SODIUM SULFACETAMIDE 10% AND SULFUR 2% CLEANSER- 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 10% - Sulfur 2% Cleanser

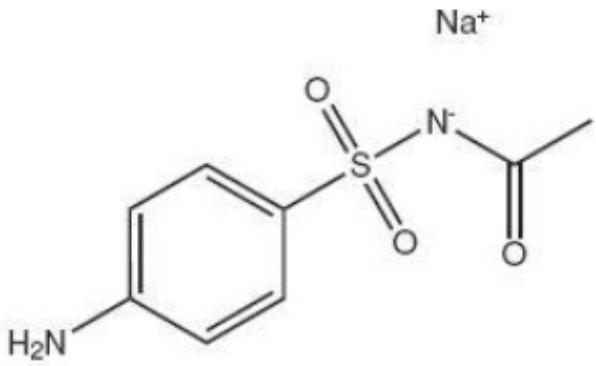
Rx Only

DESCRIPTION

Each gram of SODIUM SULFACETAMIDE 10% - SULFUR 2% CLEANSER (sodium sulfacetamide 10% w/w and sulfur 2% w/w) contains 100 mg of sodium sulfacetamide and 20 mg of colloidal sulfur in a mild aqueous based cleansing vehicle containing aloe vera gel, Ascorbic acid,cocamidopropyl betaine, cetyl alcohol, disodium edetate, glyceryl monostearate, lactic acid, magnesium aluminum silicate, methylparaben, PEG-40 stearate, PEG -6 caprylic/capric glyceride,PEG-60 almond glyceride, propylparaben, propylene glycol,purified water, sodium thiosulfate, sodium lauryl sulfate, stearyl alcohol, and xanthan gum.

Sodium sulfacetamide is a sulfonamide with antibacterial activity while sulfur acts as a keratolytic agent. Sodium sulfacetamide is C8H9N2NaO 3S·H2O with molecular weight of 254.24. Chemically, it is N-[(4-aminophenyl)sulfonyl]-acetamide, monosodium salt, monohydrate.

The structural formula is:



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 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 2% CLEANSER is indicated for use in the topical control of acne vulgaris, acne rosacea and seborrheic dermatitis.

CONTRAINDICATIONS:

SODIUM SULFACETAMIDE 10% - SULFUR 2% CLEANSER is contraindicated for use by patients having known hypersensitivity to sulfonamides, sulfur or any other component of this preparation. SODIUM SULFACETAMIDE 10% - SULFUR 2% CLEANSER 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.
Sulfonamides are known to cause Stevens-Johnson syndrome in hypersensitive individuals. Stevens-Johnson syndrome also has been reported following the use of sodium sulfacetamide topically. Cases of drug induced systemic lupus erythematosus from topical sulfacetamide also have been reported. In one of these cases, there was a fatal outcome. KEEP OUT OF REACH OF CHILDREN.

PRECAUTIONS

FOR EXTERNAL USE ONLY. NOT FOR OPHTHALMIC USE.
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.
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 10% - SULFUR 2% CLEANSER. It is also not known whether SODIUM SULFACETAMIDE 10% - SULFUR 2% CLEANSER can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. SODIUM

SULFACETAMIDE 10% - SULFUR 2% CLEANSER should be given to a pregnant woman only if clearly needed.
Nursing Mothers: It is not known whether sodium sulfacetamide is excreted in human milk following topical use of SODIUM SULFACETAMIDE 10% - SULFUR 2% CLEANSER. 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 10% - SULFUR 2% CLEANSER is administered to a nursing woman.
Pediatric Use: Safety and effectiveness in children under the age of 12 has 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 with SODIUM SULFACETAMIDE 10% - SULFUR 2% CLEANSER 1 to 2 times daily 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 to 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 cleanser less often.

HOW SUPPLIED

SODIUM SULFACETAMIDE 10% - SULFUR 2% CLEANSER is supplied in an 8 oz. (227 g) bottle, NDC 71399-0485-8.

STORAGE

Store at 25°C (77°F); excursions permitted to 15° to 30°C (59° to 86°F). [See USP “Controlled Room Temperature.”]

Note: 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 container or packet tightly closed.

Occasionally, a slight yellowish discoloration 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.
All prescription substitutions and/or recommendations using this product shall be made subject to state and federal statutes as applicable.

Please NOTE: This is not an Orange Book product and has not been subjected to FDA therapeutic 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 recommendation based on his/her professional knowledge and opinion, upon evaluating the active ingredients, inactive ingredients, excipients and chemical information provided herein.

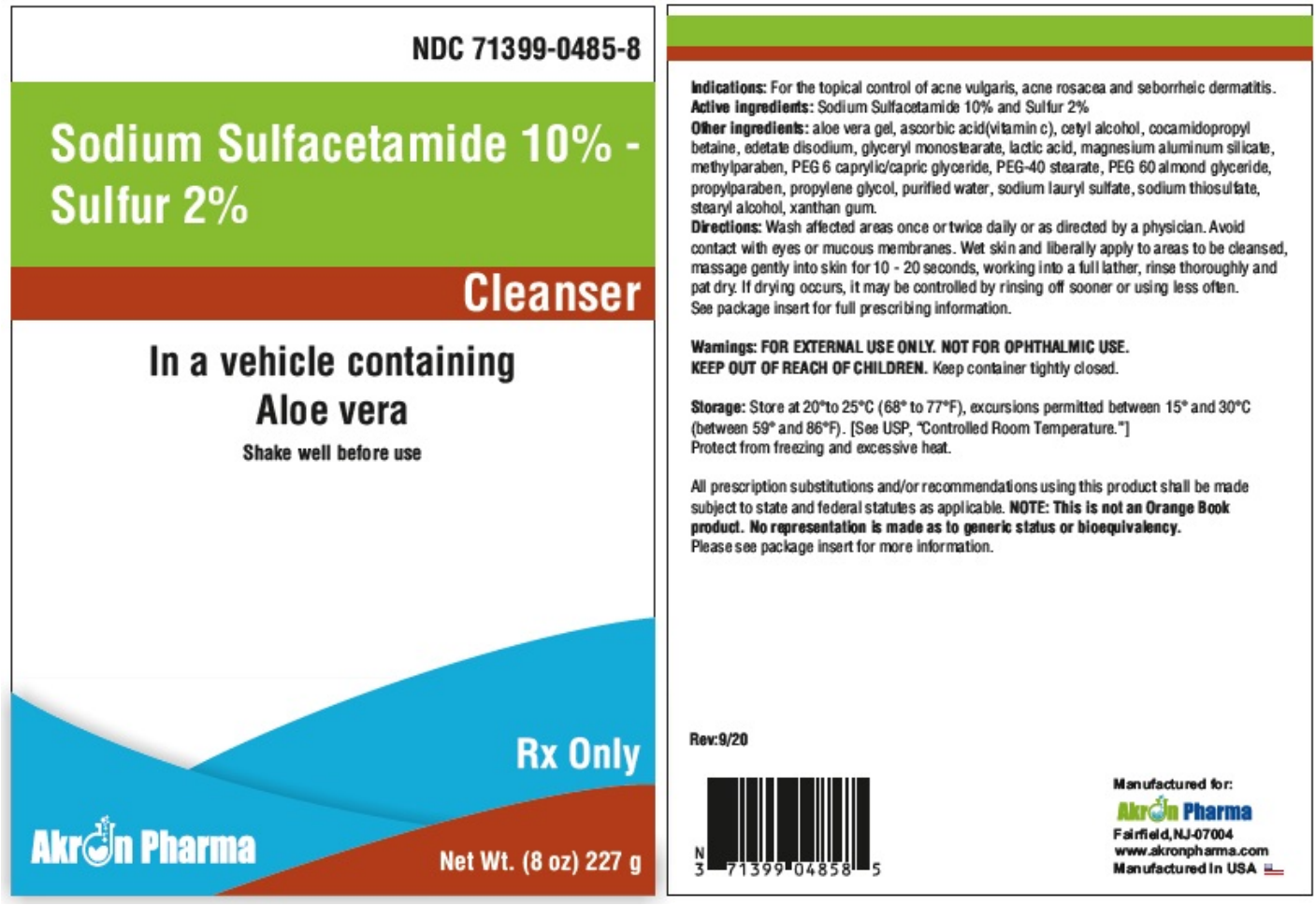
QUESTIONS?
Please Call 1(877) 225-6999

Manufactured for:

Akron Pharma, Inc.

Fairfield, NJ 07004

Manufactured in U.S.A



SODIUM SULFACETAMIDE 10% AND SULFUR 2% CLEANSER

sulfacetamide sodium, sulfur liquid

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:71399-0485
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	20 mg in 1 g

Inactive Ingredients

Ingredient Name	Strength
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
ASCORBIC ACID (UNII: PQ6CK8PD0R)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
LACTIC ACID (UNII: 33X04XA5AT)	
MAGNESIUM ALUMINUM SILICATE (UNII: 6M3P64V0NC)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PEG-40 STEARATE (UNII: ECU18C66Q7)	
PEG-6 CAPRYLIC/CAPRIC GLYCERIDES (UNII: GO50W2HWO8)	
PEG-60 ALMOND GLYCERIDES (UNII: 4Y0E651N0F)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SODIUM THIOSULFATE (UNII: HX1032V43M)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71399-0485-8	227 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)

Revised: 9/2024 Akron Pharma Inc.