SULFACETAMIDE SODIUM AND SULFUR SODIUM SULFACETAMIDE - SULFUR- sulfacetamide sodium and sulfur suspension
Allegis 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 9% - Sulfur 4.25% Suspension

NDC 28595-501-08
Rx Only

Topical Suspension in a vehicle containing Green Tea and Aloe

FOR EXTERNAL USE ONLY
NOT FOR OPHTHALMIC USE

SHAKE WELL

Net Wt. (8oz) 237 mL

Active ingredients: Sodium Sulfacetamide 9% and Sulfur 4.25%

Indications: For the topical control of acne vulgaris, acne rosacea and seborrheic dermatitis.

Directions: Shake Well before using. Apply 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 sooner or using less often.

See enclosed package insert for full prescribing information.

Warnings: For external use only. Not for ophthalmic use.

Avoid contact with eyes or mucous membranes.

KEEP OUT OF REACH OF CHILDREN. Keep bottle tightly closed.

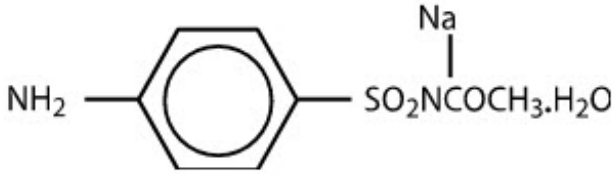
Store at controlled room temperature, 15° - 30°C (59° - 86°F). Protect from freezing.

Manufactured for: Manufactured in U.S.A
Allegis Pharmaceuticals, LLC, Canton, MS 39046 Rev. 04-2024

Rx Only

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 contains 90 mg of sodium sulfacetamide and 42.5 mg of sulfur in vehicle consisting of 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 and xanthan gum.

CLINICAL PHARMACOLOGY

Sodium sulfacetamide exerts a bacteriostatic effect against sulfonamide sensitive Gram-positive and Gram-negative microorganisms commonly isolated from secondary cutaneous pyogenic infections. It acts by restricting the synthesis of folic acid required by bacteria for growth, by its competition with para-aminobenzoic acid. There is no clinical data available on the degree and rate of systemic absorption of this product when applied to the skin or scalp. However, significant absorption of sodium sulfacetamide through the skin has been reported.

The following in vitro data is available but the clinical significance is unknown. Organisms that show susceptibility to sodium sulfacetamide are: Streptococci, Staphylococci, E. coli, Klebsiella pneumoniae, Pseudomonas pyocyanea, Salmonella species, Proteus vulgaris, Nocardia and Actinomyces.

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% - Sulfur 4.25% Suspension is indicated in the topical control of acne vulgaris, acne rosacea and seborrheic dermatitis.

CONTRAINDICATIONS

Sodium Sulfacetamide 9% - Sulfer 4.25% Supesnion is contraindicated for use by patients having known hypersensitivity to sulfonamides, sulfur or any other component of this preparation. Sodium Sulfacetamide 9% - Sulder 4.25% Supension 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.

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Avoid contact with eyes, lips and mucous membranes.

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PRECAUTIONS

General

Nonsusceptible organisms, including fungi, may proliferate with the use of this preparation. 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. Systemic absorption of topical sulfonamides is greater following application to large, infected, abraded, denuded or severely burned areas. Under these circumstances, any of the adverse effects produced by the systemic administration of these agents could potentially occur, and appropriate observations and laboratory determinations should be performed.

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, lips and mucous membranes. Patients should discontinue the use of this product if the condition becomes worse or if a rash develops in the area being treated or elsewhere. The use of this product should also be discontinued promptly and the physician notified if any arthritis, fever or sores in the mouth develop.

Drug Interactions

This product is incompatible with silver preparations.

Carcinogenesis, Mutagenesis and Impairment of Fertility

Long-term studies in animals have not been performed to evaluate carcinogenic potential. Studies on reproduction and fertility also have not been performed. Chromosomal nondisjunction has been reported in the yeast, Saccharomyces cerevisiae, following application of sodium sulfacetamide. The significance of this finding to the topical use of sodium sulfacetamide in the human is unknown.

PREGNANCY

Category C

Animal reproduction studies have not been conducted with Sodium Sulfacetamide 9% - Sulfer 4.25% Suspension. It is not known whether Sodium Sulfacetamide 9% - Sulfer 4.25% Suspension can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Sodium Silfacetamide 9% - Sulfer 4.25% should be given to a pregnant woman only if clearly needed or when potential benefits outweigh potential hazards to the fetus.

NURSING MOTHERS

It is not known whether this drug is excreted in the human milk. 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 9% - Sulfur 4.25% Supesnion is administered to a nursing woman.

PEDIATRIC USE

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

ADVERSE REACTIONS

Reports of irritation and hypersensitivity to sodium sulfacetamide are uncommon. The following adverse reactions, reported after administration of sterile ophthalmic sodium sulfacetamide, are noteworthy: instances of Stevens-Johnson syndrome and instances of local hypersensitivity which progressed to a syndrome resembling systemic lupus erythematosus; in one case a fatal outcome was reported (see **WARNINGS**).

Call your doctor for medical advice about side effects. To report **SUSPECTED ADVERSE REACTIONS**or obtain product information, contact Allegis Pharmacuticals, LLC at 1-866-633-9033 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

OVERDOSAGE

The oral LD_{50} of sulfacetamide in mice is 16.5 g/kg. In the event of overdosage, emergency treatment should be started immediately.

Manifestations

Overdosage may cause nausea and vomiting. Large oral overdosage 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

SHAKE WELL before use. Cleanse affected areas. Apply Sodium Sulfacetamide 9% - Sulfer 4.25% 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 skin

dryness occurs, it may be controlled by rinsing off Sodium Sulfacetamide 9% - Sulfer 4.25% sooner or using less often.

HOW SUPPLIED

Sodium Sulfacetamide 9% - Sulfur 4.25% Suspension is available in 8 fl oz (237 mL) bottles, NDC 28595-501-08.

STORAGE AND HANDLING

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.

Manufactured for:
Allegis Pharmaceuticals, LLC
Canton, MS 39046

Manufactured in U.S.A

Rev. 04/2024

All prescriptions 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.**

PRINCIPAL DISPLAY PANEL - 237 mL Bottle Label

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SULFACETAMIDE SODIUM AND SULFUR SODIUM SULFACETAMIDE - SULFUR

sulfacetamide sodium and sulfur suspension

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:28595-501
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 mL
SULFUR (UNII: 70FD1KFU70) (SULFUR - UNII:70FD1KFU70)	SULFUR	42.5 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
CITRIC ACID ACETATE (UNII: DSO12WL7AU)	

EDETATE DISODIUM (UNII: 7FLD91C86K)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)	
GLYCERIN (UNII: PDC6A3C0OX)	
GLYCERYL STEARATE SE (UNII: FCZ5MH785I)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
XANTHAN GUM (UNII: TTV12P4NEE)	
PEG-100 STEARATE (UNII: YD01N1999R)	
WATER (UNII: 059QF0KO0R)	
SODIUM THIOSULFATE (UNII: HX1032V43M)	
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)	
TRIACETIN (UNII: XHX3C3X673)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
SODIUM LAURETH SULFATE (UNII: BPV390UAP0)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	

Product Characteristics

Color	yellow	**Score**	
Shape		**Size**	
Flavor		**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:28595-501-08	237 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/18/2024	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		06/18/2024	

Labeler - Allegis Pharmaceuticals, LLC (792272861)

Revised: 6/2024 Allegis Pharmaceuticals, LLC