SODIUM SULFACETAMIDE 9.8%, SULFUR 4.8%- sodium sulfacetamide, sulfur solution
Bi-Coastal Pharma International 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.

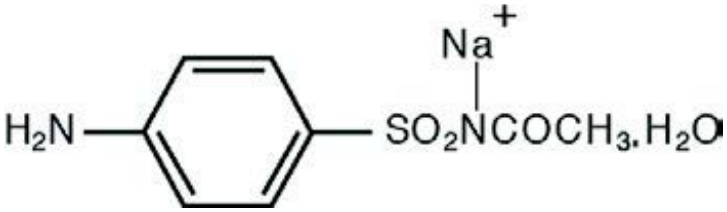
Sodium Sulfacetamide 9.8% and Sulfur 4.8% Cleanser
(Sodium Sulfacetamide 9.8%, Sulfur 4.8%)

Rx Only

FOR EXTERNAL USE ONLY.

NOT FOR OPHTHALMIC USE.

DESCRIPTION: Each gram of Sodium Sulfacetamide and Sulfur (sodium sulfacetamide 9.8% w/w and sulfur 4.8% w/w) contains 98 mg of sodium sulfacetamide and 48 mg of colloidal sulfur in a vehicle consisting of: aloe barbadensis (aloe vera) leaf extract, butylated hydroxytoluene, camellia oleifera (green tea) leaf extract, cetyl alcohol, disodium oleamido MEA sulfosuccinate, edetate disodium, fragrance, glycerin, glyceryl monostearate, magnesium aluminum silicate, methylparaben, PEG-100 stearate, propylparaben, purified water, sodium cocoyl isethionate, sodium methyl cocoyl taurate, sodium thiosulfate, stearyl alcohol, xantham 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, 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 9.8% and Sulfur 4.8% Cleanser is indicated for use in the topical control of acne vulgaris, acne rosacea and seborrheic dermatitis.

CONTRAINDICATIONS: Sodium Sulfacetamide 9.8% and Sulfur 4.8% Cleanser is contraindicated for use by patients having known hypersensitivity to sulfonamides, sulfur or any other component of this preparation. Sodium Sulfacetamide 9.8% and Sulfur 4.8% 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 SodiumNSulfacetamide 9.8% and Sulfur 4.8% Cleanser. It is also not known whether SodiumNSulfacetamide 9.8% and Sulfur 4.8% Cleanser can cause fetal harm when administered to aNpregnant woman or can affect reproduction capacity. Sodium Sulfacetamide 9.8% and SulfurN4.8% 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 9.8% and Sulfur 4.8% 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 9.8% and Sulfur 4.8% Cleanser is administered to a nursing woman.

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

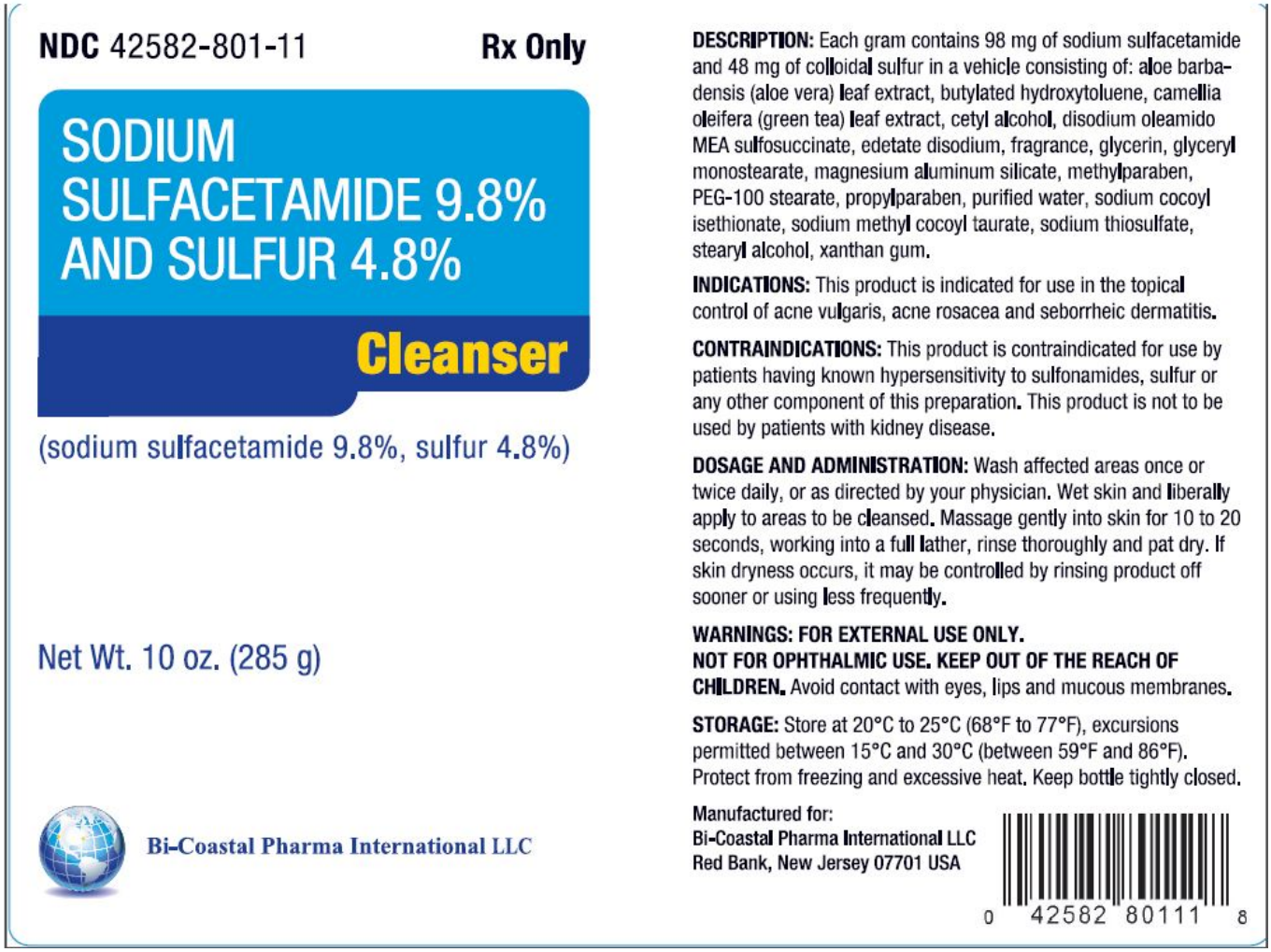
ADVERSE REACTIONS: Although rare, sodium sulfacetamide may cause local irritation. **Call your doctor for medical advice about side effects. To report SUSPECTED ADVERSE REACTIONS, contact the FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.**

DOSAGE AND ADMINISTRATION: Wash affected areas with Sodium Sulfacetamide 9.8% and Sulfur 4.8% Cleanser one to two times daily, 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 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 9.8% and Sulfur 4.8% Cleanser is supplied in an 8 oz. (227 g) bottle, NDC 42582-801-11. Store at 25°C (77°F); excursions permitted to between 15°C to 30°C (59°F 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 tube 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.

Manufactured for:
Bi-Coastal Pharma International LLC
Red Bank, New Jersey 07701 USA
6/15



SODIUM SULFACETAMIDE 9.8%, SULFUR 4.8%
sodium sulfacetamide, sulfur solution

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:42582-801
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
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
CAMELLIA OLEIFERA LEAF (UNII: 5077EL0C60)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
DISODIUM OLEAMIDO MONOETHANOLAMINE SULFOSUCCINATE (UNII: 5M1101WGSY)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
GLYCERIN (UNII: PDC6A3C0OX)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
MAGNESIUM ALUMINUM SILICATE (UNII: 6M3P64V0NC)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PEG-100 STEARATE (UNII: YD01N1999R)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0KO0R)	
SODIUM COCOYL ISETHIONATE (UNII: 518XTE8493)	
SODIUM METHYL COCOYL TAURATE (UNII: JVL98CG53G)	
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:42582-801-11	285 g in 1 BOTTLE; Type 0: Not a Combination Product	03/27/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		03/27/2017	

Labeler - Bi-Coastal Pharma International LLC (078397428)

Registrant - Bi-Coastal Pharma International LLC (078397428)

Revised: 1/2022 Bi-Coastal Pharma International LLC