**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.*

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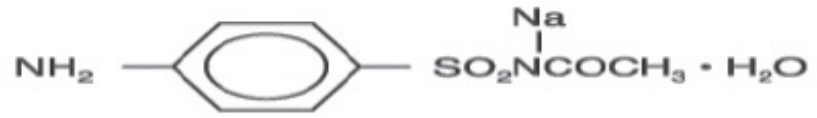
**Sulfacetamide Sodium and Sulfur**

## 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 10% and Sulfur USP 5% contains 100 mg of Sodium Sulfacetamide USP and 50 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 cleanser is indicated in the topical control of acne vulgaris, acne rosacea and seborrheic dermatitis.

## CONTRAINDICATIONS

Sulfacetamide Sodium and Sulfur cleanser is contraindicated for use by patients having known hypersensitivity to sulfonamides, Sulfur or any other component of this preparation. Sulfacetamide Sodium and Sulfur cleanser 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 long-term 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 cleanser can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Sulfacetamide Sodium and Sulfur cleanser 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 cleanser 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 10% and Sulfur 5% cleanser is supplied in
6 oz (170 g) tube **NDC 42582-600-23**
12 oz (340 g) bottle **NDC 42582-600-20**

Store at 20°-25°C (68°-77°F), excursions permitted 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**
**Shrewsbury, New Jersey 07702 USA**

## PRINCIPAL DISPLAY PANEL - 340 g Bottle Carton

**NDC # 42582-600-20**

**Sodium**
**Sulfacetamide**
**10% &**
**Sulfur 5%**

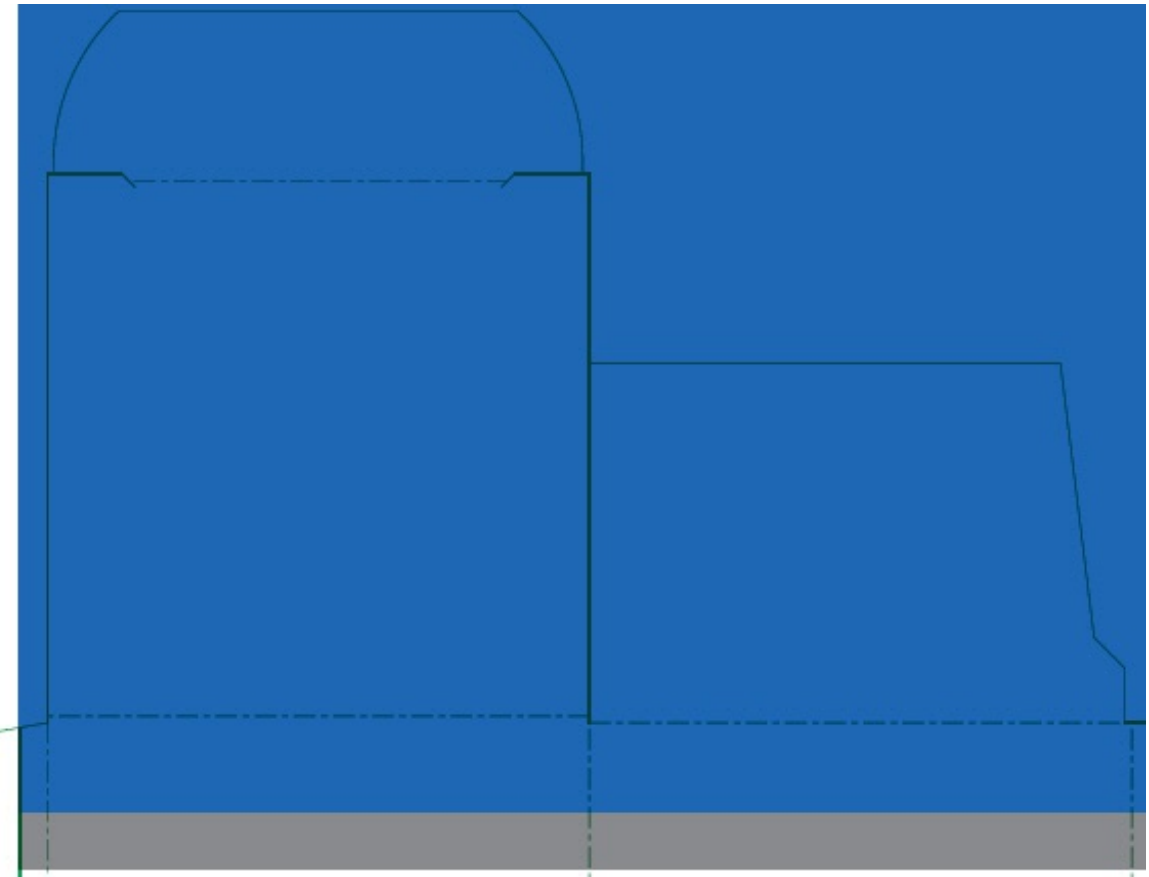
**Cleanser**

**For topical use only • Not for ophthalmic use**

**Rx Only**

**Bi-Coastal Pharma International** LLC

**NET WT. 12 OZ. (340g)**



NDC # 42582-600-20

Sodium
Sulfacetamide
10% &
Sulfur 5%
Cleanser

For topical use only • Not for ophthalmic use

NDC # 42582-600-20

Sodium
Sulfacetamide
10% &
Sulfur 5%
Cleanser

For topical use only • Not for ophthalmic use

Glue seam

Rx Only

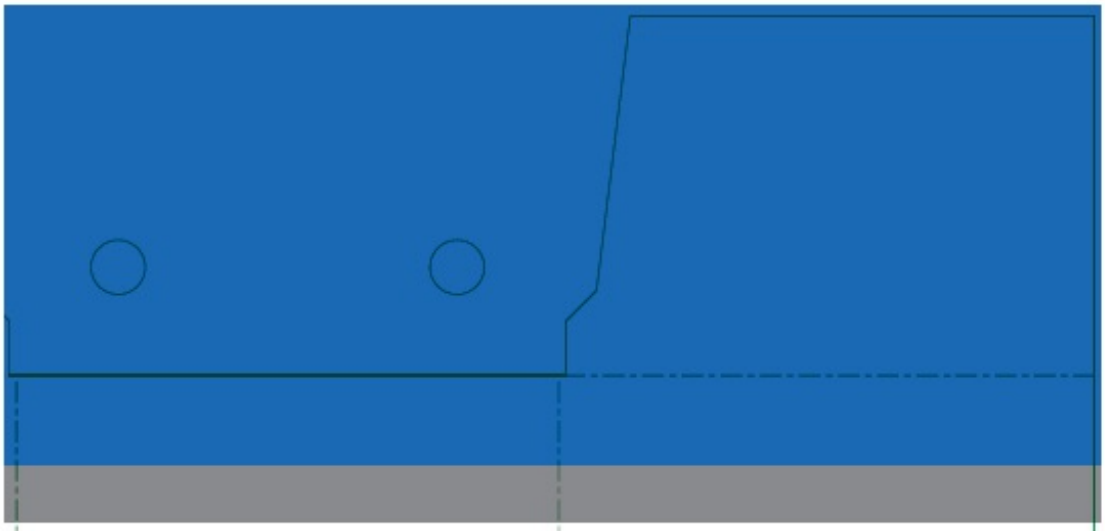
Bi-Coastal Pharma International LLC

NET WT. 12 OZ. (340g)

Rx Only

Bi-Coastal Pharma International LLC

NET WT. 12 OZ. (340g)

NDC # 42582-600-20

**INDICATIONS:** Sodium Sulfacetamide 10% and Sulfur 5% Cleanser is indicated for the topical control of acne vulgaris, acne rosacea and seborrheic dermatitis.

**DIRECTIONS:** Apply Sodium Sulfacetamide 10% and Sulfur 5% Cleanser once or twice daily to affected areas or as directed by your physician. Wet skin and liberally apply to areas to be cleaned. Massage 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 10% and Sulfur 5% Cleanser sooner or using less often.


# SULFACETAMIDE SODIUM AND SULFUR

sulfacetamide sodium and sulfur cream

| Product Information | | | |
|---|---|---|---|
| **Product Type** | HUMAN PRESCRIPTION DRUG | **Item Code (Source)** | NDC:42582-600 |
| **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 g |
| **SULFUR** (UNII: 70FD1KFU70) (SULFUR - UNII:70FD1KFU70) | SULFUR | 50 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:42582-600-23 | 1 in 1 CARTON | 01/01/2011 | |
| **1** | | 170 g in 1 TUBE; Type 0: Not a Combination Product | | |
| **2** | NDC:42582-600-20 | 1 in 1 CARTON | 01/01/2011 | |
| **2** | | 340 g in 1 BOTTLE; Type 0: Not a Combination Product | | |

## Marketing Information

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

**Labeler -** Bi-Coastal Pharma International LLC (078397428)

**Registrant -** Bi-Coastal Pharma International LLC (078397428)

Revised: 1/2022 Bi-Coastal Pharma International LLC