SODIUM SULFACETAMIDE AND SULFUR- sulfacetamide sodium, sulfur liquid
Bryant Ranch Prepack

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

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,

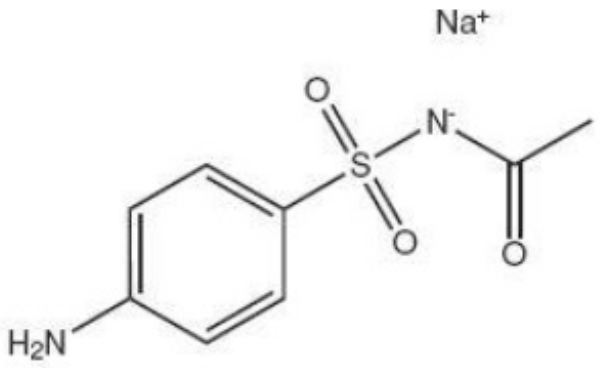
Citric Acid, Cocamidopropyl Betaine, Disodium EDTA, Glycerin, Glyceryl

Stearate SE, PEG-100 Stearate, Phenoxyethanol, Purified Water, Sodium

laureth sulfate, Sodium Thiosulfate, Stearyl alcohol, Triacetin, Xanthan Gum.

Sodium sulfacetamide is a sulfonamide with antibacterial activity while sulfur acts as a keratolytic agent. Sodium sulfacetamide is $C_8H_9N_2NaO_3S \cdot H_2O$ 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 5% CLEANSER is indicated for use in the topical control of acne vulgaris, acne rosacea and seborrheic dermatitis.

CONTRAINDICATIONS:

Sodium Sulfacetamide 10% & Sulfur 5% Cleanser is contraindicated in persons with know 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.

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.

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.

DOSAGE AND ADMINISTRATION

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.
FOR EXTERNAL USE ONLY. NOT FOR INTRAVAGINAL OR OPHTHALMIC USE. (KEEP AWAY FROM EYES).
KEEP OUT OF REACH OF CHILDREN.

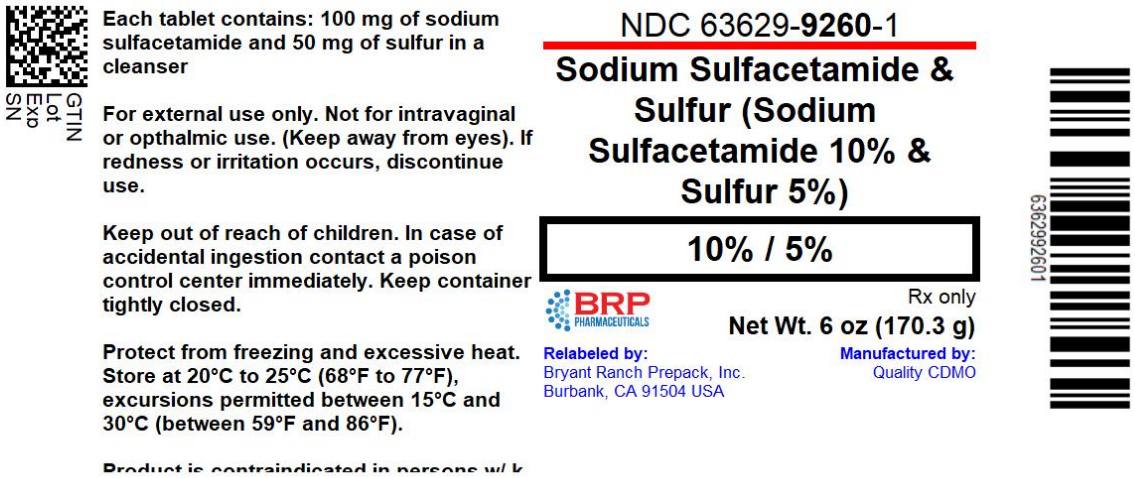
HOW SUPPLIED

Sodium Sulfacetamide 10% & Sulfur 5% Cleanser

- NDC 63629-9260-1: 170.3 g in a BOTTLE

Repackaged/Relabeled by:
Bryant Ranch Prepack, Inc.
Burbank, CA 91504

Sodium Sulfacetamide 10% & Sulfur 5% Cleanser



SODIUM SULFACETAMIDE AND SULFUR

sulfacetamide sodium, sulfur liquid

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:63629-9260(NDC:58657-472)
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
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
1-ETHYL CITRATE (UNII: Y7R23627P5)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
GLYCERYL STEARATE SE (UNII: FCZ5MH785I)	
PEG-100 STEARATE (UNII: YD01N1999R)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)	
TRIACETIN (UNII: XHX3C3X673)	
WATER (UNII: 059QF0KO0R)	
SODIUM THIOSULFATE (UNII: HX1032V43M)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)	
XANTHAN GUM (UNII: TTV12P4NEE)	
GLYCERIN (UNII: PDC6A3C0OX)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63629-9260-1	170.3 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	11/15/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		11/15/2021	

Labeler - Bryant Ranch Prepack (171714327)

Registrant - Bryant Ranch Prepack (171714327)

Establishment

Name	Address	ID/FEI	Business Operations
Bryant Ranch Prepack		171714327	REPACK(63629-9260) , RELABEL(63629-9260)