

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

Acella Pharmaceuticals, LLC

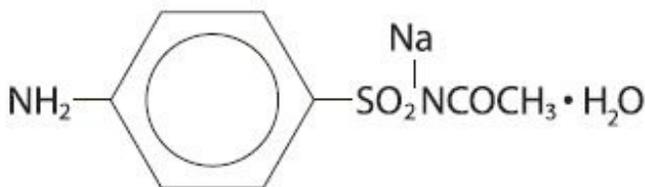
Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

Sodium Sulfacetamide 10% - Sulfur 5% Cleanser

Rx Only

DESCRIPTION: Each mL of Sodium Sulfacetamide 10% - Sulfur 5% Cleanser contains 100 mg of Sodium Sulfacetamide and 50 mg of Sulfur in a formulation containing butylated hydroxytoluene, cetyl alcohol, disodium EDTA, glyceryl stearate, PEG 100 stearate, magnesium aluminum silicate, methylparaben, propylparaben, purified water, sodium cocoyl isethionate, sodium methyl cocoyl taurate, sodium thiosulfate, stearyl alcohol, white petrolatum and xanthan gum.

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 not 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% - 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.

FOR EXTERNAL USE ONLY. Keep away from eyes. Keep out of reach of children. 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 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 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 have not been established.

ADVERSE REACTIONS: Although rare, sodium sulfacetamide may cause local irritation.

DOSAGE AND ADMINISTRATION: Apply Sodium Sulfacetamide 10% - 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% - Sulfur 5% Cleanser sooner or using less often.

HOW SUPPLIED: Sodium Sulfacetamide 10% - Sulfur 5% Topical Suspension is available in 6 oz (170.3 g) bottles, NDC 42192-136-06, 8 oz (227 g) bottles, 42192-136-08 and 12 oz (340.2 g) bottles, NDC 42192-136-12.

Store at 15° - 25°C (59° - 77°F). Protect from freezing.

KEEP THIS AND ALL MEDICATIONS OUT OF THE REACH OF CHILDREN.

All prescription substitutions using this product shall be made subject to state and federal statutes as applicable.

NOTE: this is not an Orange Book product and has not been subjected to FDA therapeutic equivalency or other equivalency testing. 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:

Acella Pharmaceuticals, LLC
Alpharetta, GA 30009 • 1-800-541-4802

Rev. 0616-03

PRINCIPAL DISPLAY PANEL - 170.3 g Bottle Label

NDC 42192-136-06

**Sodium Sulfacetamide 10% -
Sulfur 5% *Cleanser***

Rx Only

SHAKE WELL BEFORE USE

6 oz (170.3 g)

Acella
PHARMACEUTICALS, LLC

NDC 42192-136-06

Sodium Sulfacetamide 10% - Sulfur 5% Cleanser

Rx Only

SHAKE WELL BEFORE USE

6 oz (170.3 g)

Acella
PHARMACEUTICALS, LLC

Indications: For the topical control of acne vulgaris, acne rosacea and seborrheic dermatitis.

Directions: Wash affected areas once or twice daily or as directed by a 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 off sooner or using less often. See package insert for full prescribing information.

Warnings: For external use only. Avoid contact with eyes.
KEEP OUT OF REACH OF CHILDREN. Keep bottle tightly closed.

Active Ingredients: Sodium Sulfacetamide, USP 10% and Sulfur 5%

Other Ingredients: butylated hydroxytoluene, cetyl alcohol, disodium EDTA, disodium oleamido MEA sulfosuccinate, glyceryl stearate and PEG 100 stearate, magnesium aluminum silicate, methylparaben, propylparaben, purified water, sodium cocoyl isethionate, sodium methyl cocoyl taurate, sodium thiosulfate, stearyl alcohol, white petrolatum and xanthan gum.

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

Sodium Sulfacetamide 10% - Sulfur 5% Cleanser is supplied in a 6 oz (170.3 g) bottle (NDC 42192-136-06). For lot number and expiration date, see bottom of bottle.

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.** Please see package insert for more information.

Manufactured for:
Acella Pharmaceuticals, LLC
Alpharetta, GA 30009
1-800-541-4802
Rev. 0911v3



SODIUM SULFACETAMIDE 10 SULFUR 5 CLEANSER

sulfacetamide sodium and sulfur rinse

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:42192-136
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
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
PEG-100 STEARATE (UNII: YD01N1999R)	
MAGNESIUM ALUMINUM SILICATE (UNII: 6M3P64V0NC)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
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)	
PETROLATUM (UNII: 4T6H12BN9U)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Product Characteristics

Color	yellow	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:42192-136-06	170.3 g in 1 BOTTLE; Type 0: Not a Combination Product	04/20/2012	
2	NDC:42192-136-08	227 g in 1 BOTTLE; Type 0: Not a Combination Product	09/19/2016	
3	NDC:42192-136-12	340.2 g in 1 BOTTLE; Type 0: Not a Combination Product	04/20/2012	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		04/20/2012	

Labeler - Acella Pharmaceuticals, LLC (825380939)

Establishment

Name	Address	ID/FEI	Business Operations
Acella Pharmaceuticals, LLC		825380939	manufacture(42192-136)

