SODIUM SULFACETAMIDE 9% AND SULFUR 4.5% WASH- sulfacetamide sodium 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 9% & Sulfur 4.5% Cleanser

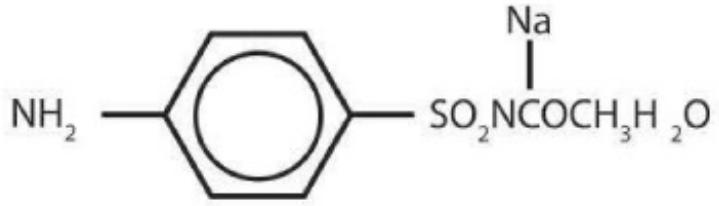
Sodium Sulfacetamide 9% Sulfur 4.5%

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 gram of Sodium Sulfacetamide 9% and Sulfur 4.5% Cleansercontains 90 mg of sodium sulfacetamide and 45 mg of sulfur in a cleanser

containing Aloe vera leaf extract, Butylated hydroxytoluene, Cetyl alcohol, Citric acid, Cocamidopropyl betaine, Disodium EDTA, Glycerin, Glyceryl
stearate SE, PEG-100 stearate, Phenoxyethanol, Purified water, Sodium laureth sulfate, Sodium thiosulfate, Stearyl alcohol, Triacetin, 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.

DIRECTIONS FOR USE:

Wash affected area once or twice daily, or as directed by your physician. Avoid contact with eyes or mucous membranes. 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 cleanser off sooner or using less often. See label booklet for Full prescribing Information.

INDICATIONS:

Sodium Sulfacetamide 9% & Sulfur 4.5% Cleanser is indicated in thetopical control of acne vulgaris, acne rosacea and seborrheic dermatitis.

CONTRAINDICATIONS

Sodium Sulfacetamide 9% & Sulfur 4.5% Cleanser is contraindicated for use by patients having known hypersensitivity to sulfonamides, sulfur or
any other component of this preparation. Sodium Sulfacetamide 9% & Sulfur 4.5% Cleanser is not to be used by patients with kidney disease.

WARNINGS

Although it is 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. NOT FOR INTRA VAGINAL OR OPHTHALMIC USE. (KEEP AWAY FROM EYES).

KEEP OUT OF REACH OF CHILDREN.
Shake well before use

In case of accidental ingestion contact a Poison Control Center immediately.
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 an imals have not been performed to evaluate carcinogenic potential.

PREGNANCY:

Category C. An imal reproduction studies have not been conducted with Sodium Sulfacetamide 9% & Sulfur 4.5% Cleanser. It is also not known whether Sodium Sulfacetamide 9% & Sulfur 4.5% Cleanser can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Sodium Sulfacetamide 9% & Sulfur 4.5% Cleanser should be given to a pregnant woman only if clearly needed.

NURSING MOTHERS:
It is not known whether sodium su lfacetamide is excreted in the human milk following topical use of Sodium Sulfacetamide 9% & Sulfur 4.5% Cleanser. However, small amounts of orally administered sulfonamides have milk. In view of this and because many drugs are excreted in human milk, caution should be exercised when Sodium Sulfacetamide 9% & Sulfur 4.5% Cleanser 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.

CAUTION:

If redness or irritation occurs, discontinue use.

DOSAGE AND ADMINISTRATION

Wash affected areas once or twice daily, or as directed by your physician. Avoid contact with eyes or mucous membranes. 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 cleanser off sooner or using less often.

HOW SUPPLIED

Sodium Sulfacetamide 9% & Sulfur 4.5% Cleanser is available:
6 oz (170 g) bottle, NDC 83720-535-06.
12 oz (340 g) bottle, NDC 83720-535-12.
16 oz (454 g) bottle, NDC 83720-535-16

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.

NOTICE:

Protect from freezing and excessive heat. The product may tend to darken slightly on storage. Slight discoloration does not impair the efficacy or safety of the product. Keep bottle tightly closed.

Occasionally, a slight discoloration of fabric may occur when an excessive amount of the product is used and comes in contact with white fabrics. This discoloration, however, presents no problem, as it is readily removed by ordinary laundering without bleaches.

This bottle is not filled to the top but does contain 16 oz of product as identified on the front panel of the bottle.

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.

Manufactured In USA For :
ONCOR PHARMACEUTICALS
8815 Center Park Dr Suite 430
Columbia
Maryland 21045
Rev. 05/24

ONCOR PHARMACEUTICALS

NDC 83720-535-16

Sodium Sulfacetamide

& Sulfur

Sodium Sulfacetamide 9%

Sulfur 4.5%

9% / 4.5%

Cleanser

Rx Only

For External Use Only

NET WT. 16 OZ. (454 g)

SODIUM SULFACETAMIDE 9% AND SULFUR 4.5% WASH

sulfacetamide sodium and sulfur liquid

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:83720-535
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
SULFACETAMIDE SODIUM (UNII: 4NRT660KJQ) (SULFACETAMIDE - UNII:4965G3J0F5)	SULFACETAMIDE SODIUM	10 mg in 1 g
SULFUR (UNII: 70FD1KFU70) (SULFUR - UNII:70FD1KFU70)	SULFUR	5 mg in 1 g

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)	
PEG-100 STEARATE (UNII: YD01N1999R)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
WATER (UNII: 059QF0KO0R)	
SODIUM THIOSULFATE (UNII: HX1032V43M)	
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)	
SODIUM LAURETH SULFATE (UNII: BPV390UAP0)	
TRIACETIN (UNII: XHX3C3X673)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:83720-535-12	340 g in 1 BOTTLE; Type 0: Not a Combination Product	05/10/2024	
2	NDC:83720-535-16	454 g in 1 BOTTLE; Type 0: Not a Combination Product	05/10/2024	
3	NDC:83720-535-06	170 g in 1 BOTTLE; 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