SODIUM SULFACETAMIDE 8% SULFUR 4% CLEANSER- sodium sulfacetamide and sulfur liquid
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.

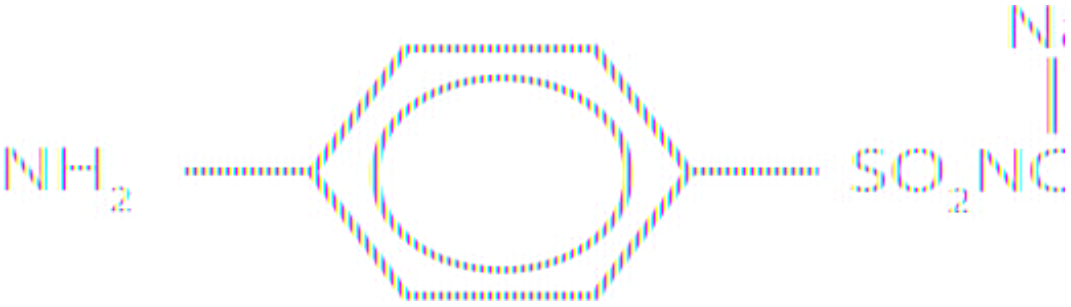
Sodium Sulfacetamide 8% Sulfur 4% Topical Suspension

In A Vehical Containing Green Tea And Aloe
Rx Only

DESCRIPTION

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.

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



INDICATIONS

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

FOR EXTERNAL USE ONLY. NOT FOR OPHTHALMIC USE.
Keep out of reach of children. Keep container tightly closed.
Shake well before use.

In case of accidental ingestion contact a Poison Control Center immediately. Keep container tightly closed.

You may report side effects by ca ling Oncor Pharmaceuticals (9 a.m. to 5 p.m. EST), at 1-443-876-7600 or FDA at 1-800-FDA-1088.

Incase of itching or redness discontinue the use.

STORAGE

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

Protect from freezing.

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.

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.

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.

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.

PRECAUTIONSGENERAL

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.

PREGNANCYCategory 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

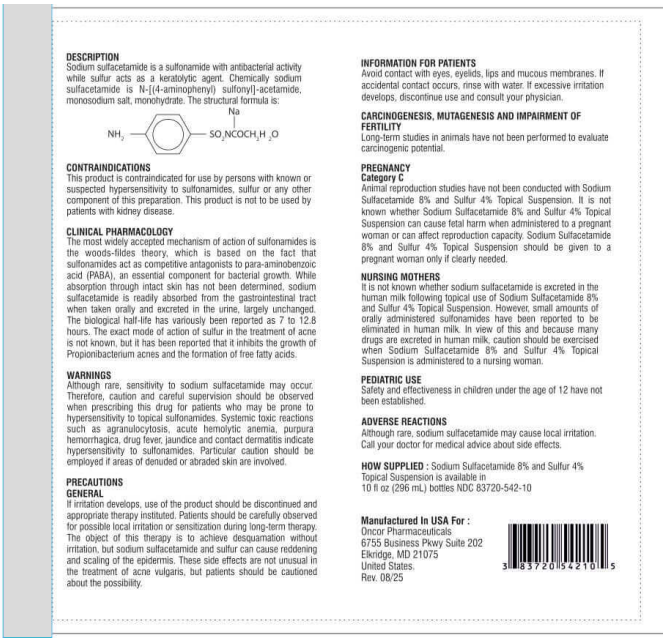
Although rare, sodium sulfacetamide may cause local irritation. Call your doctor for medical advice about side effects.

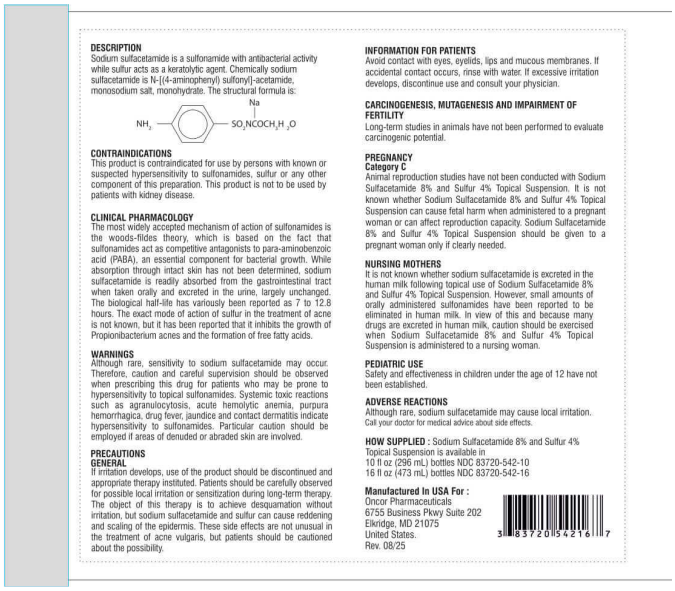
HOW SUPPLIED

Sodium Sulfacetamide 8% and Sulfur 4% Topical Suspension is available in
10 fl oz (296 mL) bottles NDC 83720-542-10.

Manufactured In USA For :

Oncor Pharmaceuticals
6755 Business Pkwy Suite 202
Elkridge, MD 21075
United States.
Rev. 08/25





SODIUM SULFACETAMIDE 8% SULFUR 4% CLEANSER

sodium sulfacetamide and sulfur liquid

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:83720-542
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 VERA LEAF (UNII: ZY81Z83H0X)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
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)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
WATER (UNII: 059QF0KO0R)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
SODIUM THIOSULFATE (UNII: HX1032V43M)	
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)	
TRIACETIN (UNII: XHX3C3X673)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:83720-542-10	296 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/14/2027	
2	NDC:83720-542-16	473 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	08/14/2025	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		08/14/2025	

Labeler - Oncor Pharmaceuticals (119032580)

Registrant - Oncor Pharmaceuticals (119032580)