# EXACT-RX SODIUM SULFACETAMIDE AND SULFER 10%/5% CLEANSER- sodium sulfacetamide, sulfur lotion 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.

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## Exact-Rx SODIUM SULFACETAMIDE and SULFUR 10%/5% Cleanser

**INDICATIONS:** Sodium Sulfacetemide 10% and Sulfer 5% Cleanser

is indicated for he topical control of acne vulgaris, acne rosacea and seborrheic dermatitis.

DIRECTIONS FOR USE: Wash affected area once or twice daily, or

as directed by your physician. Avoid contat 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 package insert for complete product information.

## FOR EXTERNAL USE ONLY. NOT FOR INTRAVAGINAL OR

## **OPHTHALMIC USE. (KEEP AWAY FROM EYES)**.

## KEEP THIS AND ALL MEDICATION OUT OF REACH OF CHILDREN.

In case of accidental ingestion contact a poison

control center immediately. Keep container tightly closed.

**CONTRAINDICATIONS**: Sodium Sulfacetamide 10% & Sulfer 5% Cleanser is

contraindicated in persons with know or suspected hypersensitivity to sulfonamides,

sulfer or any other component of this preparation. Sodium Sulfacetamide 10% & Sulfer %5%

Cleanser is not to be used by patients with kidney disease.

**CAUTION**: If redness or irritaiton occurs, discontinue use.

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.

Store at 20 to 25C (68 to 77F). See USP Controlled Room Temperature. Protect from freezing.

## Manufactured in the U.S.A. for

Exact-Rx, Inc., Melville, NY 11747

#### Sodium Sulfacetamide 10% & 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-eminophenyl)sulfonyl]-acetamide, monosodium sait, monohydrate. The structural formula is:

$$\mathsf{NH}_2 \longrightarrow \mathsf{SO}_2^\mathsf{NA} \mathsf{NCOCH}_3 \bullet \mathsf{H}_2\mathsf{O}$$

Each gram of sodium sulfacetamide 10% and auffur 5% cleaneer contains 100 mg of sodium sulfacetamide and 50 mg of sulfur in a cleaneer containing ammonium Aloe Vara leaf Extract, Butylsted Hydroxytoluana, Cetyl Alcohol, Citric Acid, Cocamidopropyl Betaine, Disodium EDTA, Glycerin, Glyceryl Stearete SE, PEG-100 Stearete, Phenoxyethanol, Purified Water, Sodium Laureth Sulfate, Sodium Thiosulfate, Stearyl alcohol, Triacetin, Xanthan Gum

CLINICAL PHARMACOLOGY: The most widely accepted mechanism of action of sulfonamides is the Woods-Fields theory which is based on the fact that sulfonamides act as competitive antagonists to para-aminoberzoic acid (PABA), an essential component for bacterial growth. While absorption through intact akin has not been determined, sodium sulfacetamide is readily absorbed from the gastrointastinal 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 rosacee 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 agranulogytosis, acute hemolytic anemia, purpura hemonhagica, drug fever, jaundice, and contact dermstitis indicate hypersensitivity to sulfonamides. Particular caution should be employed if areas of denuded or sbraded skin are involved.

FOR EXTERNAL USE ONLY. Keep away from eyes.

#### KEEP OUT OF REACH OF CHILDREN.

In case of accidental ingestion contact a polson control center immediately. Keep container tightity 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 suffacetamide and sulfur can cause reddening and scaling of the epidemis. These side effects are not unusual in the treatment of some vulgaris, but patients should be cardioned about the possibility.

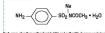
Information for Patients: Avoid contact with eyes, eyelide, lips and mucous membranes. If accidental contact occurs, rinse with water. If excessive initiation develops, discontinue use and consult your physician.

Carcinogeneeis, Mutageneeis and Impairment of Fertility: Long-term studies in animels 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.



## Sodium Sulfacetamide 10% & Sulfur 5% Cleanser



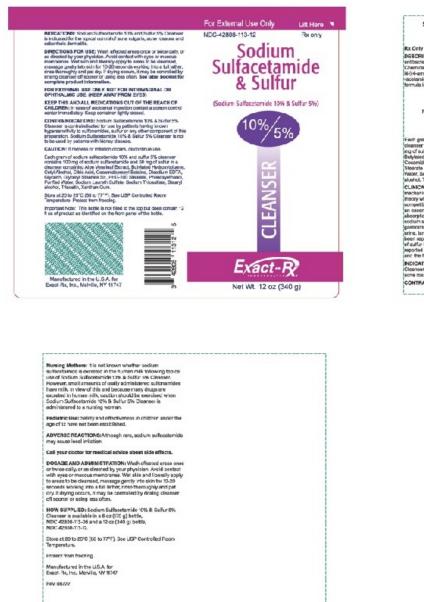
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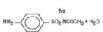
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Nursing Mothers: It is not known whether sodium suffactamide is excreted in the human milk following topical used Sodim Suffactamide (briek Suffur) 6% Classes have milk. In view of this and because many drugs are scorted in human milk, acution soluda be exercised when Sodium Suffacetamide (briek Suffur 9% Classesr is administered to a nursing workman. Sodum Sullineitemide 1914 & Sofur 594 Cleanser is a sofurnitisated to a nutraling workin. Paddintic Use: Softwy and affectiveness in children under the application of the software and the software software and the software software and the software software and software DOSAGE AND ADMINISTRATOR: Wash affected areas ones or twice daily or as chiered by your physician. Avaid contact with eyes or mucous membranes. Wet shin and contact with eyes or mucous membranes. Wet shin and contact with eyes or mucous membranes. Wet shin and contact with eyes or mucous membranes. Wet shin and contact with eyes or mucous membranes. Wet shin and thoroughly and pat day. If days are contact thoroughly and pat day. Use the shin of the shin of contact of software and shin shin of thoroughly and pat day. If days are contact thoroughly and pat day. If days are also thoroughly and pat days are also the shift days are also Rev. 08/22



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## **EXACT-RX SODIUM SULFACETAMIDE AND SULFER 10%/5%** CLEANSER

sodium sulfacetamide, sulfur lotion

Product Information								
Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)		NDC:42808-113				
Route of Administration	TOPICAL							
A ativa la una dia ut/A ativa	Malaka							
Active Ingredient/Active Moiety								
Ingredient Name		В	asis of Strengt	th Strength				
<b>SULFACETAMIDE SODIUM</b> (UNII: 4NRT660KJQ) (SULFACETAMIDE - UNII:4965G3J0F5)			ULFACETAMIDE ODIUM	100 mg in 1 g				

Ingredient Name	Strength
	j
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
COCAMIDOPROPYL BETAINE (UNII: 50CF3011KX)	
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	
GLYCERIN (UNII: PDC6A3C0OX)	
GLYCERYL STEARATE SE (UNII: FCZ5MH785I)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
SODIUM LAURETH SULFATE (UNII: BPV390UAP0)	
PEG-100 STEARATE (UNII: YD01N1999R)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
XANTHAN GUM (UNII: TTV12P4NEE)	
WATER (UNII: 059QF0KO0R)	
SODIUM THIOSULFATE (UNII: HX1032V43M)	
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)	
TRIACETIN (UNII: XHX3C3X673)	

## Packaging

#	ltem Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:42808-113- 06	170 g in 1 BOTTLE; Type 0: Not a Combination Product	08/01/2011	
2	NDC:42808-113- 12	340 g in 1 BOTTLE; Type 0: Not a Combination Product	08/01/2011	
M	larketing	Information		
	Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
un	approved drug		08/01/2011	

Labeler - Exact-Rx, Inc. (137953498)

Revised: 10/2023

Exact-Rx, Inc.