SODIUM SULFACETAMIDE- sodium sulfacetamide liquid
Laser 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.

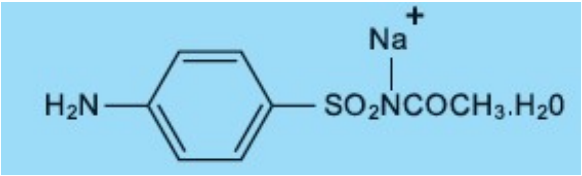
Sodium Sulfacetamide 10% Wash

SODIUM SULFACETAMIDE 10% WASH
(sodium sulfacetamide 10%)
Rx Only
FOR EXTERNAL USE ONLY
NOT FOR OPHTHALMIC USE

Description:

Each gram contains 100 mg of sodium sulfacetamide USP in a vehicle consisting of: ammonium lauryl sulfate, butylated hydroxytoluene, ceteareth-25, cetyl alcohol, cocamidopropyl betaine, disodium EDTA, glycerin, guar gum, methylparaben, propylene glycol, propylparaben, purified water, sodium thiosulfate, stearyl alcohol, triacetin.

Chemically it is Acetamide N-[4-aminophenyl)sulfonyl]-, monosodium salt, monohydrate, with the following structural formula:



Sodium sulfacetamide is an odorless, white, crystalline powder with a bitter taste. It is freely soluble in water, sparingly soluble in alcohol, while practically insoluble in benzene, in chloroform and in ether.

CLINICAL PHARMACOLOGY:

Sodium sulfacetamide exerts a bacteriostatic effect against sulfonamide sensitive Gram-positive and Gram-negative microorganisms commonly isolated from secondary cutaneous pyogenic infections. It acts by restricting the synthesis of folic acid required by bacteria for growth, by its competition with para-aminobenzoic acid. There is no clinical data available on the degree and rate of systemic competition with para-aminobenzoic acid absorption of Sodium Sulfacetamide 10% Wash when applied to the skin or scalp. However, significant absorption of sodium sulfacetamide through the sin has been reported. The following in vitro data are available but their clinical significance is unknown. Organisms which show susceptibility to sodium sulfacetamide are: Streptococci, Staphylococci, E. coli, Klebsiella pneumoniae, Pseudomonas pyocyanea, Solmonella species, Proteus vulgaris, Nocardia and Actinomyces.

INDICATIONS AND USAGE:

Sodium Sulfacetamide 10% Wash is intended for topical application in the following scaling dermatoses: seborrheic dermatitis and seborrhea sicca (dandruff). It also is indicated for the treatment of secondary bacterial infections of the skin due to organisms susceptible to sulfonamides.

CONTRAINDICATIONS:

Sodium Sulfacetamide 10% Wash is contraindicated in persons with known or suspected hypersensitivity to sulfonamides or to any of the ingredients of the product.

WARNINGS:

Sulfonamides are known to cause Stevens-Johnson syndrome in hypersensitive individuals. Stevens-Johnson syndrome also has been reported following the use of sodium sulfacetamide topically. Cases of drug-induced systemic lupus erythematosus from topical sulfacetamide also have been reported. In one of these cases, there was a fatal outcome. Keep out of the reach of children.

PRECAUTIONS:

For external use only. Not for ophthalmic use. General: Nonsusceptible organisms, including fungi, may proliferate with the use of this preparation.

Hypersensitivity reactions may recur when a sulfonamide is readministered, irrespective of the route of administration, and cross hypersensitivity between different sulfonamides may occur. If Sodium Sulfacetamide 10% Wash produces signs of hypersensitivity or other untoward reactions, discontinue use of the preparation. Systemic absorption of topical sulfonamides is greater following application to large, infected, abraded, denuded, or severely burned areas. Under these circumstances, potentially any of the adverse effects produced by the systemic administration of these agents could occur and appropriate observations and laboratory determinations should be performed.

Information For Patients:

Patients should discontinue Sodium Sulfacetamide 10% Wash if the condition becomes worse, or if a rash develops in the area being treated or elsewhere. Sodium Sulfacetamide 10% Wash also should be discontinued promptly and the physician notified if any arthritis, fever or sores in the mouth develop.

Drug Interactions:

Sodium Sulfacetamide 10% Wash is incompatible with silver preparations.

Pharmacology:

Sodium Sulfacetamide 10% Wash has a bacteriostatic effect against Gram-positive and

Gram-negative miroorganisms commonly isolated from secondary cutaneous pyogenic infections.

Carcinogenesis, Mutagenesis and Impairment of Fertility:

Long-term animal studies for carcinogenic potential have not been performed on Sodium Sulfacetamide 10% Wash to date. Studies on reprodution and fertility also have not been performed. Chromosomal nondisjunction in the yeast, Saccharomyces cerevisiae, following application of sodium sulfacetamide has been reported. The significance of this finding to the topical use of sodium sulfacetamide in the human is unknown.

Pregnancy: Category C:

Animal reproduction studies have not been conducted with Sodium Sulfacetamide 10% Wash. It also is not known whether Sodium Sulfacetamide 10% Wash can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Sodium Sulfacetamide 10% Wash should be used by a pregnant woman only if clearly needed or when potential benefits outweigh potential hazards to the fetus.

Nursing Mothers:

It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when Sodium Sulfacetamide 10% Wash is administred to a nursing woman.

Pediatric Use:

Safety and effectiveness in chlidren under the age of 12 years have not ben established.

ADVERSE REACTIONS:

Reports of irritation and hypsersensitivity to sodium sulfacetamide are uncommon. The following advrse reactions, reported after administration of sterile ophthalmic sodium sulfacetamide, are noteworthy: instances of Stevens-Johnson syndrome and instanes of local hypersensitivity which progressed to a syndrome resembling systemic lupus erythematosus; in one case a fatal outcome was reported (see WARNINGS)

Call your doctor for medical advice about side effecs. You may report side effects to the FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

OVERDOSAGE:

The oral LD_{50} of sulfacetamide in mice is 16.5 g/kg. In the event of overdosage, emergency treatment should be started immediately. Manifestations: Overdosage may cause nausea and vomiting. Large oral overdosage may cause hematuria, crystalluria, and renal shutdown due to the precipitation of sulfa crystals in the renal tubules and the urinary tract. For treatment, contact your local Poison Control Center.

DOSAGE AND ADMINISTRATION:

Seborrheic dermatitis including seborrhea sicca - Sodium Sulfacetamide 10% Wash: Wash affected areas twice daily (morning and evening), 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 working into a full lather, rinse thoroughly/pat dry and repeat after 10-20 seconds. Rinsing with plain water will remove any excess medication. Repeat application as described for eight to ten days. If skin dryness occurs it may be controlled by rinsing cleanser off sooner or using less frequently. Regular shampooing following Sodium Sulfacetamide 10% Wash is not necessary, but the hair should be shampooed at least once a week. As the condition subsides, the interval between applications may be lenghtened. Applications once or twice weeky or every other week may prevent recurrence. Should the condition recur after stopping therapy, the application of Sodium Sulfacetamide 10% Wash should be reinitiated as at the beginning of treament.

Secondary Cutaneous Bacterial Infections - 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. Rinsing with plain water will remove any excess medication. Repeat application as described for eight to ten days. If skin dryness occurs it may be controlled by rinsing cleanser off sooner or using less often.

HOW SUPPLIED:

Sodium Sulfacetamide Wash 10% is available in a 6 fl oz (170 mL) bottle, NDC 16477-410-06, and in a 12 oz (354.8 mL) bottle, NDC 16477-410-12.

STORAGE:

Store at 25°C (77°F); excursions permitted to 15° to 30°C (59° to 86°F). See USP Controlled Room Temperature. Protect from freezing.

Note: Store upright. Protect from freezing and excessive heat. The wash may tend to darken slightly on storage. Slight discoloration does not impair the efficacy or safety of the produt.

Occassionally, a slight yellowing discoloration may occur when an excessive amount of the wash is used and comes in contact with white fabrics. This discoloration, however, presents no problem, as it is readily removed by ordinary laundering without bleachers.

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 testing. No representation is made as to generic status or bioequialency**. Each person recommending a prescription substitution using this product shall make such recommendations based on each person's professional opinion and knowledge, upon evaluating the active ingredients, excipients, inactive ingredients and chemical information provided herein.

Manufactured in the U.S.A. for:

Laser Pharmaceuticals, LLC

Alpharetta, GA 30004

Rev. 07/22

Indications: Sodium Sulfacetamide 10% Wash is intended for topical application in the following scaling dermatoses: seborrheic dermatitis and seborrhea sicca (dandruff). It also is indicated for the treatment of secondary bacterial infections of the skin due to organisms susceptible to sulfonamides.

Directions for use: Wash affected areas twice daily (morning and evening) or as directed by your physician. Rinse thoroughly and pat dry. **See label booklet for complete product information.**

FOR EXTERNAL USE ONLY. NOT FOR INTRAVAGINAL OR OPHTHALMIC USE. (KEEP AWAY FROM EYES)

KEEP THIS AND ALL MEDICATION OUT OF THE REACH OF CHILDREN. In case of accidental ingestion contact a poison control center immediately. Keep container tightly closed.

CONTRAINDICATIONS: Sodium Sulfacetamide 10% Wash is contraindicated in persons with known or suspected hypersensitivity to sulfonamides.

Each gram contains 100 mg of sodium sulfacetamide USP in a vehicle consisting of: ammonium lauryl sulfate, butylated hydroxytoluene, ceteareth-25, cetyl alcohol, cocamidopropyl betaine, disodium EDTA, glycerin, guar gum, methylparaben, propylene glycol, propylparaben, purified water, sodium thiosulfate, stearyl alcohol, triacetin.

Store at 25°C (77°F); excursions permitted to 15° to 30°C (59° to 86°F). See USP Controlled Room. Protect from freezing. See bottle for lot number and exiration date.

Important Note:

This bottle is not filled to the top but does contain 12 fl oz of product as identified on the front panel of the bottle.

NDC 16477-410-12

Rx Only

For External Use Only

Sodium Sulfacetamide 10% Wash

LASER PHARMACEUTICALS, llc

12 fl oz (354.8 mL)

Manufactured in the U.S.A. for

Laser Pharmaceuticals, LLC

Alpharetta, GA 30004

Lift Here

INDICATIONS: Sodium Sulfacetamide 10% Wash is intended for topical application in the following scaling dermatoses: seborrheic dermatitis and seborrhea sicca (dandruff). It also is indicated for the treatment of secondary bacterial infections of the skin due to organisms susceptible to sulfonamides.

DIRECTIONS FOR USE: Wash affected areas twice daily (morning and evening) or as directed by your physician. Rinse thoroughly and pat dry. **See label booklet for complete product information.**

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In case of accidental ingestion contact a poison control center immediately. Keep container tightly closed.

CONTRAINDICATIONS: Sodium Sulfacetamide 10% Wash is contraindicated in persons with known or suspected hypersensitivity to sulfonamides.

Each gram contains 100 mg of sodium sulfacetamide USP in a vehicle consisting of: Butylated Hydroxytoluene, Citric Acid, Cetyl Alcohol, Cocamidopropyl Betaine, Disodium EDTA, Glycerin, Glyceryl Stearate SE, PEG-100 Stearate, Phenoxyethanol, Purified Water, Sodium Laureth Sulfate, Sodium Thiosulfate, Stearyl Alcohol, Triacetin, Xanthan Gum.

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Manufactured in the U.S.A. for
Laser Pharmaceuticals, LLC
Alpharetta, GA 30004

Store at 25°C (77°F); excursions permitted to 15° to 30°C (59° to 86°F). See USP Controlled Room. Protect from freezing. See bottle for lot number and expiration date.

Important Note:
This bottle is not filled to the top but does contain 6 fl oz of product as identified on the front panel of the bottle.

NDC 16477-410-06

Rx Only

For External Use Only

Sodium Sulfacetamide 10% Wash

LASER PHARMACEUTICALS, LLC

6 fl oz (177 mL)

INDICATIONS: Sodium Sulfacetamide 10% Wash is intended for topical application in the following scaling dermatoses: seborrheic dermatitis and seborrhea sicca (dandruff). It also is indicated for the treatment of secondary bacterial infections of the skin due to organisms susceptible to sulfonamides.

DIRECTIONS FOR USE: Wash affected areas twice daily (morning and evening) or as directed by your physician. Rinse thoroughly and pat dry. **See label booklet for complete product information.**

FOR EXTERNAL USE ONLY. NOT FOR INTRAVAGINAL OR OPHTHALMIC USE. (KEEP AWAY FROM EYES)

KEEP THIS AND ALL MEDICATION OUT OF THE REACH OF CHILDREN. In case of accidental ingestion contact a poison control center immediately. Keep container tightly closed.

CONTRAINDICATIONS: Sodium Sulfacetamide 10% Wash is contraindicated in persons with known or suspected hypersensitivity to sulfonamides.

Each gram contains 100 mg of sodium sulfacetamide USP in a vehicle consisting of: Butylated Hydroxytoluene, Citric Acid, Cetyl Alcohol, Cocamidopropyl Betaine, Disodium EDTA, Glycerin, Glyceryl Stearate SE, PEG-100 Stearate, Phenoxyethanol, Purified Water, Sodium Laureth Sulfate, Sodium Thiosulfate, Stearyl Alcohol, Triacetin, Xanthan Gum.

Store at 25°C (77°F); excursions permitted to 15° to 30°C (59° to 86°F). See USP Controlled Room. Protect from freezing. See bottle for lot number and expiration date.

Important Note:
This bottle is not filled to the top but does contain 12 fl oz of product as identified on the front panel of the bottle.

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Manufactured in the U.S.A. for
Laser Pharmaceuticals, LLC
Alpharetta, GA 30004

Lift Here

NDC 16477-410-12

Rx Only

For External Use Only

Sodium Sulfacetamide 10% Wash

LASER PHARMACEUTICALS, LLC

12 fl oz (354.8 mL)

SODIUM SULFACETAMIDE

sodium sulfacetamide liquid

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:16477-410
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

Inactive Ingredients

Ingredient Name	Strength
XANTHAN GUM (UNII: TTV12P4NEE)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
GLYCERYL STEARATE SE (UNII: FCZ5MH785I)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3O11KX)	
GLYCERIN (UNII: PDC6A3C0OX)	
PEG-100 STEARATE (UNII: YD01N1999R)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
SODIUM LAURETH SULFATE (UNII: BPV390UAP0)	
WATER (UNII: 059QF0KO0R)	
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	
CETYL ALCOHOL (UNII: 936JST6JCN)	
SODIUM THIOSULFATE (UNII: HX1032V43M)	
STEARYL ALCOHOL (UNII: 2KR89I4H1Y)	
TRIACETIN (UNII: XHX3C3X673)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:16477-410-12	354.8 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/17/2021	
2	NDC:16477-410-06	177 mL in 1 BOTTLE; Type 0: Not a Combination Product	03/17/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		03/17/2021	

Labeler - Laser Pharmaceuticals, LLC (614417132)

Revised: 8/2022 Laser Pharmaceuticals, LLC