

SODIUM SULFACETAMIDE AND SULFUR- sodium sulfacetamide and sulfur suspension

Westminster Pharmaceuticals, 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 8% and Sulfur 4% Topical Suspension

In a vehicle containing Green Tea and Aloe

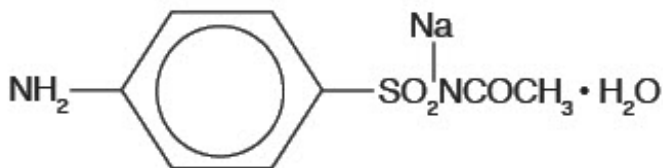
Rx Only

FOR EXTERNAL USE ONLY. NOT FOR OPHTHALMIC USE.

DESCRIPTION

Sodium sulfacetamide is a sulfonamide with antibacterial activity while 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 Sodium Sulfacetamide 8% and Sulfur 4% Topical Suspension contains 80 mg of Sodium Sulfacetamide and 40 mg of Sulfur in a formulation containing Aloe Vera leaf Extract, Butylated Hydroxytoluene, Cetyl Alcohol, Citric Acid, Cocamidopropyl Betaine, Disodium EDTA, Glycerin, Glyceryl Stearate SE, Green Tea Extract, PEG-100 Stearate, Phenoxyethanol, Purified Water, Sodium laureth sulfate, Sodium Thiosulfate, Stearyl alcohol, Triacetin, 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 not known, but it has been reported that it inhibits the growth of *Propionibacterium acnes* and the

formation of free fatty acids.

INDICATIONS

Sodium Sulfacetamide 8% and Sulfur 4% Topical Suspension is indicated in the topical control of acne vulgaris, acne rosacea and seborrheic dermatitis.

CONTRAINDICATIONS

This product is contraindicated for use by persons with known or suspected hypersensitivity to sulfonamides, sulfur or any other component of this preparation. This product 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.

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 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 Sodium Sulfacetamide 8% and Sulfur 4% Topical Suspension. It is not known whether Sodium Sulfacetamide 8% and Sulfur 4% Topical Suspension can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Sodium Sulfacetamide 8% and Sulfur 4% Topical Suspension should be given to a pregnant woman only if clearly needed.

NURSING MOTHERS

It is not known whether sodium sulfacetamide is excreted in the human milk following topical use of Sodium Sulfacetamide 8% and Sulfur 4% Topical Suspension. 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 Sodium Sulfacetamide 8% and Sulfur 4% Topical Suspension 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, sodium sulfacetamide may cause local irritation.

Call your doctor for medical advice about side effects. To report a serious adverse event, please contact Westminster Pharmaceuticals at 1-844-221-7294.

OVERDOSAGE

The oral LD₅₀ of sulfacetamide in mice is 16.5 g/kg. In the event of overdose, emergency treatment should be started immediately.

Manifestations

Overdosage may cause nausea and vomiting. Large oral overdose 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 (1-800-222-1222), or your doctor.

DOSAGE AND ADMINISTRATION

Apply Sodium Sulfacetamide 8% and Sulfur 4% Topical Suspension once or twice daily to affected areas, or as directed by your physician. Wet skin and liberally apply to areas to be cleansed. Massage gently into skin for 10-20 seconds, working into a full lather, rinse thoroughly and pat dry. If drying occurs, it may be controlled by rinsing off Sodium Sulfacetamide 8% and Sulfur 4% Topical Suspension sooner or using less often.

HOW SUPPLIED

Sodium Sulfacetamide 8% and Sulfur 4% Topical Suspension is available in 16 fl oz (473

mL) bottles, NDC 69367-245-16.

Store at controlled room temperature, 15° - 30°C (59° - 86°F). Protect from freezing.

KEEP THIS AND ALL MEDICATIONS OUT OF THE REACH OF CHILDREN.

All prescription substitutions using this product shall be made subject to state and federal statutes as applicable. **NOTE: this is not an Orange Book product and has not been subjected to FDA therapeutic equivalency or other equivalency testing. No representation is made as to generic status or bioequivalency.**

Each person recommending a prescription substitution using this product shall make such recommendations based on each such person's professional opinion and knowledge, upon evaluating the active ingredients, excipients, inactive ingredients and chemical formulation information provided herein.

Manufactured for:

Westminster Pharmaceuticals LLC

Nashville TN, 37217

Rev. 05/23

PRINCIPAL DISPLAY PANEL - 473 mL Bottle Label

NDC: 69367-245-16

Rx Only

Peel Here

Sodium

Sulfacetamide 8%

and Sulfur 4%

Topical Suspension

In a vehicle containing

Green Tea and Aloe

SHAKE WELL

16 fl. oz. (473 mL)

Westminster

Pharmaceuticals

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WP Westminster Pharmaceuticals



SODIUM SULFACETAMIDE AND SULFUR

sodium sulfacetamide and sulfur suspension

Product Information

| | | | |
|--------------------------------|-------------------------|---------------------------|---------------|
| Product Type | HUMAN PRESCRIPTION DRUG | Item Code (Source) | NDC:69367-245 |
| Route of Administration | TOPICAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|--|----------------------|---------------|
| SULFACETAMIDE SODIUM (UNII: 4NRT660KJQ) (SULFACETAMIDE - UNII:4965G3J0F5) | SULFACETAMIDE SODIUM | 80 mg in 1 mL |
| SULFUR (UNII: 70FD1KFU70) (SULFUR - UNII:70FD1KFU70) | SULFUR | 40 mg in 1 mL |

Inactive Ingredients

| Ingredient Name | Strength |
|--|----------|
| ALOE (UNII: V5VD430YW9) | |
| BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K) | |
| CETYL ALCOHOL (UNII: 936JST6JCN) | |
| COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX) | |
| EDETATE DISODIUM (UNII: 7FLD91C86K) | |
| GLYCERIN (UNII: PDC6A3C0OX) | |
| GLYCERYL STEARATE SE (UNII: FCZ5MH785I) | |
| GREEN TEA LEAF (UNII: W2ZU1RY8B0) | |
| PEG-100 STEARATE (UNII: YD01N1999R) | |
| WATER (UNII: 059QF0KO0R) | |
| SODIUM THIOSULFATE (UNII: HX1032V43M) | |
| STEARYL ALCOHOL (UNII: 2KR89I4H1Y) | |
| TRIACETIN (UNII: XHX3C3X673) | |
| XANTHAN GUM (UNII: TTV12P4NEE) | |
| CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP) | |
| PHENOXYETHANOL (UNII: HIE492ZZ3T) | |
| SODIUM LAURETH-3 SULFATE (UNII: BPV390UAP0) | |

Product Characteristics

| | | | |
|-----------------|--------|---------------------|--|
| Color | YELLOW | Score | |
| Shape | | Size | |
| Flavor | | Imprint Code | |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:69367-245-16 | 473 mL in 1 BOTTLE; Type 0: Not a Combination Product | 06/18/2021 | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------------|--|----------------------|--------------------|
| UNAPPROVED DRUG OTHER | | 06/18/2021 | |

Labeler - Westminster Pharmaceuticals, LLC (079516651)