SODIUM SULFACETAMIDE AND SULFUR- sodium sulfacetamide and sulfur solution
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.

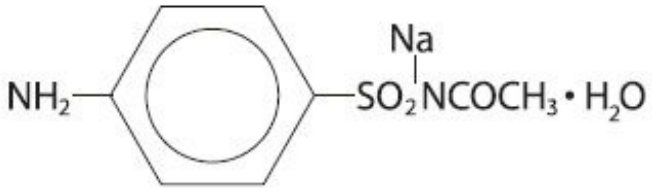
Sodium Sulfacetamide 8% - Sulfur 4% Topical Suspension

In a vehicle containing Green Tea and Aloe

Rx Only

DESCRIPTION:

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:



Each mL of Sodium Sulfacetamide 8% - Sulfur 4% Topical Suspension contains 80 mg of Sodium Sulfacetamide and 40 mg of Sulfur in a formulation containing purified water, sodium cocoyl isethionate, disodium oleamido MEA sulfosuccinate, green tea extract, cetyl alcohol, stearyl alcohol, glycerol stearate and PEG 100 stearate, methyl paraben, propyl paraben, butylated hydroxytoluene, aloe vera gel, sodium thiosulfate, disodium EDTA, magnesium aluminum silicate, xanthan gum, sodium methyl cocoyl taurate and white petrolatum.

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

CONTRAINDICATIONS:

Sodium Sulfacetamide 8% - Sulfur 4% Topical Suspension is contraindicated for use by patients having known hypersensitivity to sulfonamides, sulfur or ony other component of this preparation. Sodium Sulfacetamide 8% - Sulfur 4% Topical Suspension is not to be used by patients with kidney disease.

WARNINGS:

Although rare, sensitivity to sodium sulfacetaminde 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 8% - Sulfur 4% Topical Suspension. It is not known whether Sodium

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

ADVERSE REACTIONS:

Although rare, sodium sulfacetamide may cause local irritation.

DOSAGE AND ADMINISTRATION:

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

HOW SUPPLIED:

Sodium Sulfacetamide 8% - Sulfur 4% Topical Suspension is available in 16 fl oz (473 mL) bottles, NDC 42192-133-16.

Store at controlled room temperature, 15° - 30°C (59° - 86°F). Protect from freezing.

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 30009 • 1-800-541-4802

Rev. 0211v2

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 42192-133-16

Sodium Sulfacetamide 8% -
Sulfur 4% Topical Suspension

In a vehicle containing
Green Tea and Aloe

Rx Only

SHAKE WELL

16 fl. oz. (473 mL)

Acella
PHARMACEUTICALS, LLC

NDC 42192-133-16

Sodium Sulfacetamide 8% - Sulfur 4% *Topical Suspension*

In a vehicle containing Green Tea and Aloe

Rx Only

SHAKE WELL

16 fl. oz (473 mL)

Acella PHARMACEUTICALS, LLC

SODIUM SULFACETAMIDE AND SULFUR

sodium sulfacetamide and sulfur solution

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:42192-133
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
WATER (UNII: 059QF0KO0R)	
SODIUM COCOYL ISETHIONATE (UNII: 518XTE8493)	
DISODIUM OLEAMIDO MEA-SULFOSUCCINATE (UNII: 5M1101WGSY)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
PEG-100 STEARATE (UNII: YD01N1999R)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
SODIUM THIOSULFATE (UNII: HX1032V43M)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
MAGNESIUM ALUMINUM SILICATE (UNII: 6M3P64V0NC)	
XANTHAN GUM (UNII: TTV12P4NEE)	
SODIUM METHYL COCOYL TAURATE (UNII: JVL98CG53G)	
PETROLATUM (UNII: 4T6H12BN9U)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:42192-133-16	473 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/13/2011	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		05/13/2011	

Labeler - Acella Pharmaceuticals, LLC (825380939)

Establishment

Name	Address	ID/FEI	Business Operations
Acella Pharmaceuticals, LLC		825380939	manufacture(42192-133)