SODIUM SULFACETAMIDE, SULFUR- sulfacetamide sodium and sulfur liquid
Westminster Pharmaceuticals, LLC

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

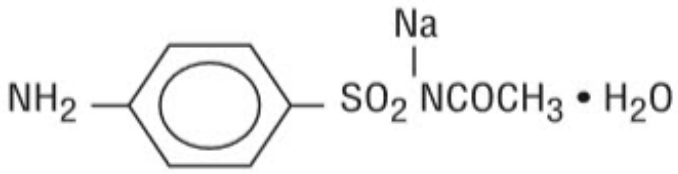
Rx Only

FOR EXTERNAL USE ONLY. NOT FOR OPHTHALMIC USE.

DESCRIPTION

Each gram of Sodium Sulfacetamide 10% and Sulfur 5% Cleanser contains 100 mg of sodium sulfacetamide and 50 mg of sulfur in a formulation containing ammonium lauryl sulfate, butylated hydroxytoluene, cetyl alcohol, cocamidopropyl betaine, disodium EDTA, glycerin, glyceryl stearate SE, guar gum, methylparaben, PEG-100 stearate, propylene glycol, propylparaben, purified water, sodium thiosulfate, stearyl alcohol, triacetin.

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:



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 known, but it has been reported that it inhibits the growth of Propionibacterium acnes and the formation of free fatty acids.

INDICATIONS

Sodium Sulfacetamide 10% and Sulfur 5% Cleanser is indicated in the topical control of acne vulgaris, acne rosacea and seborrheic dermatitis.

CONTRAINDICATIONS

Sodium Sulfacetamide 10% and 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% and 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.

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% and Sulfur 5% Cleanser. It is also not known whether Sodium Sulfacetamide 10% and Sulfur 5% Cleanser can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Sodium Sulfacetamide 10% and 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% and 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% and Sulfur 5% Cleanser is administered to a nursing woman.

Pediatric Use

Safety and effectiveness in children under the age of 12 have not been established.

ADVERSE REACTIONS

Although rare, sodium sulfacetamide may cause local irritation.

Call your doctor for medical advice about side effects. To report a serious adverse event, please contact Westminster Pharmaceuticals at 1-844-221-7294

DOSAGE AND ADMINISTRATION

Apply Sodium Sulfacetamide 10% and Sulfur 5% Cleanser once or twice daily to affected areas, or as directed by your physician. 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 off Sodium Sulfacetamide 10% and Sulfur 5% Cleanser sooner or using less often.

HOW SUPPLIED

Sodium Sulfacetamide 10% and Sulfur 5% Cleanser is available in 6 oz. (170.3 g) bottles, NDC 69367-247-06 and 12 oz. (340.2 g) bottles, NDC 69367-247-12.

Store at 15°C to 30°C (59°F to 86°F). Protect from freezing.

KEEP THIS AND ALL MEDICATIONS OUT OF THE REACH OF CHILDREN

All prescription substitutions and/or recommendations using this product shall be made subject to state and federal statutes as applicable. **NOTE: This is not an Orange Book product. No representation is made as to generic status or bioequivalency.** Each person recommending a prescription substitution using this product shall make such recommendations based on each such person's professional opinion and knowledge, upon evaluating the active ingredients, excipients, inactive ingredients and chemical formulation information provided herein.

Manufactured for:
Westminster Pharmaceuticals, LLC
Nashville, TN 37217

Rev. 05/20

PRINCIPAL DISPLAY PANEL - 170.3 g Bottle Label

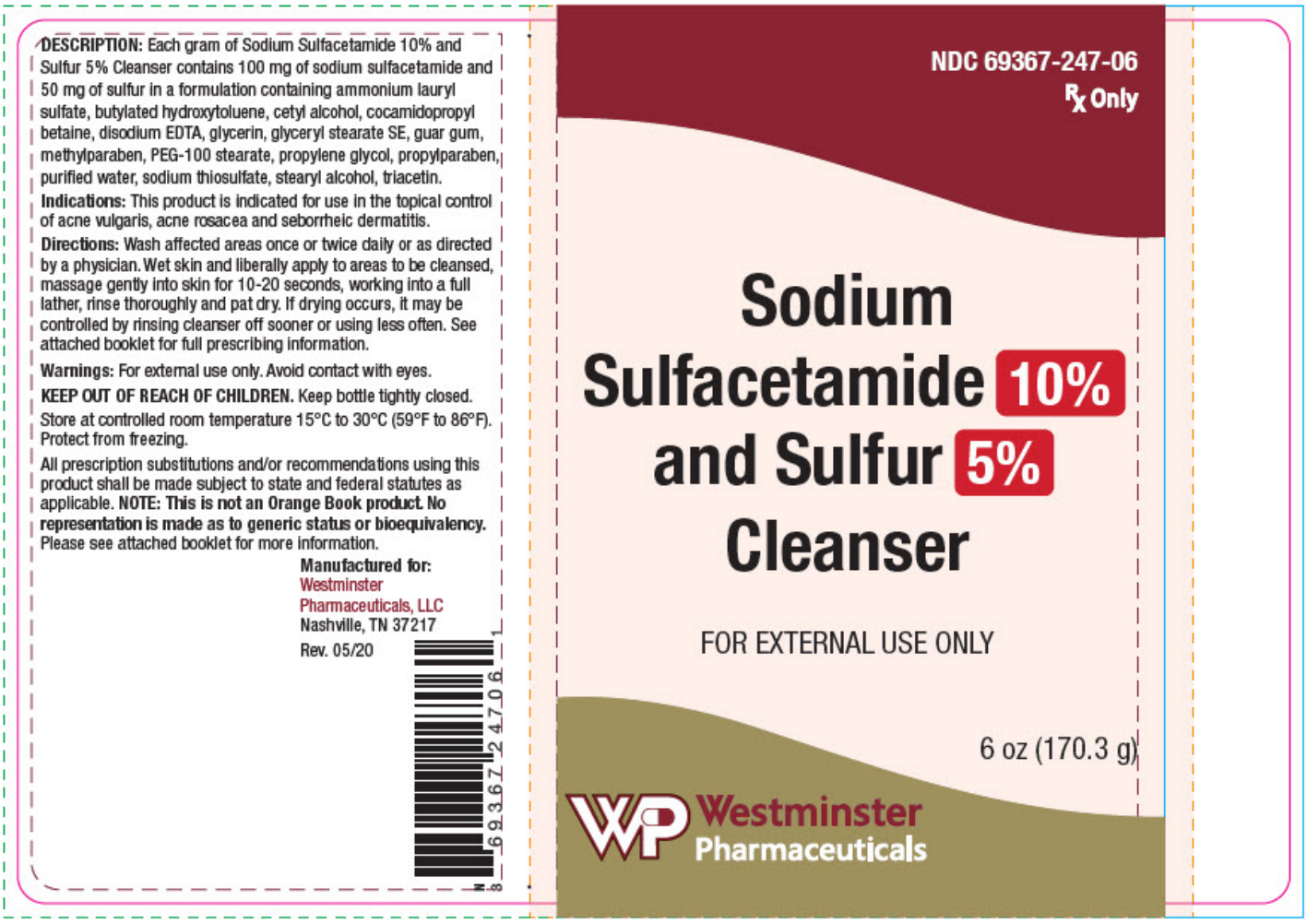
NDC 69367-247-06
Rx Only

Sodium
Sulfacetamide 10%
and Sulfur 5%
Cleanser

FOR EXTERNAL USE ONLY

6 oz (170.3 g)

Westminster
Pharmaceuticals



SODIUM SULFACETAMIDE, SULFUR

sulfacetamide sodium and sulfur liquid

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:69367-247
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
AMMONIUM LAURYL SULFATE (UNII: Q7AO2R1M0B)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)	
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	
GLYCERIN (UNII: PDC6A3C0OX)	
GLYCERYL STEARATE SE (UNII: FCZ5MH785I)	
GUAR GUM (UNII: E89I1637KE)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PEG-100 STEARATE (UNII: YD01N1999R)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0KO0R)	
SODIUM THIOSULFATE (UNII: HX1032V43M)	
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)	
TRIACETIN (UNII: XHX3C3X673)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69367-247-06	170.3 g in 1 BOTTLE; Type 0: Not a Combination Product	05/05/2020	
2	NDC:69367-247-12	340.2 g in 1 BOTTLE; Type 0: Not a Combination Product	05/05/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
UNAPPROVED DRUG OTHER		05/05/2020	

Labeler - Westminster Pharmaceuticals, LLC (079516651)

Revised: 5/2020 Westminster Pharmaceuticals, LLC