SODIUM SULFACETAMIDE 9 SULFUR 4 WASH- sulfacetamide sodium and sulfur liquid
AARNA USA INC

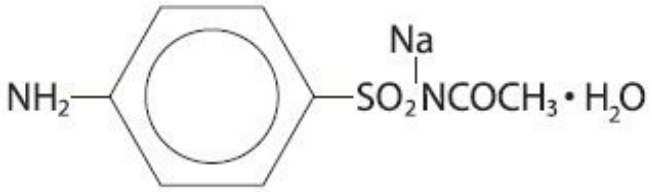
Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

Sodium Sulfacetamide 9% - Sulfur 4% Wash

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% Wash contains 90 mg of Sodium Sulfacetamide and 40 mg of Sulfur in a formulation containing: Benzyl Alcohol, Cetyl Alcohol, Glyceryl Stearate, Magnesium Aluminum Sulfate, PEG-100 Stearate, Phenoxy Ethanol, Propylene Glycol, Purified Water, Sodium Lauryl Sulfate, Sodium Magnesium Silicate,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% Wash is indicated in the topical control of acne vulgaris, acne rosacea and seborrheic dermatitis.

CONTRAINDICATIONS: Sodium Sulfacetamide 9% - Sulfur 4% Wash is contraindicated for use by patients having known hypersensitivity to sulfonamides, sulfur or ony other component of this preparation. Sodium Sulfacetamide 9% - Sulfur 4% 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. Avoid contact with eyes. **KEEP OUT OF REACH OF CHILDREN.** Keep bottle tightly closed.

PRECAUTIONS: General - If irritaition 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 withour 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 vulfaris, 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 beenperformed to evaluate carcinogenic potential.

PREGNANCY: Category C. Animal reproduction studies have not been conducted with Sodium Sulfacetamide 9% - Sulfur 4% 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% 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% Wash. 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 9% - Sulfur 4% 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: Wash affected areas once or twice daily or as directed by a 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 wash off sooner or usingless often.

HOW SUPPLIED: Sodium Sulfacetamide 9% - Sulfur 4% Wash is available in 16 oz (473 mL) bottles, NDC 82568-0152-6.

Store at controlled room temperature 15°C to 30°C (59°F to 86°F). 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.

MANUFACTURED FOR:

AARNA USA Inc.
Leland, NC-28451

Made in USA

PRINCIPAL DISPLAY PANEL - 473 mL Bottle

NDC 82568-0152-6

Sodium Sulfacetamide 9% -Sulfur 4% Wash

Rx only

Net weight 16 oz.

AARNA USA Inc.

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Aarna USA
Manufactured for:
AARNA USA Inc.
Leland, NC-28451
Made in USA

3 82568 01526 0

NDC 82568-0152-6

Sodium Sulfacetamide 9% – Sulfur 4%

Wash

For Topical Use Only
Not For Ophthalmic Use

Shake well before use

Rx Only

Aarna USA

Net Wt.(16oz) 473 mL

SODIUM SULFACETAMIDE 9 SULFUR 4 WASH

sulfacetamide sodium and sulfur liquid

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:82568-0152
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 473 mL
SULFUR (UNII: 70FD1KFU70) (SULFUR - UNII:70FD1KFU70)	SULFUR	40 mg in 473 mL

Inactive Ingredients

Ingredient Name	Strength
BENZYL ALCOHOL (UNII: LKG8494WBH)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
MAGALDRATE ANHYDROUS (UNII: 0MFM55849I)	
PEG-100 STEARATE (UNII: YD01N1999R)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
LITHIUM MAGNESIUM SODIUM SILICATE (UNII: D703131383)	
SODIUM THIOSULFATE (UNII: HX1032V43M)	
XANTHAN GUM (UNII: TTV12P4NEE)	
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)	

Product Characteristics

Color	yellow (WHITE TO PALE YELLOW)	**Score**	
Shape		**Size**	
Flavor		**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:82568-0152-6	473 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/26/2026	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		03/26/2026	

Labeler - AARNA USA INC (118515992)

Revised: 4/2026 AARNA USA INC