

SODIUM SULFACETAMIDE - SULFUR CLEANSING PADS- sodium sulfacetamide, sulfur swab

Acella Pharmaceuticals, LLC

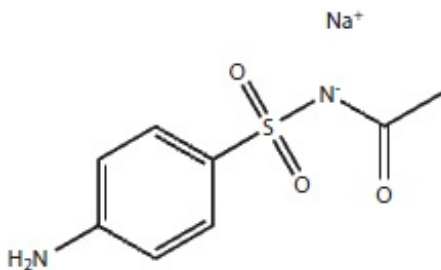
Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

Sodium Sulfacetamide 10% - Sulfur 4% Cleansing Pads In a vehicle containing Green Tea and Aloe 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 pad of Sodium Sulfacetamide 10% - Sulfur 4% Cleansing Pads are coated with a cleanser-based formulation. Each gram of this cleanser-based formulation contains 100 mg of Sodium Sulfacetamide and 40 mg of Sulfur. The cleanser base consists of: purified water, sodium cocoyl isethionate disodium oleamido MEA sulfosuccinate, green tea extract, cetyl alcohol, stearyl alcohol, glycerol stearate and PEG 100 stearate methyl paraben, propyl paraben, butylated hydroxytoluene, aloe vera gel, sodium thiosulfate, disodium EDTA, magnesium aluminum silicate, xanthan gum, sodium methyl cocoyl taurate, white petrolatum.

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 4% Cleansing Pads are indicated in the topical control of acne vulgaris, acne rosacea and seborrheic dermatitis.

CONTRAINDICATIONS: Sodium Sulfacetamide 10% - Sulfur 4% Cleansing Pads are contraindicated for use by patients having known hypersensitivity to sulfonamides, sulfur or any other component of this preparation. Sodium Sulfacetamide 10% - Sulfur 4% Cleansing Pads are 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.

PREGNANCY: Pregnancy Category C. Animal reproduction studies have not been conducted with Sodium Sulfacetamide 10% - Sulfur 4% Cleansing Pads. It is not known whether Sodium Sulfacetamide 10% - Sulfur 4% Cleansing Pads can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Sodium Sulfacetamide 10% - Sulfur 4% Cleansing Pads 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 4% Cleansing Pads. 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 4% Cleansing Pads are 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 area(s) with cleansing pad once or twice daily, or as directed by your physician. Wet area(s) with water. Wet pad with a little water and work into a full lather. Cleanse area(s) with pad for 10-20 seconds, avoiding eyes. Rinse thoroughly and pat dry. Discard pad. Do not flush.

HOW SUPPLIED: Sodium Sulfacetamide 10% - Sulfur 4% Cleansing Pads are available in boxes of 60 cloths (3.7 g), (NDC 42192-113-60).

Store at controlled room temperature, 15° - 25° (59° - 77°F).

All prescription substitutions 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 testing. 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
9005 Westside Parkway
Alpharetta, GA 30009
1-800-541-4802

Sodium Sulfacetamide 10%-

Sulfur 4% Cleansing Pads

In a vehicle containing Green Tea and Aloe

Rx Only

60 cleansing pads

Net weight 3.7g each

Acella pharmaceuticals

Directions: Wash affected areas with Sodium Sulfacetamide 10% - Sulfur 4% once or twice daily or as directed by your physician.

1. Wet affected areas with water

2. Wet Sodium Sulfacetamide 10% - Sulfur 4% cleansing pad with water and work into a full lather.

3. Cleanse face with Sodium Sulfacetamide 10% - Sulfur 4% for 10 -20 seconds, avoiding eyes

4. Rinse thoroughly and pat dry

5. Discard pad. Do not flush.

Warnings for external use only. Keep out of reach of children. Avoid contact with eyes.

Indications: for the typical control of acne vulgaris and seborrheic dermatitis. See package insert for full prescribing information.

Contraindications: Sodium Sulfacetamide 10% - Sulfur 4% cleansing pads are contraindicated for use in patients having known hypersensitivity to sulfonamides, sulfur or any other component of the preparation. Sodium Sulfacetamide 10% - Sulfur 4% cleansing pads are not to be used by patients with kidney disease.

Contents: Sodium Sulfacetamide 10% - Sulfur 4%. Other Ingredients: purified water, sodium cocoyl isethionate, disodium oleamido MEA sulfosuccinate, green tea extract, cetyl alcohol, stearyl alcohol, glycerol stearate and PEG 100 stearate methyl paraben, propyl paraben, butylated hydroxytoluene, aloe vera gel, sodium thiosulfate, disodium EDTA, magnesium aluminum silicate, xanthan gum, sodium methyl cocoyl l-taurate, white petrolatum

Acella Pharmaceuticals

Store at 15 degrees to 25 degrees C or 59-77 degrees F)

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Acella Pharmaceuticals, LLC

9005 Westside Parkway

Alpharetta, GA 30009

1-800-541-4802


NDC 42192-113-60

Sodium Sulfacetamide 10% - Sulfur 4% Cleansing Pads

In a vehicle containing Green Tea and Aloe

Rx Only

1 cleansing pad • Net weight 3.7 g



Indications: For the topical control of acne vulgaris, acne rosacea and seborrheic dermatitis. See package insert for full prescribing information.

Directions: Wash affected areas with Sodium Sulfacetamide 10% - Sulfur 4% Cleansing Pads once or twice daily, or as directed by your physician.

1. Wet affected areas with water.
2. Wet Sodium Sulfacetamide 10% - Sulfur 4% Cleansing Pad with water and work into a full lather.
3. Cleanse face with Sodium Sulfacetamide 10% - Sulfur 4% Cleansing Pad for 10 - 20 seconds, avoiding eyes.
4. Rinse thoroughly and pat dry.
5. Discard pad. Do not flush.

Warnings: For external use only. Keep out of reach of children. Avoid contact with eyes.


Contraindications: Sodium Sulfacetamide 10% - Sulfur 4% Cleansing Pads are contraindicated for use in patients having known hypersensitivity to sulfonamides, sulfur or any other component of this preparation. Sodium Sulfacetamide 10% - Sulfur 4% Cleansing Pads are not to be used by patients with kidney disease.

Contents: Sodium sulfacetamide 10% and sulfur 4%. **Other Ingredients:** purified water, sodium cocoyl isethionate, disodium oleamido MEA sulfosuccinate, green tea extract, cetyl alcohol, stearyl alcohol, glycerol stearate and PEG 100 stearate, methyl paraben, propyl paraben, butylated hydroxytoluene, aloe vera gel, sodium thiosulfate, disodium EDTA, magnesium aluminum silicate, xanthan gum, sodium methyl cocoyl taurate, white petrolatum.

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9005 Westside Parkway
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1-800-541-4802
Rev. 0510




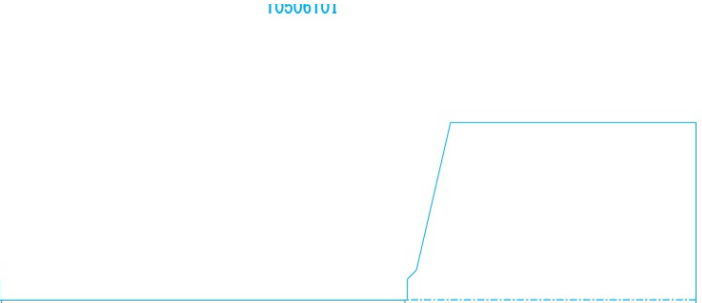
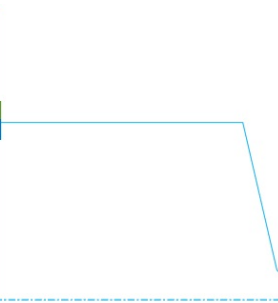
NDC 42192-113-60

Sodium Sulfacetamide 10% - Sulfur 4% Cleansing Pads

In a vehicle containing Green Tea and Aloe

Rx Only

60 cleansing pads • Net weight 3.7 g each




NDC 42192-113-60

Sodium Sulfacetamide 10% - Sulfur 4% Cleansing Pads



NDC 42192-113-60

Sodium Sulfacetamide 10% - Sulfur 4% Cleansing Pads

<p style="text-align: center;">In a vehicle containing Green Tea and Aloe</p> <p style="text-align: center;">Rx Only</p> <p style="text-align: center;">60 cleansing pads • Net weight 3.7 g each</p> 	<p>Directions: Wash affected areas with Sodium Sulfacetamide 10% - Sulfur 4% Cleansing Pads once or twice daily, or as directed by your physician.</p> <ol style="list-style-type: none"> 1. Wet affected areas with water. 2. Wet Sodium Sulfacetamide 10% - Sulfur 4% Cleansing Pad with water and work into a full lather. 3. Cleanse face with Sodium Sulfacetamide 10% - Sulfur 4% Cleansing Pad for 10 - 20 seconds, avoiding eyes. 4. Rinse thoroughly and pat dry. 5. Discard pad. Do not flush. <p>Warnings: For external use only. Keep out of reach of children. Avoid contact with eyes.</p> 	<p>Indications: For the topical control of acne vulgaris, acne rosacea and seborrheic dermatitis. See package insert for full prescribing information.</p> <p>Contraindications: Sodium Sulfacetamide 10% - Sulfur 4% Cleansing Pads are contraindicated for use in patients having known hypersensitivity to sulfonamides, sulfur or any other component of this preparation. Sodium Sulfacetamide 10% - Sulfur 4% Cleansing Pads are not to be used by patients with kidney disease.</p> <p>Contents: Sodium sulfacetamide 10% and sulfur 4%. Other Ingredients: purified water, sodium cocoyl isethionate disodium oleamido MEA sulfosuccinate, green tea extract, cetyl alcohol, stearyl alcohol, glycerol stearate and PEG 100 stearate methyl paraben, propyl paraben, butylated hydroxytoluene, aloe vera gel, sodium thiosulfate, disodium EDTA, magnesium aluminum silicate, xanthan gum, sodium methyl cocoyl taurate, white petrolatum.</p> 	<p>Store at 15° - 25°C (59° - 77°F).</p> <p>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.</p> <p>Manufactured For: Acella Pharmaceuticals, LLC 9005 Westside Parkway Alpharetta, GA 30009 1-800-541-4802</p>
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SODIUM SULFACETAMIDE - SULFUR CLEANSING PADS			
sodium sulfacetamide, sulfur swab			
Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:42192-113
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
SULFACETAMIDE SODIUM (UNII: 4NRT660KJQ) (SULFACETAMIDE - UNII:4965G3J0F5)	SULFACETAMIDE SODIUM	10 g in 100 g	
SULFUR (UNII: 70FD1KFU70) (SULFUR - UNII:70FD1KFU70)	SULFUR	4 g in 100 g	
Inactive Ingredients			

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
SODIUM THIO SULFATE (UNII: HX1032V43M)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
MAGNESIUM ALUMINUM SILICATE (UNII: 6M3P64V0NC)	
XANTHAN GUM (UNII: TTV12P4NEE)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:42192-113-60	60 in 1 BOX	07/30/2009	
1		3.7 g in 1 POUCH; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		07/30/2009	

Labeler - Acella Pharmaceuticals, LLC (825380939)

Establishment

Name	Address	ID/FEI	Business Operations
Acella Pharmaceuticals, LLC		825380939	manufacture(42192-113)

Revised: 9/2018

Acella Pharmaceuticals, LLC