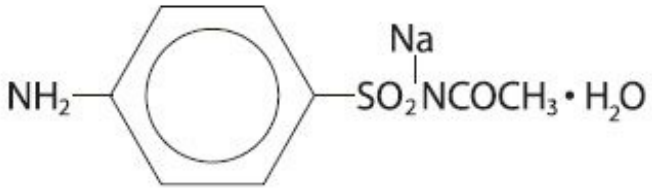
SODIUM SULFACETAMIDE, SULFUR- sodium sulfacetamide and sulfur cream
Acella Pharmaceuticals, LLC

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% Emollient Cream

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 of Sodium Sulfacetamide 10% Sulfur 5% Emollient Cream contains 100 mg of Sodium Sulfacetamide, USP and 50 mg of Sulfur in a base containing BHT, Ceteareth-20, Cetearyl Alcohol, Cetyl Alcohol, Disodium EDTA, Ethylhexyl Palmitate, Ethylparaben, Fragrance, Glyceryl Monostearate SE, Methylparaben, Phenoxyethanol, Propylene Glycol, Propylparaben, Purified Water, Sodium Thiosulfate and Xanthan Gum.

CLINICAL PHARMACOLOGY: Sodium Sulfacetamide exhibits antibacterial activity. It is believed to block bacterial growth by acting as a competitive antagonist of para-aminobenzoic acid (PABA). While absorption through intact skin has not been determined for sodium sulfacetamide, it is estimated that 1% of topically applied sulfur is absorbed. Although the exact mode of the keralytic activity of sulfur is unknown, it is reported to result from the interaction of sulfur with the cysteine content of keratinocytes. In combination with sulfacetamide, sulfur has been reported to inhibit *P. acnes*, thereby reducing the associated inflammation.

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

CONTRAINDICATIONS: Sodium Sulfacetamide 10% Sulfur 5% Emollient Cream is contraindicated for use by patients having known hypersensitivity to sulfonamides, sulfur or any other component of this preparation.Sodium Sulfacetamide 10% Sulfur 5% Emollient Cream is not to be used by patients with kidney disease.

WARNINGS: Although rare, sensitivity to sodium sulfacetaminde 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% Emollient Cream. It is not known whether Sodium Sulfacetamide 10% Sulfur 5% Emollient Cream can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Sodium Sulfacetamide 10% Sulfur 5% Emollient Cream 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% Emollient Cream. 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% Emollient Cream 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: Cleanse skin thoroughly before application. Apply a thin layer to affected areas 1-3 times daily or as directed by a physician. To minimize potential dryness, start with one application daily, then gradually increase to 2-3 times daily as needed or as directed by a physician.

HOW SUPPLIED: Sodium Sulfacetamide 10% Sulfur 5% Emollient Cream is available in 2 oz (57 g) tubes, NDC 42192-149-02 and SSS 10% - 5% (Sodium Sulfacetamide - Sulfur) Emollient Cream in 1 oz (28 g) tubes, NDC 42192-139-01.

Store at 20° - 25°C (68° - 77°F); excursions permitted to 15° - 30°C (59° - 86°F) [see USP Controlled Room Temperature]

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 30022 • 1-800-541-4802

Rev. 0514

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL - 28 g carton label

NDC 42192-139-01

SSS 10% - 5%

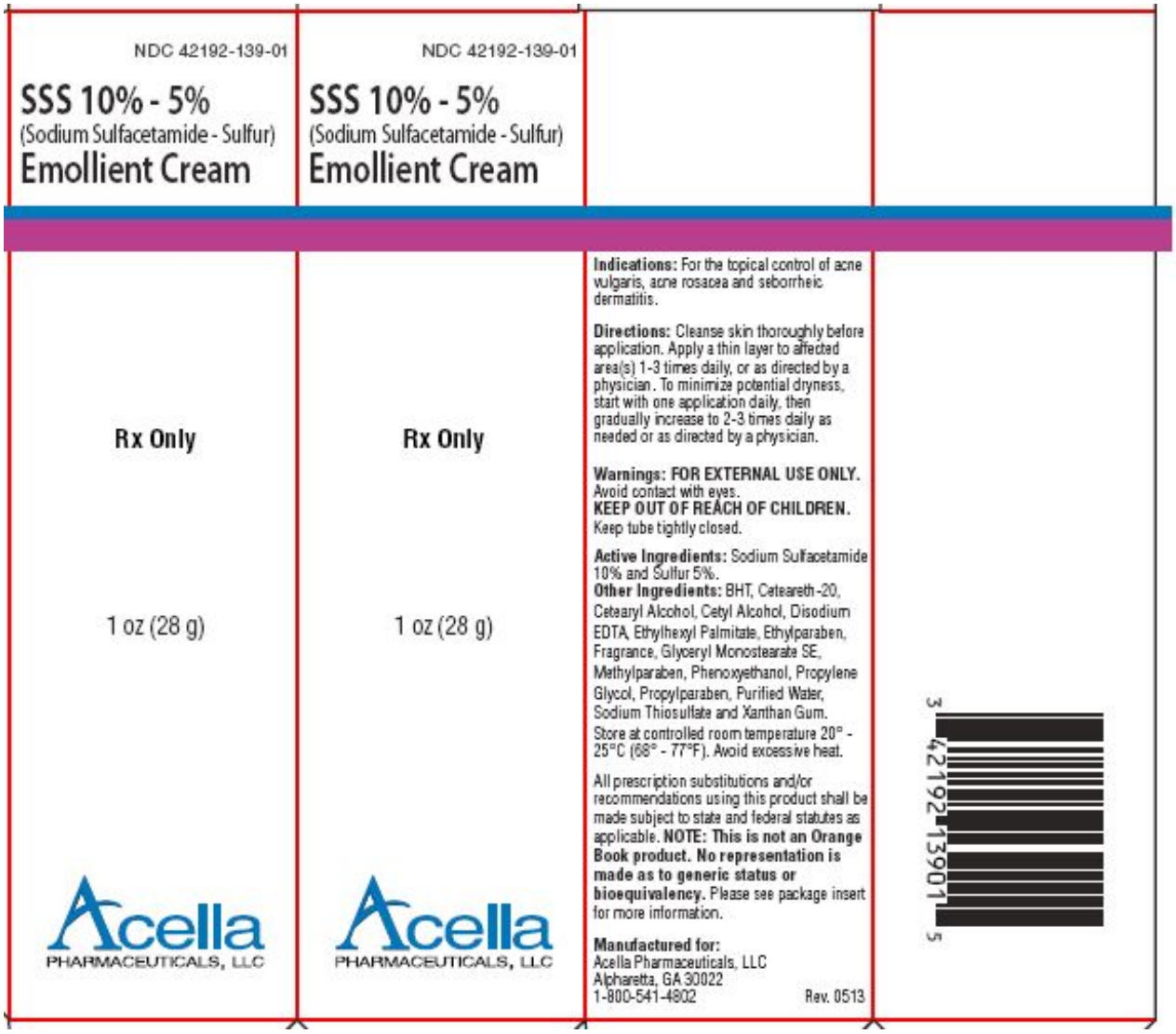
(Sodium Sulfacetamide - Sulfur)

Emollient Cream

Rx Only

1 oz (28 g)

Acella
PHARMACEUTICALS, LLC



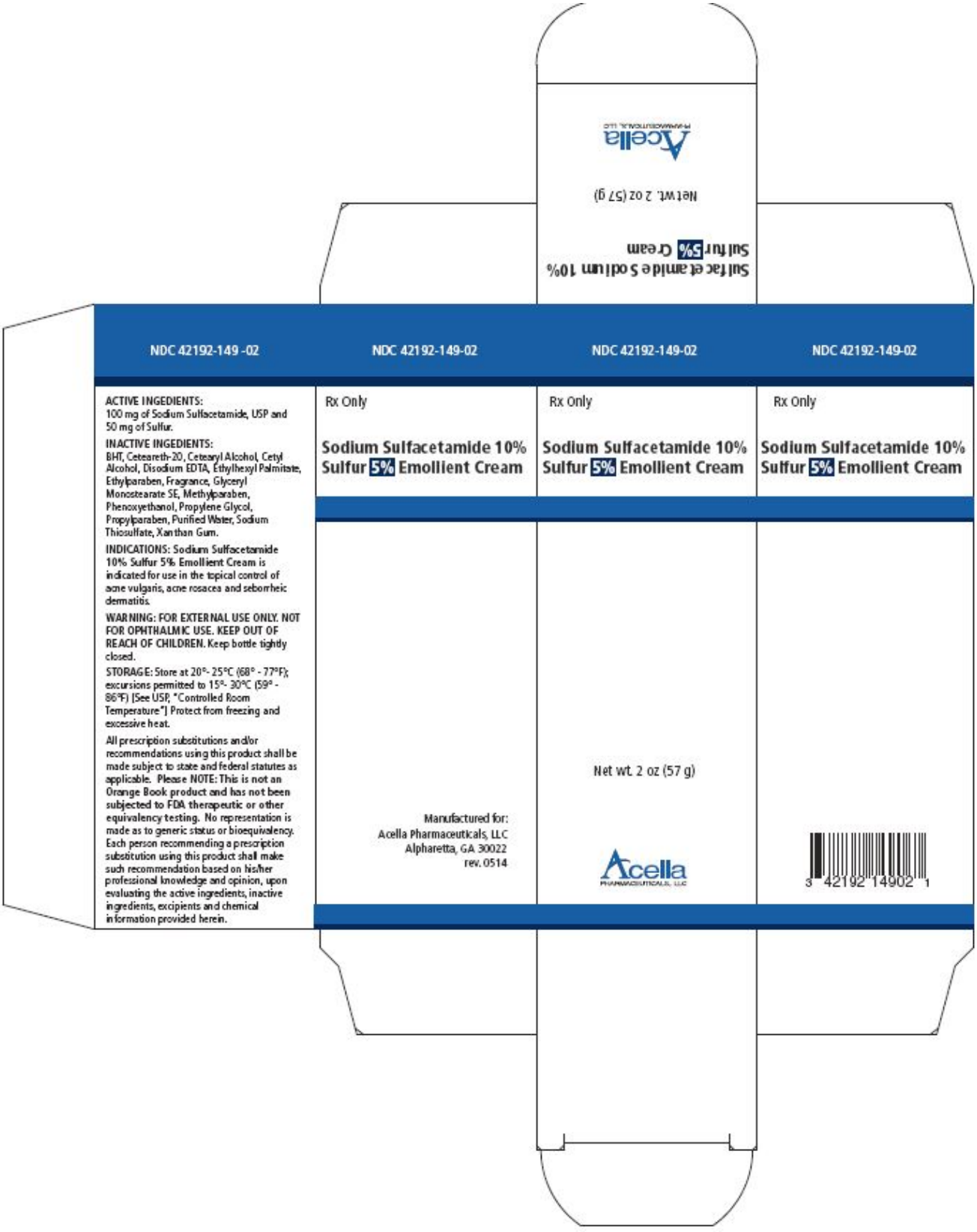
PACKAGE LABEL.PRINCIPAL DISPLAY PANEL - 57 g carton label

42192-149-02

Sodium Sulfacetamide 10%
Sulfur 5% Emollient Cream

Net wt. 2 oz (57 g)

Acella
PHARMACEUTICALS, LLC



SODIUM SULFACETAMIDE, SULFUR

sodium sulfacetamide and sulfur cream

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:42192-139

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**
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
POLYOXYL 20 CETOSTEARYL ETHER (UNII: YRC528SWUY)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
ETHYLHEXYL PALMITATE (UNII: 2865993309)	
ETHYLPARABEN (UNII: 14255EXE39)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
METHYLPARABEN (UNII: A2I8C7HI9T)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYLPARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0KO0R)	
SODIUM THIOSULFATE (UNII: HX1032V43M)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:42192-139-01	28 g in 1 TUBE; Type 1: Convenience Kit of Co-Package	06/11/2014	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		06/11/2014	

SODIUM SULFACETAMIDE, SULFUR

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PROPYLPARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0KO0R)	
SODIUM THIOSULFATE (UNII: HX1032V43M)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:42192-149-02	57 g in 1 TUBE; Type 0: Not a Combination Product	08/14/2014	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		08/14/2014	

Labeler - Acella Pharmaceuticals, LLC (825380939)

Establishment

Name	Address	ID/FEI	Business Operations
Acella Pharmaceuticals, LLC		825380939	manufacture(42192-139, 42192-149)