SODIUM SULFACETAMIDE- sodium sulfacetamide gel
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.

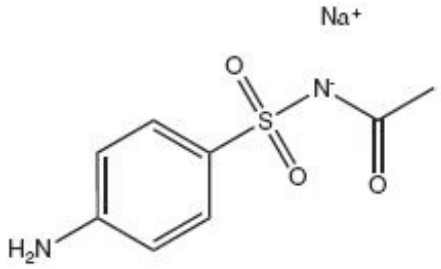
SODIUM SULFACETAMIDE 10% CLEANSING GEL

Rx Only

FOR EXTERNAL USE ONLY. NOT FOR OPHTHALMIC USE.

DESCRIPTION: Each mL of SODIUM SULFACETAMIDE 10% CLEANSING GEL contains 100 mg of sodium sulfacetamide, USP in a formulation containing Citric acid, Cocamidopropyl Betaine, Disodium EDTA, Glycerin, Glyceryl Stearate, Methylparaben, PEG-6 Caprylic/Capric Glycerides, PEG-60 Almond Glycerides, PEG-150 Pentaerythrityl Tetrastearate, Polysorbate 60, Sodium Lauryl Sulfate, Sodium Thiosulfate, Water, Xanthan Gum.

Sodium sulfacetamide is $C_8H_9N_2NaO_3S \cdot H_2O$ with molecular weight of 254.24. Chemically, it 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 SODIUM SULFACETAMIDE 10% CLEANSING GEL 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.

INDICATIONS AND USAGE: SODIUM SULFACETAMIDE 10% CLEANSING GEL is intended for topical application in the following scaling dermatoses: seborrheic dermatitis and seborrhea sicca (dandruff). It also is indicated for the treatment of secondary bacterial infections of the skin due to organisms susceptible to sulfonamides.

CONTRAINDICATIONS: SODIUM SULFACETAMIDE 10% CLEANSING GEL is contraindicated in persons with known or suspected hypersensitivity to sulfonamides or to any of the ingredients of the product.

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 THE REACH OF CHILDREN.**

PRECAUTIONS:

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General: Nonsusceptible organisms, including fungi, may proliferate with the use of this preparation. Hypersensitivity reactions may recur when a sulfonamide is readministered, irrespective of the route of administration, and cross hypersensitivity between different sulfonamides may occur. If SODIUM SULFACETAMIDE 10% CLEANSING GEL produces signs of hypersensitivity or other untoward reactions, discontinue use of the preparation. 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.

Information for Patients: Patients should discontinue SODIUM SULFACETAMIDE 10% CLEANSING GEL if the condition becomes worse, or if a rash develops in the area being treated or elsewhere. SODIUM SULFACETAMIDE 10% CLEANSING GEL also should be discontinued promptly and the physician notified if any arthritis, fever or sores in the mouth develop.

Drug Interactions: SODIUM SULFACETAMIDE 10% CLEANSING GEL is incompatible with silver preparations.

Pharmacology: SODIUM SULFACETAMIDE 10% CLEANSING GEL has a bacteriostatic effect against Gram-positive and Gram-negative microorganisms commonly isolated from secondary cutaneous pyogenic infections.

Carcinogenesis, Mutagenesis and Impairment of Fertility: Long-term animal studies for carcinogenic potential have not been performed on SODIUM SULFACETAMIDE 10% CLEANSING GEL 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

SODIUM SULFACETAMIDE 10% CLEANSING GEL. It is also not known whether SODIUM SULFACETAMIDE 10% CLEANSING GEL can affect reproduction capacity or cause fetal harm when administered to a pregnant woman. SODIUM SULFACETAMIDE 10% CLEANSING GEL 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 human milk. Because many drugs are excreted in human milk, caution should be exercised when SODIUM SULFACETAMIDE 10% CLEANSING GEL is administered to a nursing woman.

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

ADVERSE REACTIONS: Reports of irritation and hypersensitivity to sodium sulfacetamide are uncommon. The following adverse reactions, reported after administration of sterile ophthalmic sodium sulfacetamide, are noteworthy: instances of Stevens-Johnson syndrome and instances of local hypersensitivity which progressed to a syndrome resembling systemic lupus erythematosus; in one case a fatal outcome was reported (see WARNINGS). Call your doctor for medical advice about side effects.

OVERDOSAGE: The oral LD50 of sulfacetamide in mice is 16.5 g/kg. In the event of overdosage, emergency treatment should be started immediately.

To report SUSPECTED ADVERSE REACTIONS, contact the FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Manifestations: Overdosage may cause nausea and vomiting. Large oral overdosage may cause hematuria, crystalluria and renal shutdown due to the precipitation of sulfa crystals in the renal tubules and the urinary tract. For treatment, contact your local Poison Control Center or your doctor.

DOSAGE AND ADMINISTRATION: Seborrheic dermatitis including seborrhea sicca - Wash affected areas twice daily (morning and evening), 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 working into a full lather, rinse thoroughly, pat dry and repeat after 10 to 20 seconds. Rinsing with plain water will remove any excess medication. Repeat application as described for 8 to 10 days. If skin dryness occurs it may be controlled by rinsing cleanser off sooner or using less frequently. Regular shampooing following SODIUM SULFACETAMIDE 10% CLEANSING GEL is not necessary, but the hair should be shampooed at least once a week. As the condition subsides, the interval between applications may be lengthened. Applications once or twice weekly or every other week may prevent recurrence. Should the condition recur after stopping therapy, the application of SODIUM SULFACETAMIDE 10% CLEANSING GEL should be reinitiated as at the beginning of treatment.

Secondary cutaneous bacterial infections - 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. Rinsing with plain water will remove any excess medication. Repeat application as described for 8 to 10 days. If skin dryness occurs it may be controlled by rinsing cleanser off sooner or using less often.

HOW SUPPLIED:

SODIUM SULFACETAMIDE 10% CLEANSING GEL is available in a 12 fl. oz. (355 mL) bottle, NDC 42192-146-12.

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

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.

A slight yellowish discoloration may occur on occasion when an excessive amount of the product is used and comes in contact with white fabrics. This discoloration is easily removed by normal laundering; bleaching is not necessary.

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. 0914

PACKAGE LABEL - 12 fl. oz. (355 mL) bottle

NDC 42192-146-12

Sodium Sulfacetamide

10% *Cleansing Gel*

Rx Only

For External Use Only

12 fl. oz. (355 mL)

Acella

PHARMACEUTICALS, LLC

NDC 42192-146-12

Sodium Sulfacetamide 10% Cleansing Gel

Rx Only

For External Use Only

12 fl. oz. (355 mL)

Acella PHARMACEUTICALS, LLC

DESCRIPTION: Each mL of Sodium Sulfacetamide 10% Wash contains 100 mg of sodium sulfacetamide, USP in a formulation containing Citric acid, Cocamidopropyl Betaine, Disodium EDTA, Glycerin, Glyceryl Stearate, Methylparaben, PEG-6 Caprylic/Capric Glycerides, PEG-60 Almond Glycerides, PEG-150 Pentaerythrityl Tetrastearate, Polysorbate 60, Sodium Lauryl Sulfate, Sodium Thiosulfate, Water, Xanthan Gum.

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Manufactured for:
Acella Pharmaceuticals, LLC
Alpharetta, GA 30022
1-800-541-4802
Rev. 1017-01

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SODIUM SULFACETAMIDE

sodium sulfacetamide gel

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:42192-146
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 mL

Inactive Ingredients	
Ingredient Name	**Strength**

CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
GLYCERIN (UNII: PDC6A3C0OX)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
PENTAERYTHRITYL TETRASTEARATE (UNII: W9Q3DZS0EG)	
POLYSORBATE 60 (UNII: CAL22UVI4M)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
SODIUM THIOSULFATE (UNII: HX1032V43M)	
WATER (UNII: 059QF0KO0R)	
XANTHAN GUM (UNII: TTV12P4NEE)	
PEG-60 ALMOND GLYCERIDES (UNII: 4Y0E651N0F)	
PEG-6 CAPRYLIC/CAPRIC GLYCERIDES (UNII: GO50W2HWO8)	
PEG-150 PENTAERYTHRITYL TETRASTEARATE (UNII: 8L4OOQ76AM)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:42192-146-12	355 mL in 1 BOTTLE; Type 0: Not a Combination Product	10/10/2014	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		10/10/2014	

Labeler - Acella Pharmaceuticals, LLC (825380939)

Establishment

Name	Address	ID/FEI	Business Operations
Acella Pharmaceuticals, LLC		825380939	manufacture(42192-146)

Revised: 1/2024 Acella Pharmaceuticals, LLC