SODIUM SULFACETAMIDE 8% AND SULFUR 4%- sulfacetamide sodium, sulfur suspension
Oncor 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.

Sodium Sulfacetamide 8% & Sulfur 4% Topical Suspension

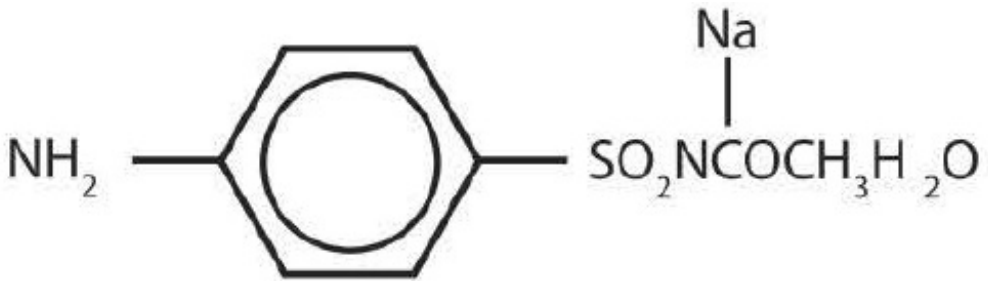
In A Vehicle Containing Green Tea And Aloe.

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 gram 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

Sodium Sulfacetamide 8% and Sulfur 4% Topical Suspension is contraindicated for use by patients having known hypersensitivity to sulfonamides, sulfur or any other component of this preparation. Sodium Sulfacetamide 8% and Sulfur 4% Topical Suspension 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 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 CAnimal 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% Topica 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.

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

6 fl oz (177 mL) bottles, NDC 83720-532-06

12 fl oz (354 mL) bottles NDC 83720-532-12

16 fl oz (473 mL) bottles NDC 83729-532-16.

Storage: Store at 20°C to 25°C (68°F to 77°F), excursions permitted between 15°C and 30°C (between 59°F and 86°F). Brief exposure to temperatures up to 40°C (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.

In case of accidental ingestion contact a poison control center immediately. Keep container tightly closed.

You may report side effects by calling Oncor Pharmaceuticals (9 a.m. to 5 p.m. EST), at 1-443-876-7900 or FDA at 1-800-FDA-1088.

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

Shake well before use.

Manufactured In USA For :
ONCOR PHARMACEUTICALS
8815 Center Park Dr Suite 430
Columbia
Maryland 21045

Rev. 05/24

ONCOR PHARMACEUTICALS

NDC 83720-532-16

Sodium Sulfacetamide

& Sulfur

Sodium Sulfacetamide 8%

Sulfur 4%

8% / 4%

Topical

Suspension

In A Vehical Containing
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Rx Only

NET WT. 16 fl. OZ. (473 mL)

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See booklet for full prescribing information.

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Caution: Incase of itching or redness discontinue the use.

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

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SODIUM SULFACETAMIDE 8% AND SULFUR 4%

sulfacetamide sodium, sulfur suspension

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:83720-532
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
TRIACETIN (UNII: XHX3C3X673)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
GLYCERYL STEARATE SE (UNII: FCZ5MH785I)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
PEG-100 STEARATE (UNII: YD01N1999R)	
WATER (UNII: 059QF0KO0R)	
SODIUM THIOSULFATE (UNII: HX1032V43M)	
SODIUM LAURETH SULFATE (UNII: BPV390UAP0)	
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)	
XANTHAN GUM (UNII: TTV12P4NEE)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
GLYCERIN (UNII: PDC6A3C0OX)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:83720-532-06	177 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/10/2024	
2	NDC:83720-532-12	354 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/10/2024	
3	NDC:83720-532-16	473 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/10/2024	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		05/10/2024	

Labeler - Oncor Pharmaceuticals (119032580)

Registrant - Oncor Pharmaceuticals (119032580)

Revised: 5/2024 Oncor Pharmaceuticals