

SODIUM SULFACETAMIDE AND SULFUR- sodium sulfacetamide 9.8% and sulfur 4.8% emulsion

Bio Comp 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 9.8% and Sulfur 4.8% Cleanser 10oz

SODIUM SULFACETAMIDE 9.8% AND SULFUR 4.8% CLEANSER

(sodium sulfacetamide 9.8%, sulfur 4.8%)

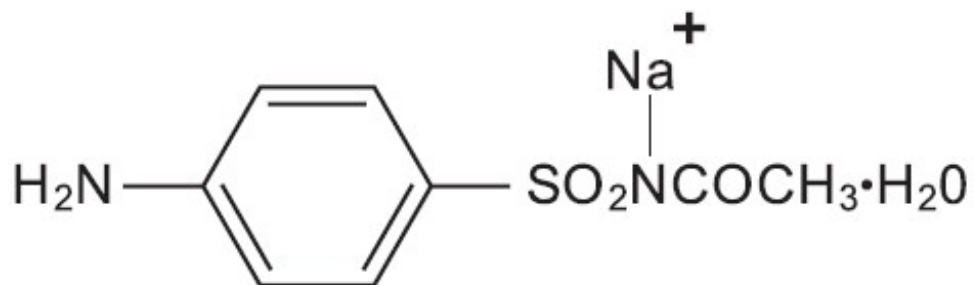
Rx Only

FOR EXTERNAL USE ONLY. NOT FOR OPHTHALMIC USE.

DESCRIPTION:

Each gram contains 98 mg of sodium sulfacetamide and 48 mg of colloidal sulfur in a vehicle consisting of: benzyl alcohol, cetyl alcohol, fragrance, glyceryl stearate (and) PEG-100 stearate, magnesium aluminum silicate, phenoxyethanol, propylene glycol, purified water, sodium lauryl sulfate, sodium magnesium silicate, 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 $C_8H_9N_2NaO_3S \cdot H_2O$ 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.

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:

This product is indicated for use in the topical control of acne vulgaris, acne rosacea and seborrheic dermatitis.

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.

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:

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. Wash affected areas once or twice daily, or as directed by your physician. 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 product off sooner or using less frequently.

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):
10 oz. (285 g) bottles, **NDC 44523-748-10**

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

BCP_T13617R0424

L74810R0224

Manufactured for:
BioComp Pharma, Inc.
San Antonio, TX 78230 1355



The following adverse reactions reported after administration of sodium sulfacetamide and sulfur emulsion are indicative of severe allergic reactions and systemic reactions which progressed to anaphylaxis. Immediate medical attention is required in any case of a life-threatening allergic reaction. In the event of an emergency, emergency treatment should be started immediately.

INDICATIONS: The emulsion of sodium sulfacetamide is used in the treatment of bacterial conjunctivitis, acute and chronic blepharitis, and acute and chronic dacryocystitis. In the event of an emergency, emergency treatment should be started immediately.

Contraindications: Overexposure may cause severe and possibly fatal overdosage. Do not use if you are allergic to any of the ingredients of this emulsion and the vehicle. For treatment, contact your local Poison Control Center or your doctor.

USAGE AND ADMINISTRATION: Emulsion will be used topically. Wash affected areas once or twice daily, or as directed by your physician. Use only the amount of emulsion needed. Shake gently for 10 to 20 seconds, working the emulsion clear through and put in the eye. Dryness occurs, it may be controlled by using product of water or using tear replacement.

DOSAGE: Store at 20°C to 25°C (68°F to 77°F), excursions permitted between 15°C and 30°C (59°F and 86°F). What excursions to temperatures up to 30°C (86°F) may be allowed provided the exact length of time does not exceed 24 (24) hours. Some excursions should be permitted.

Warnings: Please see therapy and dosage text. The product may react to certain drugs. Allergic reactions may occur. Do not use if you are allergic to any of the ingredients of this emulsion and the vehicle. Do not use if you are allergic to any of the ingredients of this emulsion and the vehicle. Do not use if you are allergic to any of the ingredients of this emulsion and the vehicle. Do not use if you are allergic to any of the ingredients of this emulsion and the vehicle.

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NDC 44523-748-10 Rx Only

SODIUM SULFACETAMIDE 9.8% AND SULFUR 4.8% Cleanser
(sodium sulfacetamide 9.8%, sulfur 4.8%)

Net wt. 10 oz. (285 g)

BioComp Pharma.

SODIUM SULFACETAMIDE 9.8% AND SULFUR 4.8% CLEANSER

PRECAUTIONS FOR EXTENSIVE USE ONLY

ADVERSE REACTIONS: Some patients may experience mild eye irritation with the use of this preparation. Although rare, anaphylaxis has been reported in patients with severe allergic reactions. Patients should be advised of the possible hazard of anaphylaxis and other allergic reactions. Anaphylaxis has been reported in patients with severe allergic reactions. Patients should be advised of the possible hazard of anaphylaxis and other allergic reactions. Anaphylaxis has been reported in patients with severe allergic reactions. Patients should be advised of the possible hazard of anaphylaxis and other allergic reactions.

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

WARNINGS: Sulfacetamide is an antibiotic with possible cross-reactivity with other sulfonamides. It is a weakly acidic emulsion. It is contraindicated in patients with known or suspected hypersensitivity to any of the ingredients of the product.

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SODIUM SULFACETAMIDE AND SULFUR

sodium sulfacetamide 9.8% and sulfur 4.8% emulsion

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:44523-748
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
BENZYL ALCOHOL (UNII: LKG8494WBH)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
XANTHAN GUM (UNII: TTV12P4NEE)	
SODIUM MAGNESIUM FLUOROSILICATE (UNII: U1QJ22MC8E)	
LAPONITE (UNII: D703131383)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
PEG-100 STEARATE (UNII: YD01N1999R)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
WATER (UNII: 059QF0KO0R)	
MAGNESIUM ALUMINUM SILICATE (UNII: 6M3P64V0NC)	
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)	
SODIUM THIOSULFATE (UNII: HX1032V43M)	
CETYL ALCOHOL (UNII: 936JST6JCN)	

Product Characteristics

Color	yellow (light yellow)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:44523-748-10	285 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	12/17/2024	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		12/17/2024	

Labeler - Bio Comp Pharma, Inc. (829249718)

Registrant - Mission Pharmacal Company (927726893)

Establishment

Name	Address	ID/FEI	Business Operations
Mission Pharmacal Company		927726893	manufacture(44523-748) , analysis(44523-748) , label(44523-748) , pack(44523-748)

