

SODIUM SULFACETAMIDE 10 % AND SULFUR 5 % CLEANSER- sodium sulfacetamide and sulfur liquid
Oncor Pharmaceuticals

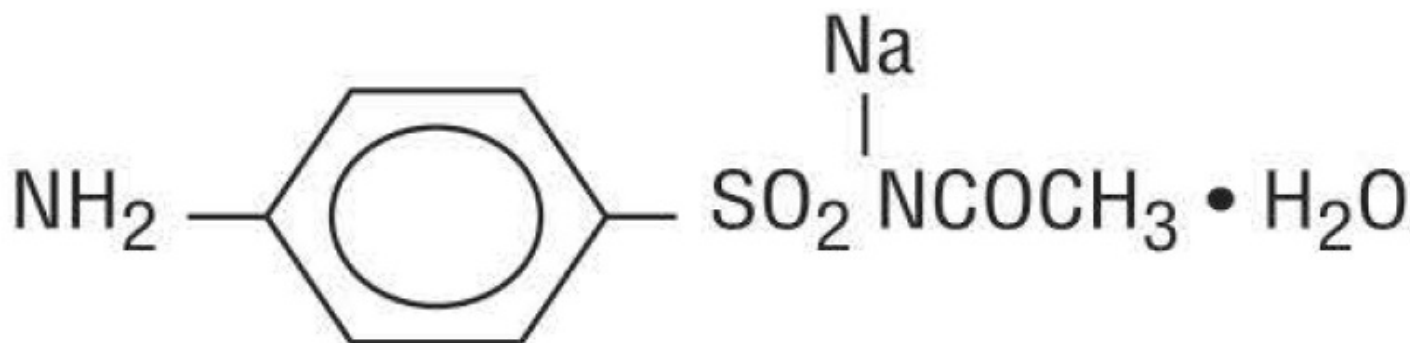
Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

Sodium Sulfacetamide 10% Sulfur 5% Cleanser

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 10% and sulfur 5% cleanser contains 100 mg of sodium sulfacetamide and 50 mg of sulfur in a cleanser containing ammonium 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: The most widely accepted mechanism of action of sulfonamides is the Woods-fields 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 1 hours. 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 10% & Sulfur 5% Cleanser is indicated in the topical control of acne vulgaris, acne rosacea and seborrheic dermatitis.

CONTRAINDICATIONS: Sodium Sulfacetamide 10% & Sulfur 5% Cleanser is contraindicated for use by patients having known hypersensitivity to sulfonamides,

sulfur or any other component of this preparation. Sodium Sulfacetamide 10% & Sulfur 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. Keep away from eyes.
Shake well before use.

KEEP OUT OF REACH OF CHILDREN.

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.

CARSINOGENESIS, 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 10% & Sulfur 5% Cleanser. It is also not known whether Sodium Sulfacetamide 10% & Sulfur 5% Cleanser can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Sodium Sulfacetamide 10% & Sulfur 5% Cleanser 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 10% & Sulfur 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 10% & Sulfur 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.

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 10% & Sulfur 5% | Cleanser is available in a 6 oz (170 g) bottle NDC 83720-537-06 and a 12 oz (340 g) bottle NDC 83720-537-12

Storage: Store at 20 to 25°C (68 to 77°F). See USP Controlled Room Temperature. Protect from freezing.

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

PRINCIPAL DISPLAY PANEL - 170.3 g Bottle Label

ONCOR PHARMACEUTICALS

NDC 83720-537-06

Rx Only

Sodium Sulfacetamide & Sulfur

Sodium Sulfacetamide 10%

Sulfur 5%

10%/5%

Cleanser

For External Use Only

NET WT.6 OZ. (170.3 g)



NDC 83720-537-06

Rx Only

Sodium Sulfacetamide & Sulfur

Sodium Sulfacetamide 10% Sulfur 5%

10% / 5%

Cleanser

For External Use Only

NET WT. 6 OZ. (170.3 g)

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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 package insert for complete product information.

FOR EXTERNAL USE ONLY. NOT FOR INTRAVAGINAL OR OPHTHALMIC USE. (KEEP AWAY FROM EYES). KEEP THIS AND ALL MEDICATION OUT OF REACH OF CHILDREN. 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 calling Oncor Pharmaceuticals (9 a.m. to 5 p.m. EST), at 1-443-876-7900 or FDA at 1-800-FDA-1088.

CONTRAINDICATIONS: Sodium Sulfacetamide 10% & Sulfur 5% Cleanser is contraindicated in persons with known or suspected hypersensitivity to sulfonamides, sulfur or any other component of this preparation. Sodium Sulfacetamide 10% & Sulfur 5% Cleanser is not to be used by patients with kidney disease.

CAUTION: If redness or irritation occurs, discontinue use.

Ingredients: Each gram of Sodium Sulfacetamide 10% and Sulfur 5% Cleanser contains 100 mg of sodium sulfacetamide and 50 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.

Storage: Store at 20°C to 25°C (68 to 77°F). See USP controlled room temperature. Protect from freezing. Sodium Sulfacetamide 10% - Sulfur 5% Cleanser is available in 6 oz (170.3 g) bottles.

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.**

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ONCOR PHARMACEUTICALS
8815 Center Park Dr Suite 430
Columbia
Maryland 21045
Rev. 05/24



SODIUM SULFACETAMIDE 10 % AND SULFUR 5 % CLEANSER

sodium sulfacetamide and sulfur liquid

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:83720-537
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SULFACETAMIDE SODIUM (UNII: 4NRT660KJQ) (SULFACETAMIDE - UNII:4965G3J0F5)	SULFACETAMIDE SODIUM	100 mg in 1 g
SULFUR (UNII: 70FD1KFU70) (SULFUR - UNII:70FD1KFU70)	SULFUR	50 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	

EDETATE DISODIUM (UNII: 7FLD91C86K)
GLYCERIN (UNII: PDC6A3C0OX)
GLYCERYL STEARATE SE (UNII: FCZ5MH785I)
PEG-100 STEARATE (UNII: YD01N1999R)
PHENOXYETHANOL (UNII: HIE492ZZ3T)
SODIUM LAURETH SULFATE (UNII: BPV390UAP0)
SODIUM THIOSULFATE (UNII: HX1032V43M)
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)
TRIACETIN (UNII: XHX3C3X673)
WATER (UNII: 059QF0KO0R)
XANTHAN GUM (UNII: TTV12P4NEE)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:83720-537-06	170 g in 1 BOTTLE; Type 0: Not a Combination Product	05/10/2024	
2	NDC:83720-537-12	340 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)