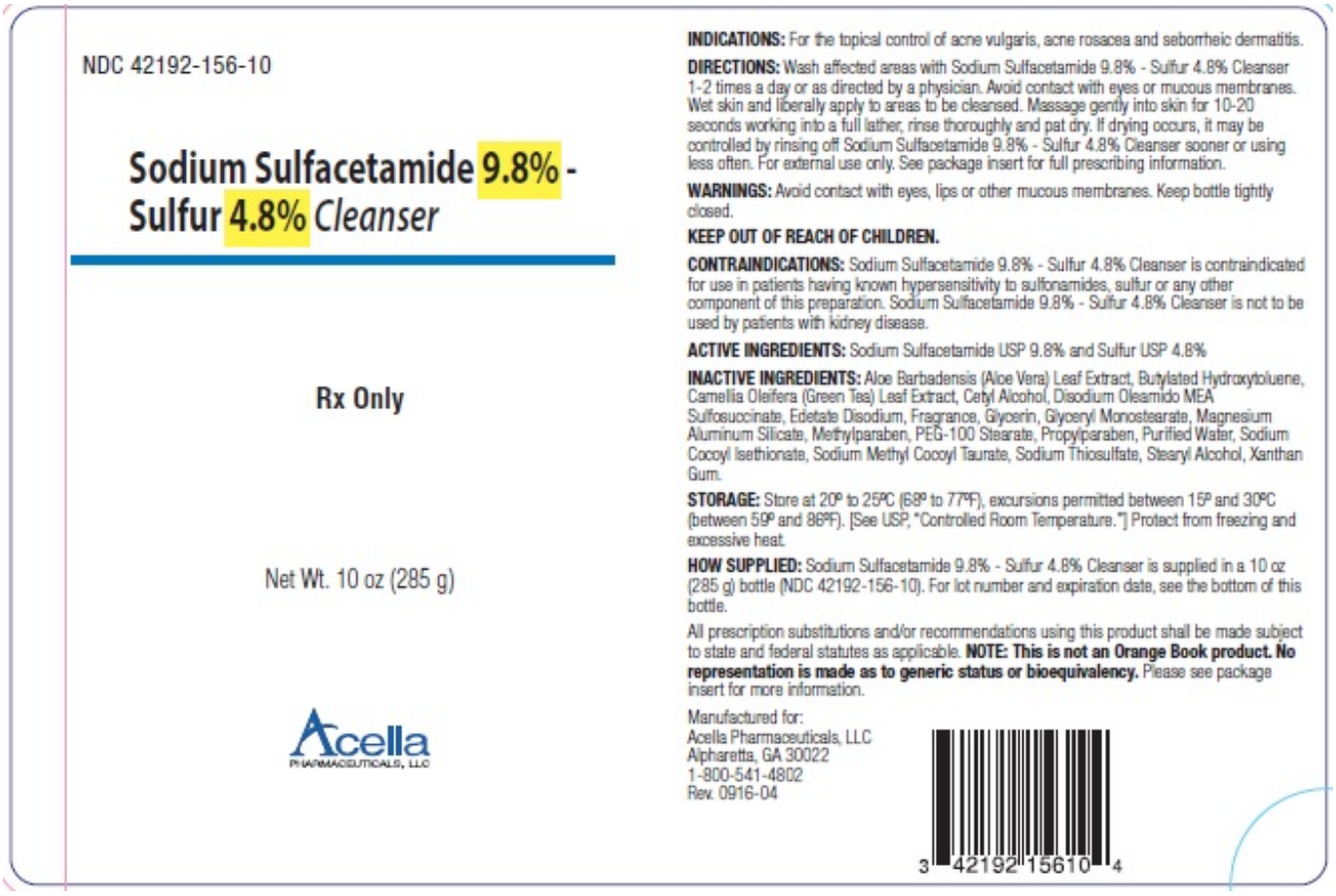
NDC 42192-156-10

Sodium Sulfacetamide 9.8% - Sulfur 4.8% Cleanser

Rx Only

Net Wt. 10 oz (285 g)

Acella Pharmaceuticals, LLC



SODIUM SULFACETAMIDE 9.8% AND SULFUR 4.8% CLEANSER

sulfacetamide sodium, sulfur liquid

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:42192-156
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
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
CAMELLIA OLEIFERA LEAF (UNII: 5077EL0C60)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
DISODIUM OLEAMIDO MONOETHANOLAMINE SULFOSUCCINATE (UNII: 5M1101WGSY)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
GLYCERIN (UNII: PDC6A3C0OX)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
MAGNESIUM ALUMINUM SILICATE (UNII: 6M3P64V0NC)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PEG-100 STEARATE (UNII: YD01N1999R)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0KO0R)	
SODIUM COCOYL ISETHIONATE (UNII: 518XTE8493)	
SODIUM METHYL COCOYL TAURATE (UNII: JVL98CG53G)	
SODIUM THIOSULFATE (UNII: HX1032V43M)	
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:42192-156-10	285 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	12/12/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		12/12/2016	

Labeler - Acella Pharmaceuticals, LLC (825380939)

Establishment

Name	Address	ID/FEI	Business Operations
Acella Pharmaceuticals, LLC		825380939	manufacture(42192-156)