**SODIUM SULFACETAMIDE- sodium sulfacetamide liquid**
**Laser Pharmaceuticals, LLC**

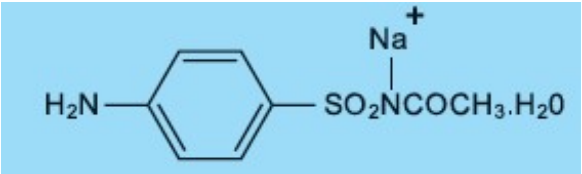
*Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.*

---

**Sodium Sulfacetamide 10% Wash**

## Description:

Each mL contains 100 mg of sodium sulfacetamide in a vehicle consisting of: citric acid, cocamidopropyl betaine, edetate disodium, glycerin, glyceryl stearate, methylparaben, PEG-6 caprylic/capric glycerides, PEG-60 almond glycerides, PEG-150 pentaerythrityl tetrastearate, polysorbate 60, purified water, sodium lauryl sulfate, sodium thiosulfate, xanthan gum. Sodium sulfacetamide is a sulfonamide with antibacterial activity. Sodium sulfacetamide is C 8H 9N 2NaO 3S•H2O with molecular weight of 254.24. Chemically, sodium sulfacetamide is N-[(4-aminophenyl) sulfonyl]-acetamide, monosodium salt, monohydrate. The structural formula is:




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 absorption of Sodium Sulfacetamide 10% Wash 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 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 THIS AND ALL MEDICATION 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 hyper sensitivity 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, 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 Sodium Sulfacetamide 10% Wash if the condition becomes worse or if a rash develops in the area being treated or elsewhere. The use of 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 is also not known whether Sodium Sulfacetamide 10% Wash can affect reproduction capacity or cause fetal harm when administered to a pregnant woman. This 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 this product is administered to a nursing woman.

**Pediatric Use:**

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

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 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 or your doctor.

**DOSAGE AND ADMINISTRATION:**

*Seborrheic dermatits including seborrhea sica* - Sodium Sulfacetamide 10% Wash: Wash affected areas twice daily (morning and evening), or as directed by your phyiscian. Avoid contact with eyes or mucous membranes. Wet skin and liberally apply to areas to be cleansed, message 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 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 lengthened. Applications once or twice a 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 treatment.
*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 10% Wash is supplied in the following size(s): 6 fl. oz. (177 mL) bottle, NDC 16477-410-06, and 12 fl. oz (354.8mL) bottle, NDC 16477-410-12

**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). See USP Controlled Room Temperature. Protect from freezing.

**NOTICE**: 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 product. 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.

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 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, inactive ingredients (excipients) and other chemical information provided herein. To report a serious adverse event or obtain product information, call 1-844-302-5227.

NDC 16477-410-06

**Rx Only**

For External Use Only

**Sodium**

**Sulfacetamide**

**10% Wash**

LASER Pharmaceuticals, LLC

6 fl oz (177 mL)

**INGREDIENTS:** Each mL of Sodium Sulfacetamide 10% Wash contains 100 mg of sodium sulfacetaide USP in a vehicle consisting of: citric acid, cocamidopropyl betaine, edetate disodium, glycerin, glyceryl stearate, methylparaben, PEG-6 caprylic/capric glycerides, PEG-60 almond glycerides, PEG-150 pentaerythrityl tetrastearate, polysorbate 60, purified water, sodium lauryl sulfate, sodium thiosulfate, xanthan gum.

**DIRECTIONS FOR USE:**

Wash affected areas twice daily (morning and evening) or as directed by your physician. Rinse thoroughly and pat dry.

See package insert for complete product information.

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

**STORAGE**: Store at controlled room temperature 20 to 25C (68 to 77F). Protect from freezing. See bottle for lot number and expiration date.

All prescription substitutions and/or recommendations using this produt 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 pakage insert for more informatio.

Marketed by:

Laser Pharmaceuticals, LLC

Alpharetta, GA 30004

Rev. 0924-01

NDC 16477-410-06

**Rx Only**

For External Use Only

# Sodium Sulfacetamide 10% Wash

LASER PHARMACEUTICALS, LLC

6 fl oz (177 mL)

**INGREDIENTS:** Each mL of Sodium Sulfacetamide 10% Wash contains 100 mg of sodium sulfacetamide USP in a vehicle consisting of: citric acid, cocamidopropyl betaine, edetate disodium, glycerin, glyceryl stearate, methylparaben, PEG-6 caprylic/capric glycerides, PEG-60 almond glycerides, PEG-150 pentaerythrityl tetrastearate, polysorbate 60, purified water, sodium lauryl sulfate, sodium thiosulfate, xanthan gum.

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

**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.

3 16477 41006 9

NDC 16477-410-06

**Rx Only**

For External Use Only

# Sodium Sulfacetamide 10% Wash

LASER PHARMACEUTICALS, LLC

6 fl oz (177 mL)

**STORAGE:** Store at controlled room temperature 20° to 25°C (68° to 77°F). Protect from freezing. See bottle for lot number and expiration date.

All prescription substitutions and/or recommendations using this product shall be made subject to state and federal statues as applicable. **NOTE: This is not an Orange Book product. No representaion is made as to generic status or bioequivalency.** Please see package insert for more information.

Marketed by:
Laser Pharmaceuticals, LLC
Alpharetta, GA 30004

Rev. 0924-01

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

**WARNINGS: FOR EXTERNAL USE ONLY. NOT FOR INTRA-VAGINAL 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.

**INGREDIENTS:** Each mL of Sodium Sulfacetamide 10% Wash contains 100 mg of sodium sulfacetamide USP in a vehicle consisting of: citric acid, cocamidopropyl betaine, edetate disodium, glycerin, glyceryl stearate, methylparaben, PEG-6 caprylic/capric glycerides, PEG-60 almond glycerides, PEG-150 pentaerythrityl tetrastearate, polysorbate 60, purified water, sodium lauryl sulfate, sodium thiosulfate, xanthan gum.

Store at controlled room temperature 20° to 25°C (68° to 77°F). Protect from freezing. See bottle for lot number and expiration date.

All prescription substitutions and/or recommendations using this product shall be made subject to state and federal statues 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.

Marketed by:
Laser Pharmaceuticals, LLC
Alpharetta, GA 30004
Rev. 0924-01

3 16477 41006 9

NDC 16477-410-06

**Rx Only**

For External Use Only

# Sodium Sulfacetamide 10% Wash

LASER PHARMACEUTICALS, LLC

**6 fl oz (177 mL)**

NDC 16477-410-12

**Rx Only**

For External Use Only

# Sodium Sulfacetamide 10% Wash

LASERx PHARMACEUTICALS, LLC

**12 fl oz (354.8 mL)**

**INGREDIENTS:** Each mL of Sodium Sulfacetamide 10% Wash contains 100 mg of sodium sulfacetamide USP in a vehicle consisting of: citric acid, cocamidopropyl betaine, edetate disodium, glycerin, glyceryl stearate, methylparaben, PEG-6 caprylic/capric glycerides, PEG-60 almond glycerides, PEG-150 pentaerythrityl tetrastearate, polysorbate 60, purified water, sodium lauryl sulfate, sodium thiosulfate, xanthan gum.

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

**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.

3 16477 41012 0

NDC 16477-410-12

**Rx Only**

For External Use Only

# Sodium Sulfacetamide 10% Wash

LASERx PHARMACEUTICALS, LLC

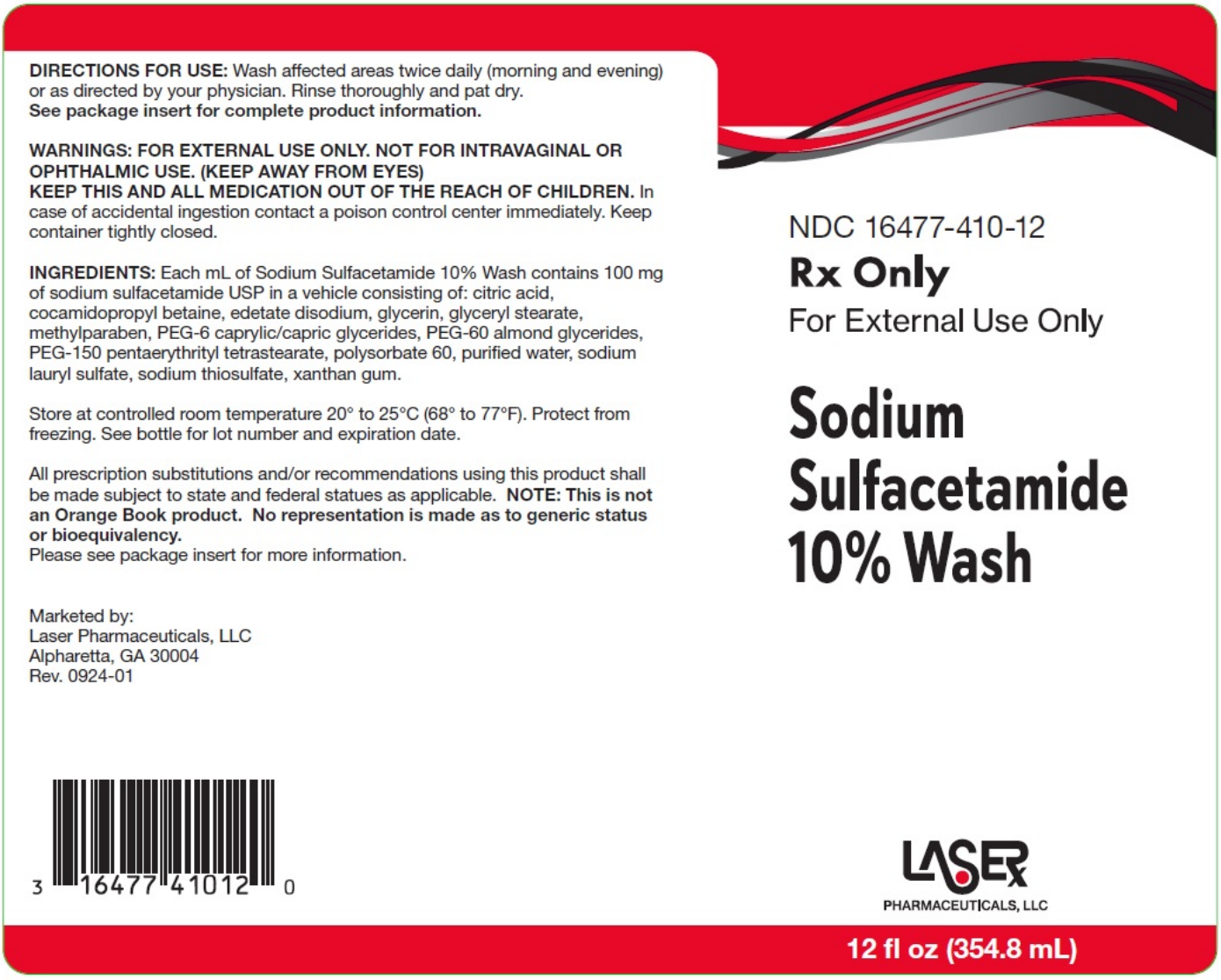
**12 fl oz (354.8 mL)**

**STORAGE:** Store at controlled room temperature 20° to 25°C (68° to 77°F). Protect from freezing. See bottle for lot number and expiration date.

All prescription substitutions and/or recommendations using this product shall be made subject to state and federal statues as applicable.
**NOTE: This is not an Orange Book product. No representaion is made as to generic status or bioequivalency.** Please see package insert for more information.

Marketed by:
Laser Pharmaceuticals, LLC
Alpharetta, GA 30004

Rev. 0924-01




# 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) | |
| **METHYLPARABEN** (UNII: A2I8C7HI9T) | |

| | |
|---|---|
| **GLYCERYL STEARATE SE** (UNII: FCZ5MH785I) | |
| **COCAMIDOPROPYL BETAINE** (UNII: 5OCF3O11KX) | |
| **GLYCERIN** (UNII: PDC6A3C0OX) | |
| **PEG-6 CAPRYLIC/CAPRIC GLYCERIDES** (UNII: GO50W2HWO8) | |
| **PEG-60 ALMOND GLYCERIDES** (UNII: 4Y0E651N0F) | |
| **PEG-150 PENTAERYTHRITYL TETRASTEARATE** (UNII: 8L4OOQ76AM) | |
| **WATER** (UNII: 059QF0KO0R) | |
| **EDETATE DISODIUM ANHYDROUS** (UNII: 8NLQ36F6MM) | |
| **POLYSORBATE 60** (UNII: CAL22UVI4M) | |
| **SODIUM THIOSULFATE** (UNII: HX1032V43M) | |
| **SODIUM LAURYL SULFATE** (UNII: 368GB5141J) | |
| **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: 4/2025 Laser Pharmaceuticals, LLC