SODIUM SULFACETAMIDE 10% AND SULFUR 5% CLEANSER- sulfacetamide sodium and sulfur rinse
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.

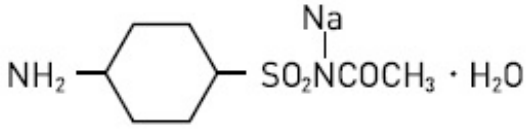
SODIUM
SULFACETAMIDE 10%
& SULFUR 5%
Cleanser

Rx only

DESCRIPTION

Each gram of Sodium Sulfacetamide and Sulfur (sodium sulfacetamide 10% w/w and sulfur 5% w/w) contains 100 mg of sodium sulfacetamide and 50 mg of colloidal sulfur in a vehicle consisting of: aloe vera leaf extract, butylated hydroxytoluene, cetyl alcohol, disodium oleamido monoethanolamine sulfosuccinate, edetate disodium, fragrance, glycerin, glyceryl monostearate, magnesium aluminum silicate, methylparaben, PEG-100 stearate, propylparaben, purified water, sodium cocoyl isethionate, sodium methyl cocoyl taurate, sodium thiosulfate, stearyl alcohol, 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, sodium sulfacetamide 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 AND USAGE

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 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 this product should be discontinued and appropriate therapy instituted. Patients should be very 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 9% &

Sulfur 4.5% Wash. 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 human milk following topical use of Sodium Sulfacetamide 10% & Sulfur 5% Cleanser. 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 10% & Sulfur 5% 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. To report SUSPECTED ADVERSE REACTIONS, contact the FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.**

DOSAGE AND ADMINISTRATION

Wash affected areas with Sodium Sulfacetamide 10% and Sulfur 5% Cleanser one to two times 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 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 5% Cleanser is supplied in an 8oz. (227g) bottle, NDC 63629-2033-1.

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). 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 bottle 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.

Manufactured for:
Noble Pharmaceuticals, LLC

Cooper City, FL 33024 USA

Rev 6/17

Sulfacetamide Sodium Rinse, 8 oz

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

Manufactured by:
Noble Pharmaceuticals, LLC
Cooper City, FL 33024

Each gram contains: 100 mg of sodium sulfacetamide and 50 mg of colloidal sulfur in a vehicle consisting of aloe vera, butylated hydroxytoluene, cetyl alcohol, disodium EDTA, oleamido MEA sulfosuccinate, glyceryl stearate, green tea extract, methylparaben, propylparaben, purified water, sodium methyl cocoyl, stearly alcohol, xanathan gum

Keep this and all medication out of the reach of children.

Store at 20° to 25°C (68° to 77°F) [See USP Controlled Room Temperature].

For topical use only

Dispense in a tight, light-resistant container as defined in USP

NDC 63629-2033-1

Sodium Sulfacetamide & Sulfur Cleanser

10% and 5%

BRP PHARMACEUTICALS

Rx only

227 grams

SODIUM SULFACETAMIDE 10% AND SULFUR 5% CLEANSER

sulfacetamide sodium and sulfur rinse

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:63629-2033(NDC:70156-107)
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
SULFACETAMIDE SODIUM (UNII: 4NRT660KJQ) (SULFACETAMIDE - UNII:4965G3J0F5)	SULFACETAMIDE SODIUM	10 mg in 1 g
SULFUR (UNII: 70FD1KFU70) (SULFUR - UNII:70FD1KFU70)	SULFUR	5 mg in 1 g

Inactive Ingredients	
Ingredient Name	**Strength**
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
CAMELLIA OLEIFERA LEAF (UNII: 5077EL0C60)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
DISODIUM OLEAMIDO MONOETHANOLAMINE SULFOSUCCINATE (UNII: 5M1101WGSY)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
GLYCERIN (UNII: PDC6A3C0OX)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
MAGNESIUM ALUMINUM SILICATE (UNII: 6M3P64V0NC)	
METHYLPARABEN (UNII: A2I8C7HI9T)	

PEG-100 STEARATE (UNII: YD01N1999R)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0KO0R)	
SODIUM COCOYL ISETHIONATE (UNII: 518XTE8493)	
SODIUM METHYL COCOYL TAURATE (UNII: JVL98CG53G)	
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:63629-2033-1	227 g in 1 BOTTLE; Type 0: Not a Combination Product	12/21/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
UNAPPROVED DRUG OTHER		12/11/2017	

Labeler - Bryant Ranch Prepack (171714327)

Registrant - Bryant Ranch Prepack (171714327)

Establishment

Name	Address	ID/FEI	Business Operations
Bryant Ranch Prepack		171714327	REPACK(63629-2033) , RELABEL(63629-2033)

Revised: 4/2022 Bryant Ranch Prepack