

SODIUM SULFACETAMIDE 10 SULFUR 2 CLEANSER- sulfacetamide sodium 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 10% - Sulfur 2% Cleanser

Rx Only

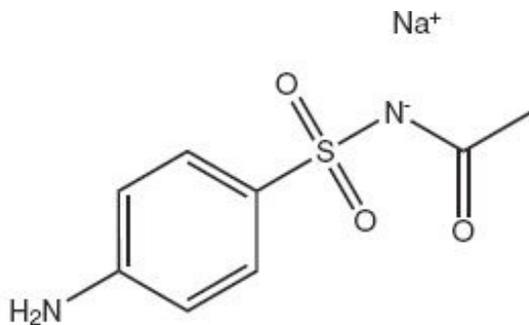
FOR EXTERNAL USE ONLY.

NOT FOR OPHTHALMIC USE.

DESCRIPTION:

Each gram of SODIUM SULFACETAMIDE 10% - SULFUR 2% CLEANSER (sodium sulfacetamide 10% w/w and sulfur 2% w/w) contains 100 mg of sodium sulfacetamide and 20 mg of colloidal sulfur in a mild aqueous based cleansing vehicle containing BHT, cetyl alcohol, disodium edta, glyceryl stearate, lactic acid, magnesium aluminum silicate, methylparaben, PEG-100 stearate, petrolatum, propylparaben, purified water, sodium C14-16 olefin sulfonate, sodium thiosulfate, stearyl alcohol, and xanthan gum.

Sodium sulfacetamide is a sulfonamide with antibacterial activity while sulfur acts as a keratolytic agent. Sodium sulfacetamide is $C_8H_9N_2NaO_3 \cdot H_2O$ with molecular weight of 254.24. Chemically, it 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 unknown, but it has been

reported that it inhibits the growth of *Propionibacterium acnes* and the formation of free fatty acids.

INDICATIONS:

SODIUM SULFACETAMIDE 10% - SULFUR 2% CLEANSER is indicated for use in the topical control of acne vulgaris, acne rosacea and seborrheic dermatitis.

CONTRAINDICATIONS:

SODIUM SULFACETAMIDE 10% - SULFUR 2% CLEANSER is contraindicated for use by patients having known hypersensitivity to sulfonamides, sulfur or any other component of this preparation. SODIUM SULFACETAMIDE 10% - SULFUR 2% CLEANSER is not to be used by patients with kidney disease.

WARNINGS:

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.

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.

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.

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 10% - SULFUR 2% CLEANSER. It is also not known whether SODIUM SULFACETAMIDE 10% - SULFUR 2% CLEANSER can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. SODIUM SULFACETAMIDE 10% - SULFUR 2% CLEANSER should be given to a pregnant woman only if clearly needed.

Nursing Mothers: It is not known whether sodium sulfacetamide is excreted in human milk following topical use of SODIUM SULFACETAMIDE 10% - SULFUR 2% CLEANSER. However, small amounts of orally administered sulfonamides have been reported to be excreted in human milk. In view of this and because many drugs are excreted in human milk, caution should be exercised when SODIUM SULFACETAMIDE 10% - SULFUR 2% CLEANSER is administered to a nursing woman.

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

ADVERSE REACTIONS:

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

DOSAGE AND ADMINISTRATION:

Wash affected areas with SODIUM SULFACETAMIDE 10% - SULFUR 2% CLEANSER 1 to 2 times daily or as directed by a 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 drying occurs, it may be controlled by rinsing cleanser off sooner or using cleanser less often.

HOW SUPPLIED:

SODIUM SULFACETAMIDE 10% - SULFUR 2% CLEANSER is supplied in an 8 oz. (227 g) bottle, NDC 42192-147-08.

Store at 25°C (77°F); excursions permitted to 15° to 30°C (59° to 86°F). [See USP "Controlled Room Temperature."]

Note: 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 container or packet tightly closed.

Occasionally, a slight yellowish discoloration 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.

All prescription substitutions and/or recommendations using this product shall be made subject to state and federal statutes as applicable. **Please NOTE: This is not an Orange Book product and has not been subjected to FDA therapeutic 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 recommendation based on his/her professional knowledge and opinion, upon evaluating the active ingredients, inactive ingredients, excipients and chemical information provided herein.

Manufactured for:

Acella Pharmaceuticals, LLC

11675 Great Oaks Way
Alpharetta, GA 30022
1-800-541-4802

Rev. 0514

PRINCIPAL DISPLAY PANEL - 227 g Bottle Label

NDC 42192-147-08

Sodium Sulfacetamide 10%
Sulfur 2%
Cleanser

Rx Only

SHAKE WELL BEFORE USE

8 oz. (227 g)

Acella
PHARMACEUTICALS, LLC

NDC 42192-147-08

Sodium Sulfacetamide 10% - Sulfur 2% Cleanser

Rx Only

SHAKE WELL BEFORE USE

8 oz. (227 g)



Active Ingredients: Sodium Sulfacetamide 10% and Sulfur 2%
Other Ingredients: BHT, Cetyl Alcohol, Disodium EDTA, Glyceryl Stearate, Lactic Acid, Magnesium Aluminum Silicate, Methylparaben, PEG-100 Stearate, Petrolatum, Propylparaben, Purified Water, Sodium C14-16 Olefin Sulfonate, Sodium Thiosulfate, Stearyl Alcohol, Xanthan Gum.

Indications: For the topical control of acne vulgaris, acne rosacea and seborrheic dermatitis.

Directions: Wash affected areas once or twice daily or as directed by a physician. Avoid contact with eyes or mucous membranes. 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 sooner or using less often. See package insert for full prescribing information.

WARNINGS: FOR EXTERNAL USE ONLY. NOT FOR OPHTHALMIC USE. KEEP OUT OF REACH OF CHILDREN. Keep container tightly closed.

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). [See USP, "Controlled Room Temperature."] Protect from freezing and excessive heat.

All prescription substitutions and/or recommendations using this product shall be made subject to state and federal statutes as applicable. **NOTE: This is not an Orange Book product. No representation is made as to generic status or bioequivalency.** Please see package insert for more information.

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Acella Pharmaceuticals, LLC
Alpharetta, GA 30022
1-800-541-4802

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SODIUM SULFACETAMIDE 10 SULFUR 2 CLEANSER

sulfacetamide sodium and sulfur solution

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:42192-147
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SULFACETAMIDE SODIUM (UNII: 4NRT660KJQ) (SULFACETAMIDE - UNII:4965G3J0F5)	SULFACETAMIDE SODIUM	100 mg in 1 g
SULFUR (UNII: 70FD1KFU70) (SULFUR - UNII:70FD1KFU70)	SULFUR	20 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
LACTIC ACID (UNII: 33X04XA5AT)	
MAGNESIUM ALUMINUM SILICATE (UNII: 6M3P64V0NC)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PEG-100 STEARATE (UNII: YD01N1999R)	
PETROLATUM (UNII: 4T6H12BN9U)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0KO0R)	
SODIUM C14-16 OLEFIN SULFONATE (UNII: O9W3D3YF5U)	
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:42192-147-08	227 g in 1 BOTTLE; Type 0: Not a Combination Product	08/14/2014	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		08/14/2014	

Labeler - Acella Pharmaceuticals, LLC (825380939)

Establishment

Name	Address	ID/FEI	Business Operations
Acella Pharmaceuticals, LLC		825380939	manufacture(42192-147)

Revised: 1/2024

Acella Pharmaceuticals, LLC