SODIUM SULFACETAMIDE 10% AND SULFUR 5% EMOLLIENT FOAM- sulfacetamide sodium and sulfur aerosol, foam
Acella Pharmaceuticals, LLC

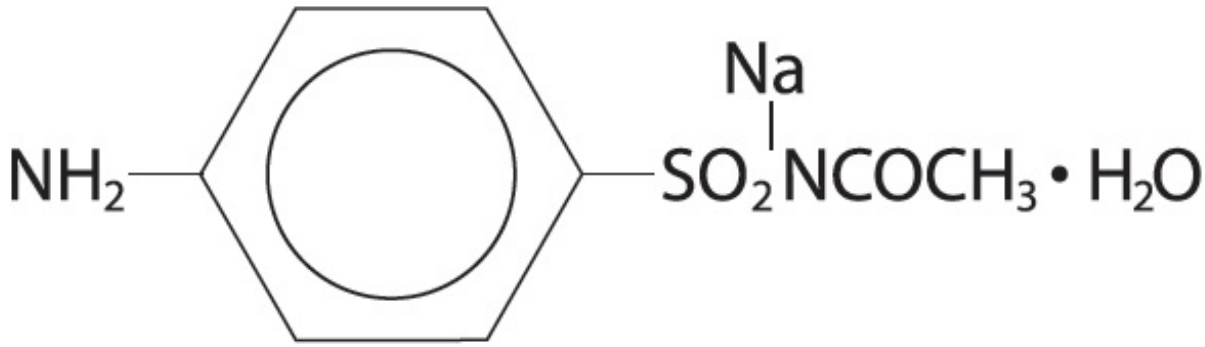
Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

SSS 10 - 5 Emollient Foam
(Sodium Sulfacetamide 10% and Sulfur 5%)

Rx Only

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 gram of SSS 10 - 5 Emollient Foam contains 100 mg of Sodium Sulfacetamide and 50 mg of Sulfur in an aqueous based emollient foam vehicle containing: Butane, Butylene Glycol, Cellulose Gum, Ceteareth-20, Cetearyl Alcohol, Dimethicone, Glycerin, Magnesium Aluminum Silicate, Polysorbate 20, Propane, Titanium Dioxide, Water.

CLINICAL PHARMACOLOGY

Sodium sulfacetamide exhibits antibacterial activity. 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 is reported to result from the interaction of sulfur with the cysteine content of keratinocytes. Furthermore, in combination with sulfacetamide, sulfur has been reported to inhibit the growth of *Propionibacterium*

acnes, thereby adding to the product's antibacterial activity and reducing associated inflammation.

INDICATIONS

SSS 10 - 5 Emollient Foam is indicated in the topical control of acne vulgaris, acne rosacea and seborrheic dermatitis.

CONTRAINDICATIONS

SSS 10 - 5 Emollient Foam is contraindicated for use by patients having known hypersensitivity to sulfonamides, sulfur or any other component of this preparation. SSS 10 - 5 Emollient Foam is not to be used by patients with kidney disease.

WARNINGS

Although rare, sensitivity to sodium sulfacetamide may occur. Stevens-Johnson syndrome, toxic epidermal necrolysis, fulminant hepatic necrosis, agranulocytosis, aplastic anemia and other blood dyscrasias. Hypersensitivity reactions may occur when a sulfonamide is readministered, irrespective of the route of administration. At the first sign of hypersensitivity or skin rash, discontinue use of this preparation. Particular caution should be employed if areas of involved skin to be treated are denuded or abraded.

FOR EXTERNAL USE ONLY.

Keep away from eyes. KEEP OUT OF REACH OF CHILDREN. Contents under pressure. Do not puncture or incinerate container. Do not expose to temperatures above 120°F (49°C).

PRECAUTIONS

General

The object of this therapy is to achieve desquamation without irritation, but sodium sulfacetamide and sulfur can cause reddening and scaling of the skin. These side effects are not unusual in the treatment of acne vulgaris, but patients should be cautioned about the possibility. 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.

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 SSS 10 - 5 Emollient Foam. When administered to a pregnant woman, it also is not known whether SSS 10 - 5 Emollient Foam can affect reproduction capacity or cause fetal harm. SSS 10 - 5 Emollient Foam 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 SSS 10 - 5 Emollient Foam. 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 SSS 10 - 5 Emollient Foam 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

Wash affected areas before use, 1 to 2 times daily as directed by physician. **Before each use,** shake can vigorously, then gently tap the bottom of the can on a firm surface or in palm of other hand. Tap can 1 - 2 times, then shake and tap again.

Dispense can upright. Depress the actuator and dispense a small amount of foam (not more than a dollop the size of a golf ball). Pointing the can down will cause propellant loss.

Wash affected areas and apply foam 1 or 2 times a day as directed by a physician. Avoid contact with the eyes.

Wash-off Application: Massage the dispensed foam into the affected areas and wait 1 to 2 minutes. Rinse thoroughly with water and pat dry. Treat the affected area 1 to 2 times daily, as directed by a physician.

Leave-on Application: Massage the foam into the affected areas 1 to 2 times daily, as directed by a physician. Wipe off any excess foam from actuator after use.

HOW SUPPLIED

SSS 10 - 5 Emollient Foam is available in a 100 g aluminum can, NDC 42192-143-01. Contents under pressure. Do not puncture or incinerate container. Do not expose to heat or store at temperatures above 120°F (49°C).

Storage: Store SSS 10 - 5 Emollient Foam between 68° and 77°F (20° and 25°C).

Protect from freezing. Store upright.

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. **Please note: This is not an Orange Book product and has not been subjected to FDA therapeutic equivalency or other equivalency. 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 information provided herein.

Manufactured For:
Acella Pharmaceuticals, LLC
Alpharetta, GA 30022
1-800-541-4802
Rev. 0917-05

PRINCIPAL DISPLAY PANEL - 100 g Bottle Label

NDC 42192-143-01

SSS 10 - 5
(Sodium Sulfacetamide 10% and Sulfur 5%)
Emollient Foam

Rx only

For Dermatologic Use Only.
Not for Opthaamic Use.
100 g

Acella Pharmaceuticals, LLC

NDC 42192-143-01

SSS 10 - 5
(Sodium Sulfacetamide 10% and Sulfur 5%)
Emollient Foam

Rx Only

For Dermatologic Use Only.
Not for Ophthalmic Use.

100 g

Acella PHARMACEUTICALS, LLC

Dosage and Administration: Wash affected areas before use, 1 to 2 times daily as directed by physician. **Before each use,** shake can vigorously, then gently tap the bottom of the can on a firm surface or in palm of other hand. Tap can 1 - 2 times, then shake and tap again. Dispense can upright. Depress the actuator and dispense a small amount of foam (not more than a dollop the size of a golf ball). Pointing the can down will cause propellant loss.

Wash affected areas and apply foam 1 or 2 times a day as directed by a physician. Avoid contact with the eyes.

Wash-off Application: Massage the dispensed foam into the affected areas and wait 1 to 2 minutes. Rinse thoroughly with water and pat dry. Treat the affected area 1 to 2 times daily, as directed by a physician.

Leave-on Application: Massage the foam into the affected areas 1 to 2 times daily, or as directed by a physician.Wipe off any excess foam from actuator after use.

Ingredients: Active: Sodium Sulfacetamide 10% and Sulfur 5%; **Inactive:** Butane, Butylene Glycol, Cellulose Gum, Ceteareth-20, Cetearyl Alcohol, Dimethicone, Glycerin, Magnesium Aluminum Silicate, Polysorbate 20, Propane, Titanium Dioxide, Water.

Storage: Store between 68°-77°F (20°-25°C). Protect from freezing. Store upright.

Caution: Contents under pressure. Do not puncture or incinerate container. Do not expose to heat or store at temperatures above 120°F (49°C).Avoid contact with eyes, lips or other mucus membranes.

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.** See package insert for more information.

Manufactured for:
Acella Pharmaceuticals, LLC
Alpharetta, GA 30022
1-800-541-4802

Rev. 0917-05

3 42192 14301 2

SODIUM SULFACETAMIDE 10% AND SULFUR 5% EMOLLIENT FOAM

sulfacetamide sodium and sulfur aerosol, foam

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:42192-143
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**

BUTANE (UNII: 6LV4FOR43R)	
BUTYLENE GLYCOL (UNII: 3XUS85K0RA)	
CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM (UNII: K679OBS311)	
POLYOXYL 20 CETOSTEARYL ETHER (UNII: YRC528SWJY)	
CETOSTEARYL ALCOHOL (UNII: 2DMT128M1S)	
DIMETHICONE (UNII: 92RU3N3Y1O)	
GLYCERIN (UNII: PDC6A3C0OX)	
MAGNESIUM ALUMINUM SILICATE (UNII: 6M3P64V0NC)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
PROPANE (UNII: T75W9911L6)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:42192-143-01	100 g in 1 CAN; Type 0: Not a Combination Product	06/18/2013	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
UNAPPROVED DRUG OTHER		06/18/2013	

Labeler - Acella Pharmaceuticals, LLC (825380939)

Establishment

Name	Address	ID/FEI	Business Operations
Acella Pharmaceuticals, LLC		825380939	manufacture(42192-143)

Revised: 1/2024 Acella Pharmaceuticals, LLC