

**SODIUM SULFACETAMIDE 10% AND SULFUR 2% CLEANSER- 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.*

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**Sodium Sulfacetamide 10% - Sulfur 2% Cleanser**

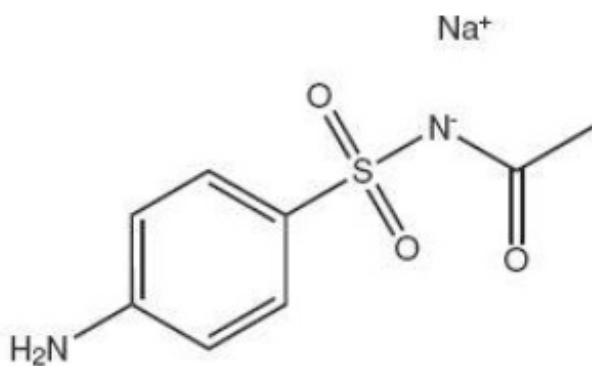
**Rx Only**

**DESCRIPTION**

Each gram of sodium sulfacetamide 10% and sulfur 2% cleanser contains 100 mg of sodium sulfacetamide and 20 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  $C_8H_9N_2NaO_3 \cdot H_2O$  with molecular weight of 254.24. Chemically, it is N-[(4-aminophenyl)sulfonyl]-acetamide, monosodium salt, monohydrate.

The structural formula is:



**Clinical Pharmacology**

Sodium sulfacetamide exerts a bacteriostatic effect against sulfonamide sensitive Gram-positive and Gram-negative microorganisms commonly isolated from secondary cutaneous pyogenic infections. It acts by restricting the synthesis of folic acid required by bacteria for growth, by its competition with para-aminobenzoic acid. There is no

clinical data available on the degree and rate of systemic absorption of this product when applied to the skin or scalp. However, significant absorption of sodium sulfacetamide through the skin has been reported.

The following in vitro data is available but the clinical significance is unknown. Organisms that show susceptibility to sodium sulfacetamide are: Streptococci, Staphylococci, E. coli, Klebsiella pneumoniae, Pseudomonas pyocyanea, Salmonella species, Proteus vulgaris, Nocardia and Actinomyces.

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 it is 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. NOT FOR INTRAVAGINAL OR OPHTHALMIC USE. (KEEP AWAY FROM EYES).

KEEP OUT OF REACH OF CHILDREN.

In case of accidental ingestion contact a poison control center immediately. Keep container tightly closed.

## **Precaution**

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 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 the human milk following topical use of Sodium Sulfacetamide 10% & Sulfur 2% Cleanser. However, small amounts of orally administered sulfonamides have 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 have not been established.

## **Adverse Reaction**

Although rare, sodium sulfacetamide may cause local irritation.

Call your doctor for medical advice about side effects.

To report a serious adverse event or obtain product information, call 1-877-250-3427.

## **DOSAGE AND ADMINISTRATION**

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.**

## **HOW SUPPLIED**

### **Sodium Sulfacetamide & Sulfur Cleanser**

NDC: 72162-2248-2: 8 oz (227 g) Cleansers in a BOTTLE, PLASTIC

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.

**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.

This bottle is not filled to the top but does contain 8 fl oz of product as identified on the front panel of the bottle.

**Repackaged/Relabeled by:**

Bryant Ranch Prepack, Inc.  
Burbank, CA 91504

**Sulfacetamide Sodium /Sulfur 10/2% #227**



Each gram contains: 100 mg of sodium sulfacetamide and 20 mg of sulfur in a cleanser.  
**CONTRAINDICATIONS:** This product is not to be used by patients with kidney disease. This product is contraindicated in persons with known or suspected hypersensitivity to any of the ingredients of the product (See link below).

**PHARMACIST:** Dispense the Instructions for Use: <https://dailymed.nlm.nih.gov/dailymed/>

This product is indicated for use in the topical control of acne vulgaris, acne rosacea and seborrheic dermatitis.

Store at 20°-25°C (68°-77°F); excursions permitted to 15°-30°C (59°-86°F) [See USP]. Protect from freezing and excessive heat.

For external use only. Not for ophthalmic use. Keep out of reach of children.

**NDC 72162-2248-2**

**Sodium Sulfacetamide & Sulfur Cleanser**

**10% / 2%**



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

Rx only  
**Net Wt. 8 oz (227 g)**

Manufactured by:  
Method Pharmaceuticals, LLC



**SODIUM SULFACETAMIDE 10% AND SULFUR 2% CLEANSER**

sulfacetamide sodium, sulfur liquid

**Product Information**

|                                |                         |                           |                               |
|--------------------------------|-------------------------|---------------------------|-------------------------------|
| <b>Product Type</b>            | HUMAN PRESCRIPTION DRUG | <b>Item Code (Source)</b> | NDC:72162-2248(NDC:58657-471) |
| <b>Route of Administration</b> | TOPICAL                 |                           |                               |

**Active Ingredient/Active Moiety**

| Ingredient Name  | Basis of Strength    | Strength      |
|--|----------------------|---------------|
| <b>SULFACETAMIDE SODIUM</b> (UNII: 4NRT660KJQ) (SULFACETAMIDE - UNII:4965G3J0F5) | SULFACETAMIDE SODIUM | 100 mg in 1 g |

|   |        |              |
|---|--------|--------------|
| <b>SULFUR</b> (UNII: 70FD1KFU70) (SULFUR - UNII:70FD1KFU70) | SULFUR | 20 mg in 1 g |
|---|--------|--------------|

### Inactive Ingredients

| Ingredient Name                                    | Strength |
|--|----------|
| <b>PHENOXYETHANOL</b> (UNII: HIE492ZZ3T)           |          |
| <b>TRIACETIN</b> (UNII: XHX3C3X673)                |          |
| <b>ALOE VERA LEAF</b> (UNII: ZY81Z83H0X)           |          |
| <b>BUTYLATED HYDROXYTOLUENE</b> (UNII: 1P9D0Z171K) |          |
| <b>COCAMIDOPROPYL BETAINE</b> (UNII: 5OCF3O11KX)   |          |
| <b>CETYL ALCOHOL</b> (UNII: 936JST6JCN)            |          |
| <b>EDETATE DISODIUM</b> (UNII: 7FLD91C86K)         |          |
| <b>GLYCERYL STEARATE SE</b> (UNII: FCZ5MH785I)     |          |
| <b>PEG-100 STEARATE</b> (UNII: YD01N1999R)         |          |
| <b>WATER</b> (UNII: 059QF0K00R)                    |          |
| <b>SODIUM THIOSULFATE</b> (UNII: HX1032V43M)       |          |
| <b>SODIUM LAURYL SULFATE</b> (UNII: 368GB5141J)    |          |
| <b>STEARYL ALCOHOL</b> (UNII: 2KR89I4H1Y)          |          |
| <b>XANTHAN GUM</b> (UNII: TTV12P4NEE)              |          |

### Packaging

| # | Item Code        | Package Description   | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:72162-2248-2 | 227 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 01/30/2024           |                    |

### Marketing Information

| Marketing Category       | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------------|--|----------------------|--------------------|
| unapproved drug<br>other |  | 02/01/2022           |                    |

**Labeler** - Bryant Ranch Prepack (171714327)

**Registrant** - Bryant Ranch Prepack (171714327)

### Establishment

| Name                 | Address | ID/FEI    | Business Operations                      |
|----------------------|---------|-----------|--|
| Bryant Ranch Prepack |         | 171714327 | REPACK(72162-2248) , RELABEL(72162-2248) |