

SODIUM SULFACETAMIDE 9% - SULFUR 4.5% WASH- sulfacetamide sodium, sulfur liquid
Akron Pharma Inc.

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.

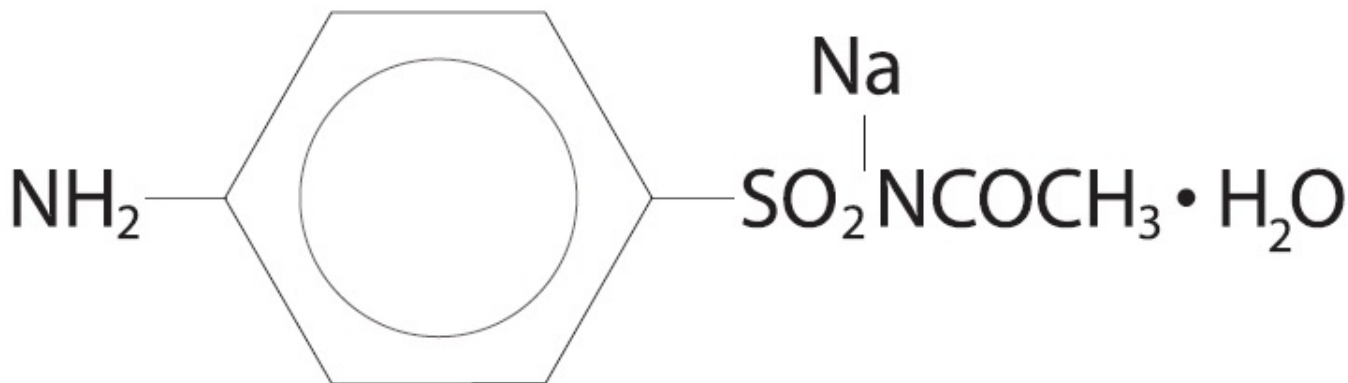
Sodium Sulfacetamide 9% - Sulfur 4.5% Wash
In a vehicle containing Aloe vera
Shake well before use

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% - Sulfur 4.5% Wash contains 90 mg of Sodium Sulfacetamide and 45 mg of Sulfur in a formulation containing: aloe vera gel, butylated hydroxytoluene, cetyl alcohol, edetate disodium glyceryl monostearate, magnesium aluminum silicate, PEG-40 stearate, PEG-60 almond glyceride, PEG -6 caprylic/capric glyceride, methyl paraben, propyl paraben, propylene glycol, purified water, sodium lauryl sulfate, sodium thiosulfate, stearyl alcohol, 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 9% - Sulfur 4.5% Wash is indicated in the topical control of acne vulgaris, acne rosacea and seborrheic dermatitis.

CONTRAINDICATIONS:

Sodium Sulfacetamide 9% - Sulfur 4.5% Wash 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% Wash 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 C. Animal reproduction studies have not been conducted with Sodium Sulfacetamide 9% - Sulfur 4.5% Wash. It is not known whether Sodium Sulfacetamide 9% - Sulfur 4% Wash can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Sodium Sulfacetamide 9% - Sulfur 4.5% Wash 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 9% - Sulfur 4.5% Wash. However, small amounts of orally administered sulfonamides have been reported to be

excreted 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 4.5% Wash 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.

DOSAGE AND ADMINISTRATION

Apply Sodium Sulfacetamide 9% - Sulfur 4.5% Wash 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 9% - Sulfur 4.5% Wash sooner or using less often.

HOW SUPPLIED

Sodium Sulfacetamide 9% - Sulfur 4.5% Wash is available in 16 oz (454 g) bottles, NDC 71399-0484-6.

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.

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

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.** Each person recommending a prescription substitution using this product shall make such recommendations based on each such person's professional opinion and knowledge, upon evaluating the active ingredients, excipients, inactive ingredients and chemical formulation information provided herein.

QUESTIONS?

Please Call 1(877) 225-6999

Manufactured for:

Akron Pharma, Inc.
Fairfield, NJ 07004
Manufactured in U.S.A

NDC 71399-0484-6

Sodium Sulfacetamide 9% - Sulfur 4.5%

Wash

In a vehicle containing
Aloe vera

Shake well before use

Akron Pharma

Rx Only

Net Wt. (16 oz)

Indications: For the topical control of acne vulgaris, acne rosacea and seborrheic dermatitis.
Directions: Apply Sodium Sulfacetamide 9% - Sulfur 4.5% Wash once or twice a day to affected areas or as directed by a 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 off Sodium Sulfacetamide 9% - Sulfur 4.5% Wash sooner or using less often. See package insert for full prescribing information.

Warnings: For external use only. Avoid contact with eyes.

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

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

Active ingredients: Sodium Sulfacetamide USP 9% and Sulfur USP 4.5%

Inactive ingredients: aloe vera gel, butylated hydroxytoluene, cetyl alcohol, edetate disodium, glyceryl monostearate, magnesium aluminum silicate, methylparaben, PEG-40 stearate, PEG-60 almond glyceride, PEG-6 caprylic/capric glyceride, propylene glycol, propylparaben, purified water, sodium lauryl sulfate, sodium thiosulfate, stearyl alcohol, xanthan gum.

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). Protect from freezing.

Sodium Sulfacetamide 9% - Sulfur 4.5% Wash is supplied in a 16 ounce bottle (NDC 71399-0484-6). For lot number and expiration date, see bottom of bottle.

All prescription substitutions and/or recommendations using this product shall be made subject to state and federal statutes as applicable. **NOTE: This is not an Orange Book product. No representation is made as to generic status or bioequivalency.** Please see package insert for more information.

Rev: 9/20



N 3 71399 0484 6 2

Manufactured for:

Akron Pharma

Fairfield, NJ-07004

www.akronpharma.com

Manufactured in USA

SODIUM SULFACETAMIDE 9% - SULFUR 4.5% WASH

sulfacetamide sodium, sulfur liquid

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:71399-0484
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 g
SULFUR (UNII: 70FD1KFU70) (SULFUR - UNII:70FD1KFU70)	SULFUR	45 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	

GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
MAGNESIUM ALUMINUM SILICATE (UNII: 6M3P64V0NC)	
PEG-40 STEARATE (UNII: ECU18C66Q7)	
PEG-60 ALMOND GLYCERIDES (UNII: 4Y0E651N0F)	
PEG-6 CAPRYLIC/CAPRIC GLYCERIDES (UNII: GO50W2HWO8)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
SODIUM THIOSULFATE (UNII: HX1032V43M)	
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71399-0484-6	454 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	09/13/2024	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		09/13/2024	

Labeler - Akron Pharma Inc. (067878881)