

SODIUM SULFACETAMIDE, SULFUR- sodium sulfacetamide, sulfur solution

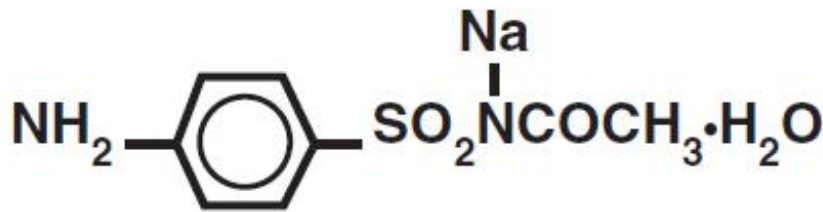
Exact-Rx, Inc.

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% and Sulfur 5% Cleanser

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 contains sodium sulfacetamide 10% (100 mg) and sulfur 5% (50 mg), purified water, disodium laureth sulfosuccinate and disodium lauryl sulfoacetate, PPG-hydroxyethyl coco isostearamide, sodium cocoyl isethionate, mineral oil, butylated hydroxytoluene, emulsifying wax, methyl paraben, propyl paraben, sodium thiosulfate, disodium EDTA and hydrochloric acid.

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 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 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. 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.

PRECAUTIONS: 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 5% Cleanser. 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 the human milk following topical use of Sodium Sulfacetamide 10% & Sulfur 5% 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 5% Cleanser is administered to a nursing woman.

Pediatric Use: Safety and effectiveness in children under the age of 12 years have 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 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.

HOW SUPPLIED: Sodium Sulfacetamide 10% & Sulfur 5% Cleanser is available in a 6 oz (170 g) tube, NDC 42808-0110-06 and 12 oz carton that contains (2) 6 oz tubes, NDC 42808-0110-12.

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

Protect from freezing.

Manufactured in the U.S.A. for Exact-Rx, Inc., Melville, NY 11747

00-0100-99-205-00

Iss:6/11

PACKAGE LABEL - 12 oz (340 g)

For External Use Only

NDC 42808-0110-12 Rx Only

**Sodium Sulfacetamide
& Sulfur**

(Sodium Sulfacetamide 10% & Sulfur 5%)

10%/5%

CLEANSER

Exact-Rx.

INCORPORATED

Contains 2 x 6 oz. tubes (170 g each)

Net Wt. 12 oz (340 g)



SODIUM SULFACETAMIDE, SULFUR

sodium sulfacetamide, sulfur solution

Product Information

| | | | |
|--------------------------------|-------------------------|---------------------------|---------------|
| Product Type | HUMAN PRESCRIPTION DRUG | Item Code (Source) | NDC:42808-110 |
| 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 |
|---|-----------------|
| WATER (UNII: 059QF0KO0R) | |
| DISODIUM LAURETH SULFO SUCCINATE (UNII: D6DH1DTN7E) | |
| SODIUM LAURYL SULFOACETATE (UNII: D0Y70F2B9J) | |
| SODIUM COCOYL ISETHIONATE (UNII: 518XTE8493) | |
| MINERAL OIL (UNII: T5L8T28FGP) | |
| BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K) | |
| METHYLPARABEN (UNII: A2I8C7HI9T) | |
| PROPYLPARABEN (UNII: Z8IX2SC1OH) | |
| SODIUM THIO SULFATE (UNII: HX1032V43M) | |
| EDETATE DISODIUM (UNII: 7FLD91C86K) | |
| HYDROCHLORIC ACID (UNII: QTT17582CB) | |
| YELLOW WAX (UNII: 2ZA36H0S2V) | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|----------------------------|-----------------------------|---------------------------|
| 1 | NDC:42808-110-06 | 170 g in 1 TUBE | | |
| 2 | NDC:42808-110-12 | 2 in 1 CARTON | | |
| 2 | | 170 g in 1 TUBE | | |

Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---------------------------|---|-----------------------------|---------------------------|
| unapproved drug other | | 08/01/2011 | |

Labeler - Exact-Rx, Inc. (137953498)