**SODIUM SULFACETAMIDE AND SULFUR- sodium sulfacetamide and sulfur solution**
**Seton Pharmaceuticals**

*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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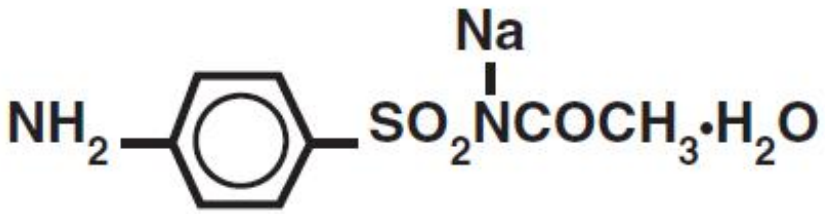
**10% Sodium Sulfacetamide**
**5% Sulfur Cleanser (in a Urea vehicle)**

**Rx Only**

## DESCRIPTION:

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




**Each mL of 10% Sodium Sulfacetamide 5% Sulfur Cleanser (in a Urea vehicle)** contains 100 mg of sodium sulfacetamide and 50 mg of sulfur in an emulsion base containing 10% Urea, butylated hydroxytoluene, cetyl alcohol, disodium EDTA, disodium oleamido MEA sulfosuccinate, fragrance, glyceryl stearate and PEG 100 stearate, magnesium aluminum silicate, methylparaben, propylparaben, purified water, sodium cocoyl isethionate, sodium methyl cocoyl taurate, sodium thiosulfate, stearyl alcohol and 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, 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:

**10% Sodium Sulfacetamide 5% Sulfur Cleanser (in a Urea vehicle)** is indicated in the topical control of acne vulgaris, acne rosacea and seborrheic dermatitis.

## CONTRAINDICATIONS:

**10% Sodium Sulfacetamide 5% Sulfur Cleanser (in a Urea vehicle)** is contraindicated for patients having known hypersensitivity to sulfonamides, sulfur or any other component of this preparation. **10%**

**Sodium Sulfacetamide 5% Sulfur Cleanser (in a Urea vehicle)** is not to be used by patients with kidney disease.

**WARNINGS:**

Rarely, 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. Use particular caution on areas of denuded or abraded skin.

**FOR EXTERNAL USE ONLY**. Keep away from eyes. **Keep out of reach of children**.

**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 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:** 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:** Long-term studies in animals have not been performed to evaluate carcinogenic potential.

**Pregnancy:** Category C. Animal reproduction studies have not been conducted with **10% Sodium Sulfacetamide 5% Sulfur Cleanser (in a Urea vehicle).** It also is not known whether **10% Sodium Sulfacetamide 5% Sulfur Cleanser (in a Urea vehicle)** can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. **10% Sodium Sulfacetamide 5% Sulfur Cleanser (in a Urea vehicle)** 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 **10% Sodium Sulfacetamide 5% Sulfur Cleanser (in a Urea vehicle)**. However, small amounts of orally administered sulfonamides have been reported to be excreted in human milk. For this reason, and because many drugs are excreted in human milk, caution should be exercised when **10% Sodium Sulfacetamide 5% Sulfur Cleanser (in a Urea vehicle)** is administered to a nursing woman.

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

**ADVERSE REACTIONS:**

Rarely, sodium sulfacetamide may cause local irritation.

**DOSAGE AND ADMINISTRATION:**

**10% Sodium Sulfacetamide 5% Sulfur Cleanser (in a Urea vehicle)**. Wash affected area once or twice daily, or as directed by a physician. Avoid contact with eyes and mucous membranes. Wet skin and apply a generous amount to areas to be cleansed. Gently work into a full lather, massaging into the skin for 10-20 seconds. If drying of the skin occurs, it may be controlled by rinsing off the cleanser sooner or using less often.

**HOW SUPPLIED:**

**10% Sodium Sulfacetamide 5% Sulfur Cleanser (in a Urea vehicle)** is available in a 12 oz. (355 mL) bottle, NDC 13925-161-12.

Store **10% Sodium Sulfacetamide 5% Sulfur Cleanser (in a Urea vehicle)** at 15°-25° C (59°-77° F). 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 DRUGS OUT OF REACH OF CHILDREN**

All prescriptions using this product shall be pursuant to state statutes as applicable. This is not an Orange Book product.

This product may be administered only under a physician's supervision. There are no implied or explicit claims on therapeutic equivalence.

Manufactured for:
Seton Pharmaceuticals
Manasquan, NJ 08736
1-800-510-3401
Iss. 5/11

**PACKAGE LABEL.PRINCIPAL DISPLAY PANEL**

NDC 13925-161-12

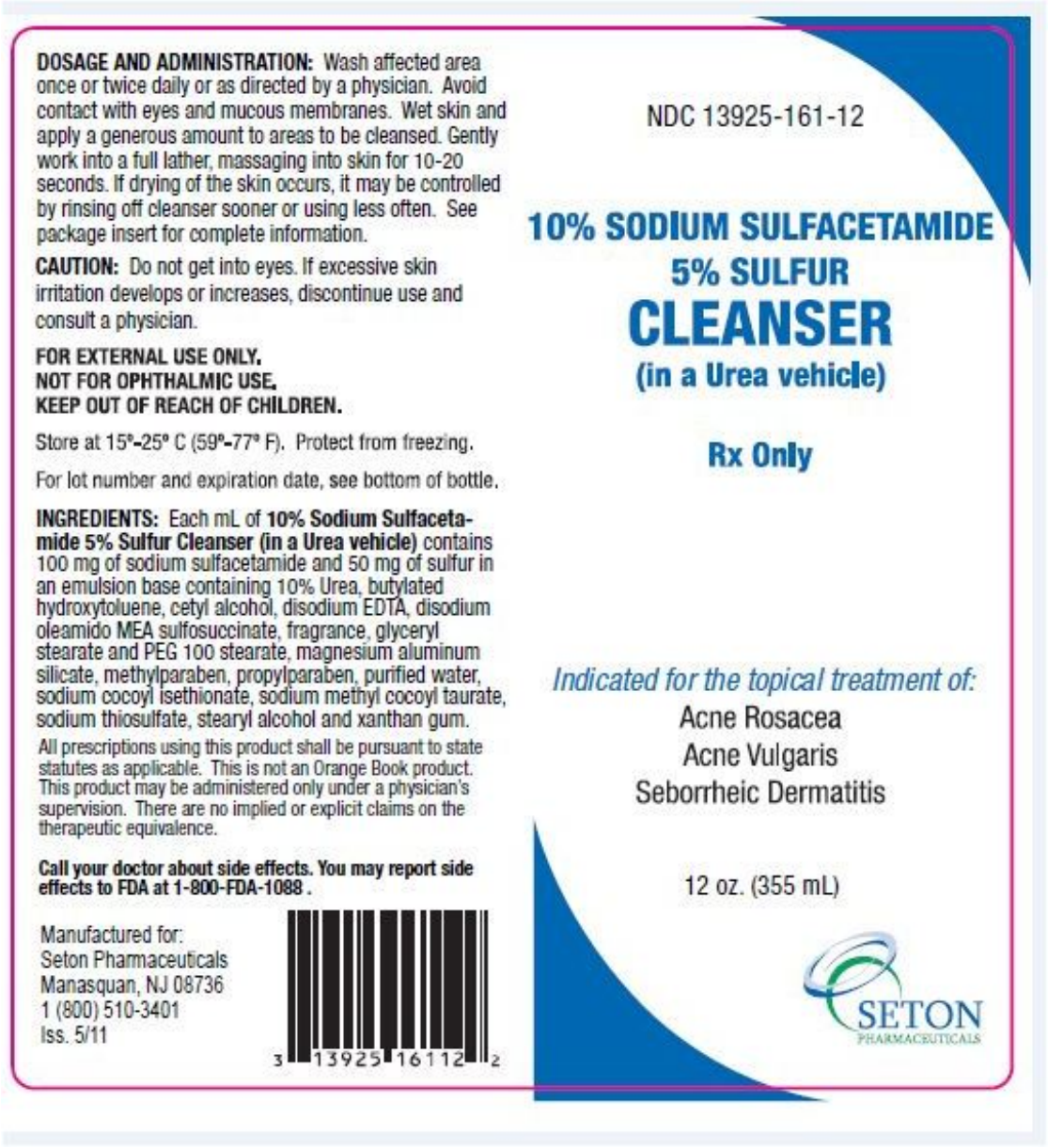
**10% SODIUM SULFACETAMIDE**
**5% SULFUR**
**CLEANSER**
**(in a Urea vehicle)**

**Rx Only**

*Indicated for the topical treatment of:*
Acne Rosacea
Acne Vulgaris
Seborrheic Dermatitis

12 oz. (355 mL)

**SETON**




# SODIUM SULFACETAMIDE AND SULFUR

sodium sulfacetamide and sulfur solution

| Product Information | | | |
|---|---|---|---|
| **Product Type** | HUMAN PRESCRIPTION DRUG | **Item Code (Source)** | NDC:13925-161 |
| **Route of Administration** | TOPICAL | | |

| Active Ingredient/Active Moiety | | |
|---|---|---|
| **Ingredient Name** | **Basis of Strength** | **Strength** |
| **Sulfacetamide** (UNII: 4965G3J0F5) (Sulfacetamide - UNII:4965G3J0F5) | Sulfacetamide | 100 mg in 1 mL |
| **Sulfur** (UNII: 70FD1KFU70) (Sulfur - UNII:70FD1KFU70) | Sulfur | 50 mg in 1 mL |

| Inactive Ingredients |
|---|

| Ingredient Name | Strength |
|---|---|
| **UREA** (UNII: 8W8T17847W) | |
| **BUTYLATED HYDROXYTOLUENE** (UNII: 1P9D0Z171K) | |
| **CETYL ALCOHOL** (UNII: 936JST6JCN) | |
| **EDETATE DISODIUM** (UNII: 7FLD91C86K) | |
| **DISODIUM OLEAMIDO MEA-SULFOSUCCINATE** (UNII: 5M1101WGSY) | |
| **GLYCERYL MONOSTEARATE** (UNII: 230OU9XXE4) | |
| **PEG-100 STEARATE** (UNII: YD01N1999R) | |
| **MAGNESIUM ALUMINUM SILICATE** (UNII: 6M3P64V0NC) | |
| **METHYLPARABEN** (UNII: A2I8C7HI9T) | |
| **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:13925-161-12 | 355 mL in 1 BOTTLE; Type 0: Not a Combination Product | 05/27/2011 | |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| unapproved drug other | | 05/27/2011 | |

## Labeler - Seton Pharmaceuticals (828898002)

Revised: 4/2019 Seton Pharmaceuticals