

SODIUM SULFACETAMIDE- sodium sulfacetamide liquid
Akron Pharma Inc

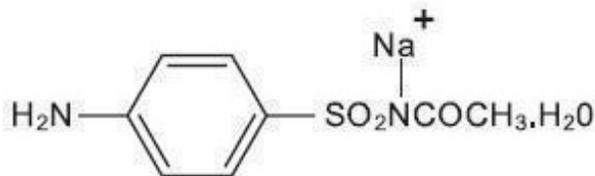
Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

SODIUM SULFACETAMIDE 10% WASH
Rx Only
FOR EXTERNAL USE ONLY. NOT FOR OPHTHALMIC USE.

CLINICAL PHARMACOLOGY:

Each gram contains 100 mg of sodium sulfacetamide USP in a vehicle consisting of: citric acid, cocamidopropyl betaine, disodium EDTA, glyceryl monostearate, methylparaben, PEG-6 caprylic/capric glycerides, PEG-60 almond glycerides, PEG-150 pentaerythrityl tetrastearate, polysorbate 60, purified water, cetyl alcohol, glycerin, sodium lauryl sulfate, sodium thiosulfate and xanthan gum.

Sodium sulfacetamide is a sulfonamide with antibacterial activity. Sodium sulfacetamide is $C_8H_9N_2NaO_3S \cdot H_2O$ with molecular weight of 254.24. Chemically, sodium sulfacetamide is N-[(4-aminophenyl) sulfonyl]-acetamide, monosodium salt, monohydrate. The structural formula is:



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 absorption of this product when applied to the skin or scalp. However, significant absorption of sodium sulfacetamide through the skin has been reported.

The following in vitro data is available but the clinical significance is unknown. Organisms that show susceptibility to sodium sulfacetamide are: Streptococci, Staphylococci, E. coli, Klebsiella pneumoniae, Pseudomonas pyocyanea, Salmonella species, Proteus vulgaris, Nocardia and Actinomyces.

INDICATIONS:

This product 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:

This product is contraindicated in persons with known or suspected hypersensitivity to any of the ingredients of the product. This product is not to be used by patients with kidney disease.

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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.

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. If the use of this product produces signs of hypersensitivity or other untoward reactions, discontinue use of the preparation. Patients should be carefully observed for possible local irritation or sensitization during long-term therapy. 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. Systemic absorption of topical sulfonamides is greater following application to large, infected, abraded, denuded or severely burned areas. Under these circumstances, any of the adverse effects produced by the systemic administration of these agents could potentially occur, and appropriate observations and laboratory determinations should be performed.

Information for Patients:

Patients should discontinue the use of this product if the condition becomes worse or if a rash develops in the area being treated or elsewhere. The use of this product also should be discontinued promptly and the physician notified if any arthritis, fever or sores in the mouth develop. Avoid contact with eyes, lips and mucous membranes.

Drug Interactions: This product is incompatible with silver preparations.

Carcinogenesis, Mutagenesis and Impairment of Fertility: Long-term animal studies for carcinogenic potential have not been performed on this product to date. Studies on reproduction and fertility also have not been performed. Chromosomal nondisjunction has been reported in the yeast, *Saccharomyces cerevisiae*, following application of sodium sulfacetamide. 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 this product. It is also not known whether this product can affect reproduction capacity or cause fetal harm when administered to a pregnant woman. This product 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 this product is administered to a nursing woman.

Pediatric Use: Safety and effectiveness in children under the age of 12 years have not been established.

ADVERSE REACTIONS:

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

OVERDOSAGE:

The oral LD 50 of sulfacetamide in mice is 16.5 g/kg. In the event of overdose, emergency treatment should be started immediately.

Manifestations: Overdosage may cause nausea and vomiting. Large oral overdose 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 or your doctor.

DOSAGE AND ADMINISTRATION:

Seborrheic dermatitis including seborrhea sicca - 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 to 20 seconds. Rinsing with plain water will remove any excess medication. Repeat application as described above for 8 to 10 days or as directed by your physician. If skin dryness occurs it may be controlled by rinsing cleanser off sooner or using less frequently. Regular shampooing following the use of this product is not necessary, but the hair should be shampooed at least once a week. As the condition subsides, the interval between applications may be lengthened. Applications once or twice weekly or every other week may prevent recurrence. Should the condition recur after stopping therapy, the application of this product should be reinitiated as at the beginning of treatment.

Secondary cutaneous bacterial infections - 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 for 10 to 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 above for 8 to 10 days or as directed by your physician. If skin dryness occurs it may be controlled by rinsing cleanser off sooner or using less frequently.

STORAGE: Store at 20°C to 25°C (68°F to 77°F), excursions permitted between 15°C and 30°C (between 59°F and 86°F). Brief exposure to temperatures up to 40°C (104°F) may be tolerated provided the mean kinetic temperature does not exceed 25°C (77°F); however, such exposure should be minimized.

NOTICE: Protect from freezing and excessive heat. The product may tend to darken slightly on storage. Slight discoloration does not impair the efficacy or safety of the product. Keep bottle tightly closed.

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

HOW SUPPLIED:

This product is supplied in the following size(s):

8 fl. oz. (240 mL) bottles, NDC 71399-0480-8

12 fl. oz. (360 mL) bottles, NDC 71399-0480-2

16 fl. oz. (480 mL) bottles, NDC 71399-0480-6

To report a serious adverse event or obtain product information, call 973-227-2000.

Manufactured for:

Akron Pharma Inc.

Fairfield, NJ 07004

NDC 71399-0480-8

SODIUM SULFACETAMIDE 10%

Wash

(sodium sulfacetamide 10%)

Fragrance Free

Shake well before use.

8 fl. Oz. (240 mL)

FOR EXTERNAL USE ONLY. NOT FOR OPHTHALMIC USE.

Rx Only

Akron Pharma

Manufactured in USA

DESCRIPTION: Each gram contains 100 mg of sodium sulfacetamide USP in a vehicle consisting of: citric acid, cocamidopropyl betaine, disodium EDTA, glyceryl monostearate, methylparaben, PEG-6 caprylic/capric glycerides, PEG-60 almond glycerides, PEG-150 pentaerythrityl tetrastearate, polysorbate 60, purified water, cetyl alcohol, glycerin, sodium lauryl sulfate, sodium thiosulfate and xanthan gum.

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DOSAGE AND ADMINISTRATION: Seborrheic dermatitis including seborrhea sicca - 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 to 20 seconds. Rinsing with plain water will remove any excess medication. Repeat application as described above for 8 to 10 days or as directed by your physician. If skin dryness occurs it may be controlled by rinsing cleanser off sooner or using less frequently. Regular shampooing following the use of this product is not necessary, but the hair should be shampooed at least once a week. As the condition subsides, the interval between applications may be lengthened. Applications once or twice weekly or every other week may prevent recurrence. Should the condition recur after stopping therapy, the application of this product should be reinitiated as at the beginning of treatment.

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See package insert for full prescribing information.

WARNING: FOR EXTERNAL USE ONLY. NOT FOR OPHTHALMIC USE.

KEEP OUT OF REACH OF CHILDREN. Avoid contact with eyes, lips and mucous membranes.

STORAGE: Store at 20°C to 25°C (68°F to 77°F), excursions permitted between 15°C and 30°C (between 59°F and 86°F) Protect from freezing and excessive heat. Keep bottle tightly closed. Lot number and expiration date on bottom of bottle.

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Manufactured for:
Akron Pharma, Inc.
Fairfield, NJ 07004

REV: 06/19



NDC 71399-0480-6

SODIUM
SULFACETAMIDE 10%

Wash

(sodium sulfacetamide 10%)

Fragrance Free

16 fl. Oz. (480 mL)

FOR EXTERNAL USE ONLY. NOT FOR OPHTHALMIC USE.

Rx Only

Akron Pharma

Manufactured in USA

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Manufactured for:
Akron Pharma, Inc.
Fairfield, NJ 07004

LOT : 12302018A
EXP : 12/2020

REV : 01/19



SODIUM SULFACETAMIDE

sodium sulfacetamide liquid

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC: 71399-0480
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
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
COCAMIDOPROPYL BETAINE (UNII: 5OCF3011KX)	
EDETATE DISODIUM ANHYDROUS (UNII: 8NLQ36F6MM)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	

METHYLPARABEN (UNII: A2I8C7HI9T)
PEG-6 CAPRYLIC/CAPRIC GLYCERIDES (UNII: GO50W2HWO8)
PEG-60 ALMOND GLYCERIDES (UNII: 4Y0E651N0F)
PEG-150 PENTAERYTHRITYL TETRASTEARATE (UNII: 8L4OOQ76AM)
POLYSORBATE 60 (UNII: CAL22UVI4M)
WATER (UNII: 059QF0KO0R)
CETYL ALCOHOL (UNII: 936JST6JCN)
GLYCERIN (UNII: PDC6A3C0OX)
SODIUM LAURYL SULFATE (UNII: 368GB5141J)
SODIUM THIOSULFATE (UNII: HX1032V43M)
XANTHAN GUM (UNII: TTV12P4NEE)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71399-0480-8	240 mL in 1 BOTTLE; Type 0: Not a Combination Product	06/07/2019	
2	NDC:71399-0480-2	360 mL in 1 BOTTLE; Type 0: Not a Combination Product	01/10/2019	
3	NDC:71399-0480-6	480 mL in 1 BOTTLE; Type 0: Not a Combination Product	01/10/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		01/10/2019	

Labeler - Akron Pharma Inc (067878881)

Establishment

Name	Address	ID/FEI	Business Operations
SLV PHARMACEUTICALS LLC		081225162	manufacture(71399-0480)

Revised: 3/2023

Akron Pharma Inc