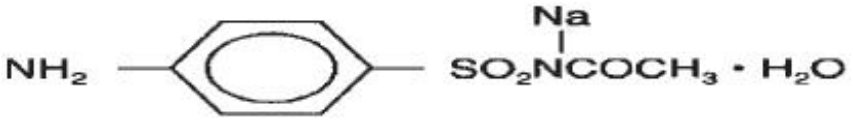
SULFACETAMIDE SODIUM AND SULFUR- sulfacetamide sodium and sulfur cream
Bi-Coastal Pharma International LLC

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% & Sulfur 4.5% Wash

DESCRIPTION

Sulfacetamide sodium is a sulfonamide with antibacterial activity while sulfur acts as a keratolytic agent. Chemically sulfacetamide sodium is N-[(4-aminophenyl) sulfonyl]-acetamide, monosodium salt, monohydrate. The structural formula is:



Each gram of sulfacetamide sodium USP 9% and sulfur USP 4.5% contains 90 mg of Sodium Sulfacetamide USP and 45 mg of Sulfur USP in a cream containing: 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, Xanthan Gum.

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, sulfacetamide sodium 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

Sulfacetamide sodium and sulfur wash is indicated in the topical control of acne vulgaris, acne rosacea and seborrheic dermatitis.

CONTRAINDICATIONS

Sulfacetamide sodium and sulfur wash is contraindicated for use by patients having known hypersensitivity to sulfonamides, sulfur or any other component of this preparation. Sulfacetamide sodium and sulfur wash is not to be used by patients with kidney disease.

WARNINGS

Although rare, sensitivity to sulfacetamide sodium 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.

FOR EXTERNAL USE ONLY. Keep away from eyes. Keep out of reach of children. Keep container tightly closed.

PRECAUTIONS

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 longterm therapy. The object of this therapy is to achieve desquamation without irritation, but sulfacetamide sodium 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

Avoid contact with eyes, eyelids, lips and mucous membranes. If accidental contact occurs, rinse with water. If excessive irritation develops, discontinue use and consult your physician.

Carcinogenesis, Mutagenesis and Impairment of Fertility

Longterm studies in animals have not been performed to evaluate carcinogenic potential.

Pregnancy

Category C

Animal reproduction studies have not been conducted with sulfacetamide sodium and sulfur lotion. It is also not known whether sulfacetamide sodium and sulfur wash can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Sulfacetamide sodium and sulfur wash should be given to a pregnant woman only if clearly needed.

Nursing Mothers

It is not known whether sulfacetamide sodium is excreted in the human milk following topical use of sulfacetamide sodium and sulfur lotion. However, small amounts of orally administered sulfonamides have been reported to be eliminated in human milk. In view of this and because many drugs are excreted in human milk, caution should be exercised when sulfacetamide sodium and sulfur wash is administered to a nursing woman.

Pediatric Use

Safety and effectiveness in children under the age of 12 have not been established.

ADVERSE REACTIONS

Although rare, sulfacetamide sodium may cause local irritation.

DOSAGE AND ADMINISTRATION

Use once daily or as directed by your physician. Wet skin. Apply in a film to entire face, avoiding contact with eyes or mucous membranes. Wait 10 minutes or until dry. Rinse thoroughly with water and pat dry.

HOW SUPPLIED

Sulfacetamide sodium 9% and sulfur 4.5% wash is supplied in
16 oz (454 g) bottle **NDC 42582-500-21**

Store at 20°-25°C (68°-77°F), excursions permited between 15°-30°C (59°-86°F). Brief exposure to temperatures up to 40° (104°F) may be tolerated provided the mean kinetic temperature does not exceed 25°C (77°F); however such exposure should be minimized. Protect from freezing.

Call your doctor about side effects. You may report side effects to FDA at 1-800-FDA-1088.

KEEP THIS AND ALL MEDICATIONS OUT OF THE REACH OF CHILDREN

Rx Only

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

PRINCIPAL DISPLAY PANEL - 454 g Bottle Carton

NDC # 42582-500-21

Sodium Sulfacetamide 9%
&
Sulfur 4.5%
Wash

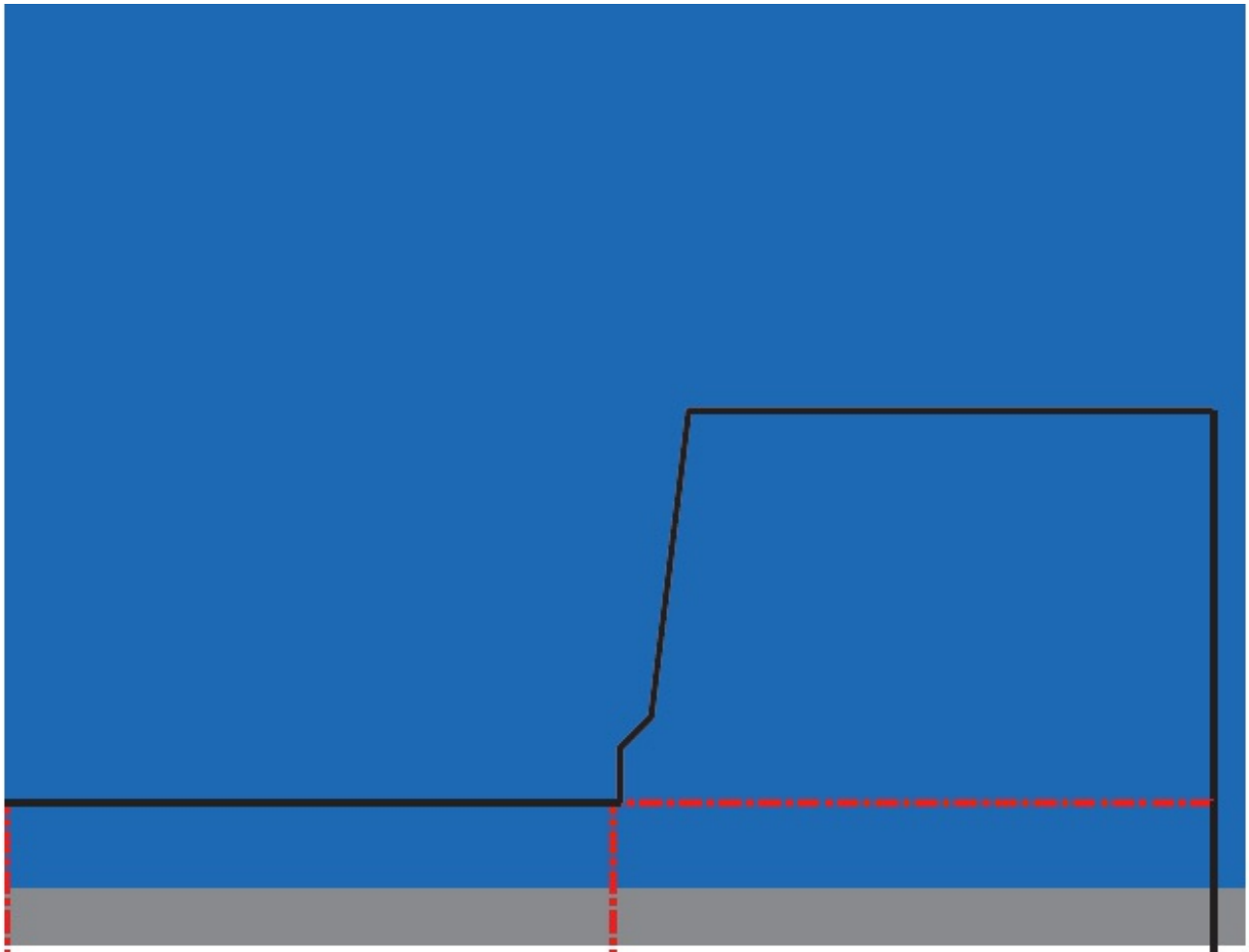
For topical use only • Not for

ophthalmic use

Rx Only

Bi-Coastal Pharma International LLC

NET WT. 16 OZ. (454g)



NDC # 42582-500-21

Sodium Sulfacetamide 9% & Sulfur 4.5% Wash

INDICATIONS: Sodium Sulfacetamide 9% and Sulfur 4.5% Wash is indicated for the topical control of acne vulgaris, acne rosacea and seborrheic dermatitis.

DIRECTIONS: Apply Sodium Sulfacetamide 9% and Sulfur 4.5% Wash once or twice daily to affected areas or as directed by your physician. Wet skin and liberally apply to areas to be cleaned. Message gently into skin for 10-20 seconds. Working into a lather. Rinse thoroughly and pat dry. If drying occurs, it may be controlled by rinsing off Sodium Sulfacetamide 9% and Sulfur 4.5% Wash sooner or using less often.

FOR EXTERNAL USE ONLY. NOT FOR OPTHALMIC USE.

KEEP THIS AND ALL MEDICATIONS OUT OF REACH OF CHILDREN. Keep this bottle tightly closed.

CONTRAINDICATIONS: Sodium Sulfacetamide 9% and Sulfur 4.5% Wash is contraindicated for use by patients having known hypersensitivity to sulfonamides, sulfur or any other component of this preparation. Sodium Sulfacetamide 9% and Sulfur 4.5% Wash is not to be used by patients with kidney disease.

INGREDIENTS: Each gram of Sodium Sulfacetamide

For topical use only • Not for ophthalmic use

Rx Only

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NET WT. 16 OZ. (454g)

9% and Sulfur 4.5% Wash contains 90 mg of sodium sulfacetamide and 45 mg of sulfur in a formulation containing: 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, Xanthan Gum.

Store at 20°C to 25°C (68°F to 77°F), excursions permitted between 15°C to 30°C (between 59°F to 86°F). Protect from freezing.

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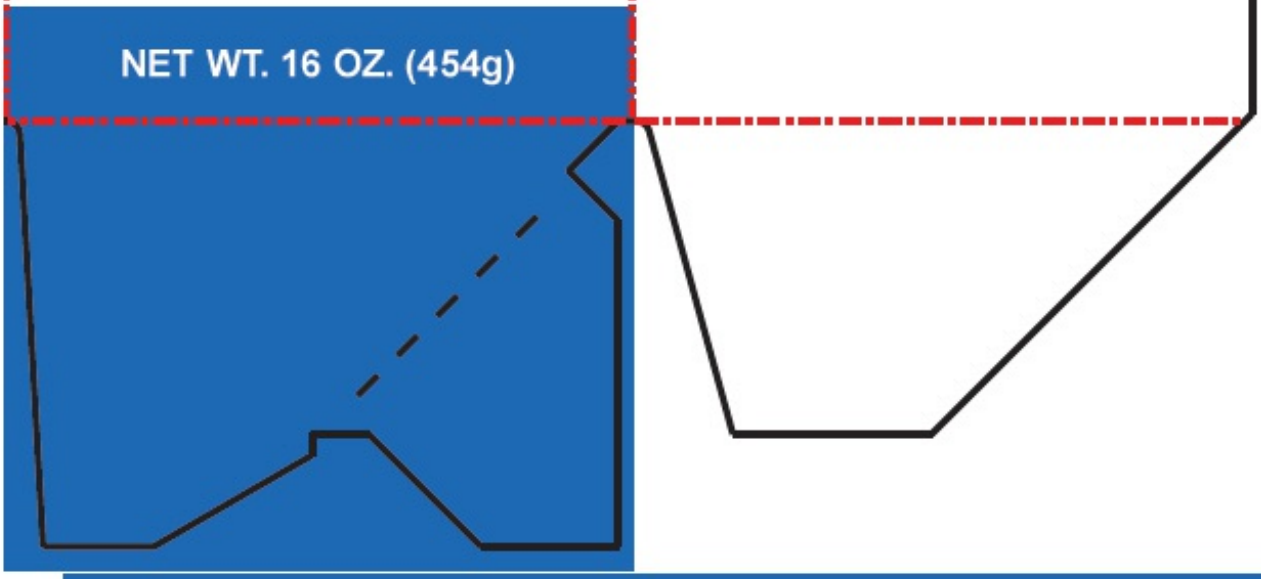

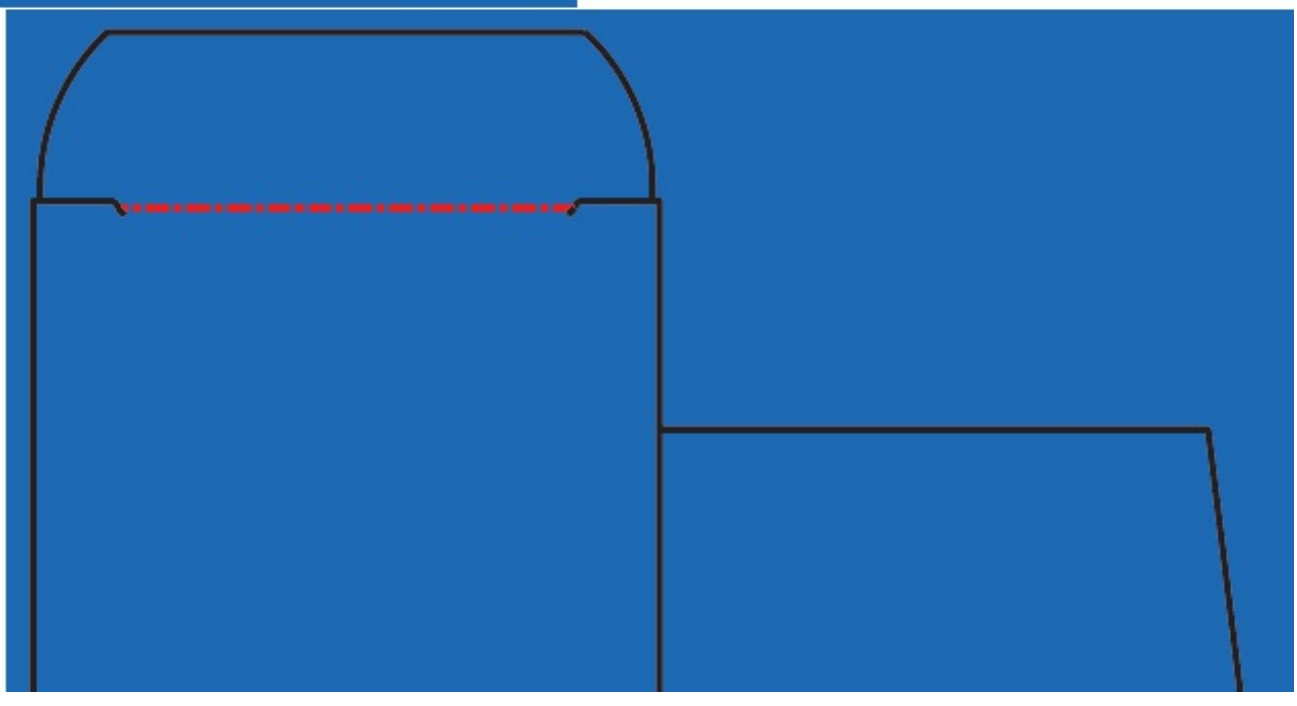

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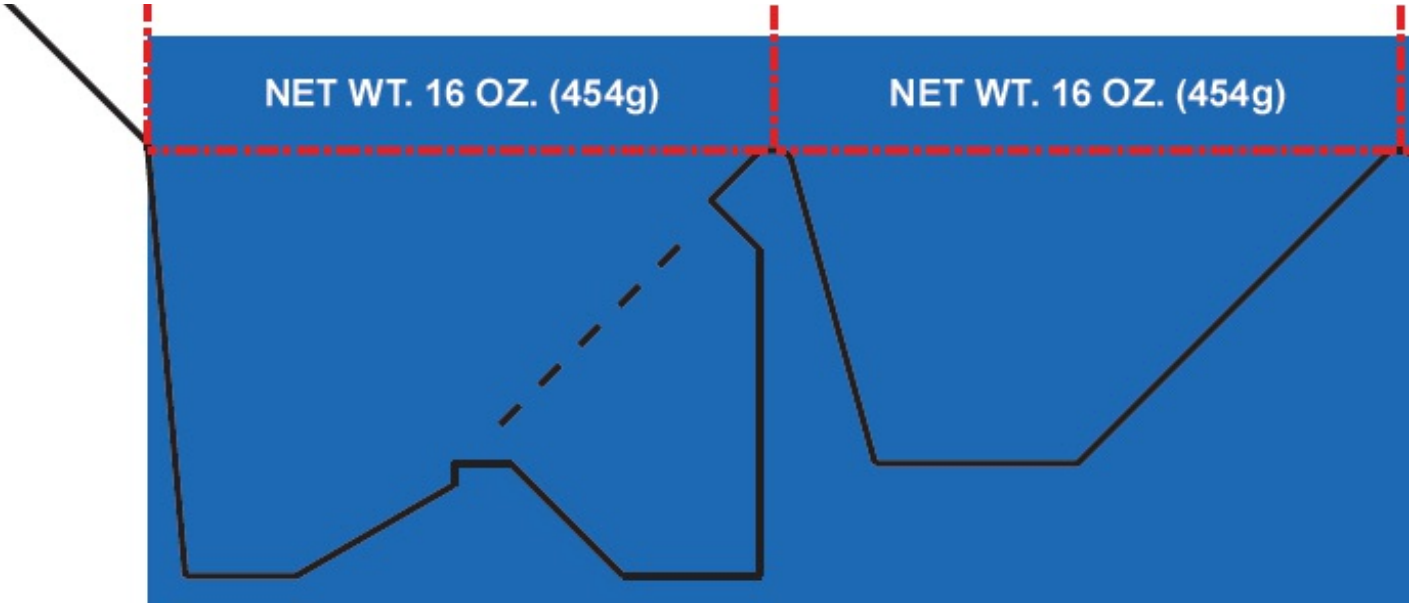

SULFACETAMIDE SODIUM AND SULFUR

sulfacetamide sodium and sulfur cream

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:42582-500
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SULFACETAMIDE SODIUM (UNII: 4NRT660KJQ) (SULFACETAMIDE - UNII:4965G3J0F5)	SULFACETAMIDE SODIUM	90 mg in 1 g
SULFUR (UNII: 70FD1KFU70) (SULFUR - UNII:70FD1KFU70)	SULFUR	45 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
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:42582-500-21	1 in 1 CARTON	06/01/2011	
1		454 g in 1 BOTTLE; Type 6: Drug/Biologic Combination		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
UNAPPROVED DRUG OTHER		06/01/2011	

Labeler - Bi-Coastal Pharma International LLC (078397428)

Registrant - Bi-Coastal Pharma International LLC (078397428)

Revised: 1/2022 Bi-Coastal Pharma International LLC