BP CLEANSING WASH- sodium sulfacetamide and sulfur liquid
Acella Pharmaceuticals, LLC

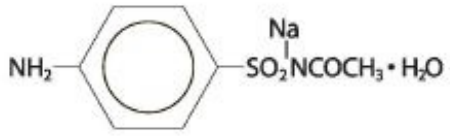
Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

BP Cleansing Wash

(Sodium Sulfacetamide 10% and Sulfur 4%)

In a Urea Vehicle

DESCRIPTION: Sodium sulfacetamide is a sulfonamide with antibacterial activity. Sulfur acts as a keratolytic agent. Chemically sodium sulfacetamide is N-[(4-aminophenyl)sulfonyl]-acetamide, monosodium salt, monohydrate. The structural formula is:



Each mL of Sodium Sulfacetamide 10% and Sulfur 4% contains 100 mg of sodium sulfacetamide and 40 mg of sulfur in an emulsion base containing urea 10%, 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.

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: BP Cleansing Wash is indicated in the topical control of acne vulgaris, acne rosacea and seborrheic dermatitis.

CONTRAINDICATIONS: BP Cleansing Wash is contraindicated for use by patients having known hypersensitivity to sulfonamides, sulfur or any other component of this preparation. BP Cleansing Wash 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 bottle tightly closed. Keep away from eyes. Keep out of reach of children.

PRECAUTIONS: If irritation develops, use of the product should be discontinued and appropriate therapy started. 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 BP Cleansing Wash. When administered to a pregnant woman, it also is not known whether BP Cleansing Wash can affect reproduction capacity or cause fetal harm. BP Cleansing Wash should be given to a pregnant woman only if clearly needed.

Nursing Mothers - It is not known whether sodium sulfacetamide is excreted in human milk following topical use of BP Cleansing Wash. However, small amounts of orally administered sulfonamides have been reported to be eliminated in human milk. Because many drugs are excreted in human milk, caution should be exercised when BP Cleansing Wash 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: BP Cleansing Wash: Wash affected area 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 off cleansing wash sooner or using less often.

HOW SUPPLIED: BP Cleansing Wash is available in a 16 fl. oz. (473 mL) bottle, NDC 42192-103-16. Store BP Cleansing Wash at controlled room temperature 15°-30° C (59°-86° F). Protect from freezing.

KEEP OUT OF REACH OF CHILDREN.

MANUFACTURED FOR: Acella Pharmaceuticals, LLC
Alpharetta, GA 30009
1-800-541-4802
Rev. 1209

PACKAGE LABEL.PRINCIPAL DISPLAY - 473 mL bottle label

NDC 42192-103-16

R_x Only **BP**
Cleansing
Wash

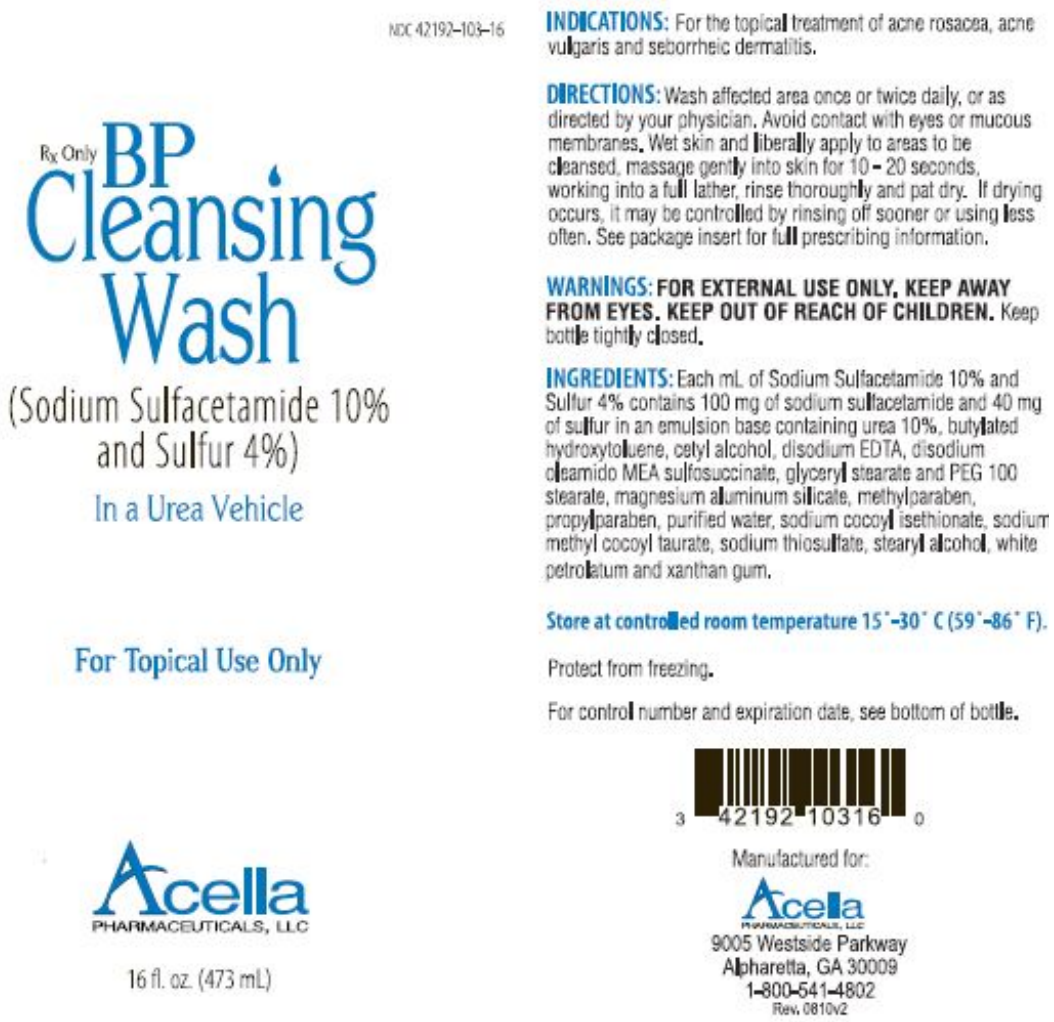
(Sodium Sulfacetamide 10%
and Sulfur 4%)

In a Urea Vehicle

For Topical Use Only

Acella
PHARMACEUTICALS, LLC

16 fl. oz. (473 mL)



BP CLEANSING WASH

sodium sulfacetamide and sulfur liquid

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:42192-103
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 mL
SULFUR (UNII: 70FD1KFU70) (SULFUR - UNII:70FD1KFU70)	SULFUR	40 mg in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
DISODIUM OLEAMIDO MEA-SULFOSUCCINATE (UNII: 5M1101WGSY)	

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)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:42192-103-16	473 mL in 1 BOTTLE; Type 0: Not a Combination Product	04/23/2008	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		04/23/2008	

Labeler - Acella Pharmaceuticals, LLC (825380939)

Establishment

Name	Address	ID/FEI	Business Operations
Acella Pharmaceuticals, LLC		825380939	manufacture(42192-103)

Revised: 9/2018 Acella Pharmaceuticals, LLC