

SODIUM SULFACETAMIDE- sodium sulfacetamide shampoo **BioComp Pharma, Inc.**

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% Shampoo

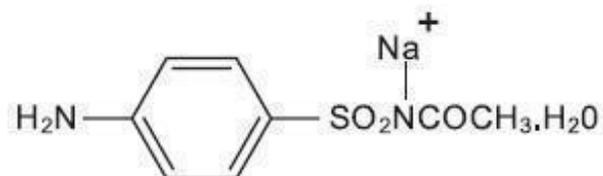
Rx Only

FOR EXTERNAL USE ONLY. NOT FOR OPHTHALMIC USE.

DESCRIPTION:

Each gram contains 100 mg of sodium sulfacetamide in a vehicle consisting of: citric acid, disodium EDTA, fragrance, methylparaben, PEG-150 pentaerythrityl tetrastearate (and) aqua (and) PEG-6 caprylic/capric glycerides, PEG-60 almond glycerides, propylene glycol, propylparaben, purified water, sodium chloride, and sodium laureth sulfate (and) cocamide DEA (and) cocamidopropyl betaine (and) glycol stearate.

Sodium sulfacetamide is a sulfonamide with antibacterial activity. Sodium sulfacetamide is $C_8H_9N_2NaO_3 \cdot H_2O$ 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.

INDICATIONS:

This product is intended for topical application in the following scaling dermatoses: seborrheic dermatitis and seborrhea sicca (dandruff).

CONTRAINDICATIONS:

This product is contraindicated in persons with known or suspected hypersensitivity to any of the ingredients of the 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 THE REACH OF CHILDREN.

PRECAUTIONS:

FOR EXTERNAL USE ONLY. NOT FOR OPHTHALMIC USE.

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, discontinue use of the preparation. Patients should be carefully observed for possible local irritation or sensitization during long-term therapy. 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. 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 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, 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 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 years have 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).

OVERDOSAGE:

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

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:

Shake well before using. Apply to wet hair and massage vigorously into scalp. Rinse thoroughly. For best results, use at least twice a week or as directed by a doctor. Avoid contact with eyes or mucous membranes. Do not use on an infant less than 2 months of age.

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). Brief exposure to temperatures up to 40°C (104°F) may be tolerated provided the mean kinetic temperature does not exceed 25°C (77°F); however, such exposure should be minimized.

NOTICE: 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 bottle tightly closed.

Occasionally, a slight discoloration of fabric 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.

HOW SUPPLIED:

This product is supplied in the following size(s):

8 fl. oz. (237 mL) bottles, **NDC** 44523-510-08

To report a serious adverse event or obtain product information, call 1-866-762-2365.

L71008R1225

Manufactured for:
BioComp Pharma, Inc.
San Antonio, TX 78230

BCP_T14142R1225



Pediatric Use: Safety and effectiveness in children under the age of 12 years have 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).

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

Manifestations: Overdosage may cause nausea and vomiting. Large oral overdosage may cause hematuria, cystitis 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: Shake well before using. Apply to wet hair and massage vigorously into scalp. Rinse thoroughly. For best results, use at least twice a week or as directed by a doctor. Avoid contact with eyes or mucous membranes. Do not use on an infant less than 2 months of age.

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). Brief exposure to temperatures up to 40°C (104°F) may be tolerated provided the mean kinetic temperature does not exceed 25°C (77°F); however, such exposure should be minimized.

NOTICE: 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 bottle tightly closed.

Occasionally, a slight discoloration of fabric 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.

HOW SUPPLIED: This product is supplied in the following size(s):
8 fl. oz. (237 mL) bottles, NDC 44523-510-08

To report a serious adverse event or obtain product information, call 1-866-762-2365.



Manufactured for:
BioComp Pharma, Inc.
San Antonio, TX 78230

L71008R0625

Rx only. Usual dosage. See prescribing information. 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.

L71008R0625

NDC 44523-510-08

Rx Only

SODIUM
SULFACETAMIDE 10%
Shampoo

(sodium sulfacetamide 10%)

8 fl. oz. (237 mL)



1
008
51008
44523



PAGE 4

PAGE 1

SODIUM SULFACETAMIDE 10% SHAMPOO

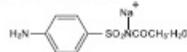
(sodium sulfacetamide 10%)

Rx Only

FOR EXTERNAL USE ONLY, NOT FOR OPHTHALMIC USE.

DESCRIPTION: Each gram contains 100 mg of sodium sulfacetamide in a vehicle consisting of: citric acid, disodium EDTA, fragrance, methylparaben, PEG-150 pentaerythrityl tetrastearate (and) aqua (and) PEG-6 caprylic/capric glycerides, PEG-60 almond glycerides, propylene glycol, propylparaben, purified water, sodium chloride, and sodium lauryl sulfate (and) cocamide DEA (and) cocamidopropyl betaine (and) glycol stearate.

Sodium sulfacetamide is a sulfonamide with antibacterial activity. Sodium sulfacetamide is C₈H₉N₃NaO₃S · H₂O with molecular weight of 254.24. Chemically, sodium sulfacetamide is N-(4-aminophenyl) sulfonamide 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 pyocyanus, Salmonella species, Proteus vulgaris, Nocardia and Actinomyces.

INDICATIONS: This product is intended for topical application in the following scaling dermatoses: seborrheic dermatitis and seborrhea sicca (dandruff).

CONTRAINDICATIONS: This product is contraindicated in persons with known or suspected hypersensitivity to any of the ingredients of the 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.

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, discontinue use of the preparation. Patients should be carefully observed for possible local irritation or sensitization during long-term therapy. 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. 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 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, nose 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 human milk. Because many drugs are excreted in human milk, caution should be exercised when this product is administered to a nursing woman.

PAGE 2

PAGE 3

SODIUM SULFACETAMIDE

sodium sulfacetamide shampoo

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:44523-510
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		
COCO DIETHANOLAMIDE (UNII: 92005F972D)				
GLYCOL STEARATE (UNII: 0324G66D0E)				
METHYLPARABEN (UNII: A2I8C7HI9T)				
PEG-150 PENTAERYTHRITYL TETRASTEARATE (UNII: 8L400Q76AM)				
PEG-60 ALMOND GLYCERIDES (UNII: 4Y0E651N0F)				
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)				
EDETATE DISODIUM (UNII: 7FLD91C86K)				
PEG-6 CAPRYLIC/CAPRIC GLYCERIDES (UNII: GO50W2HW08)				
PROPYLPARABEN (UNII: Z8IX2SC1OH)				
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)				
WATER (UNII: 059QF0KO0R)				
SODIUM CHLORIDE (UNII: 451W47IQ8X)				
SODIUM LAURETH SULFATE (UNII: BPV390UAP0)				
COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)				
Product Characteristics				
Color	yellow (Off white to yellow)	Score		
Shape		Size		
Flavor		Imprint Code		
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:44523-510-08	237 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	09/15/2011	
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
unapproved drug other		09/15/2011		

Labeler - BioComp Pharma, Inc. (829249718)